

Effectiveness of a Self- and Family Management Support Program among Older People with Diabetic Retinopathy and Visual Impairment: A Randomized Controlled Trial

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Abstract: Diabetic retinopathy is a microvascular complication of diabetes resulting in visual impairment. Controlling the progression of diabetic retinopathy and living with visual impairment are crucial tasks and skills for older people with diabetic retinopathy and visual impairment. This randomized controlled trial investigated the effects of a self- and family management support program on health outcomes of Thai older people with diabetic retinopathy and visual impairment who lived with family members in the community and on family satisfaction. Eighty-four participants were recruited at an eye-specialized hospital in a central province of Thailand and randomly assigned to either the experimental group (n = 42) or the comparison group (n = 42). The experimental group received the intervention program plus usual care, while the comparison group received only usual care. Instruments for data collection included a Demographic Data Form, the Perceived Security in Performance of Daily Life Activities Questionnaire, the Self-Management Behavior Questionnaire, the Sirindhorn National Medical Rehabilitation Center Functional Assessment, the Thai Visual Function Questionnaire 28, and the Family Satisfaction Questionnaire. Data analyses were performed using descriptive statistics, t-test, chi-square, two-way repeated measures ANOVA, and ANCOVA.

Results showed that the experimental group had significantly more improved perceived security, self-management behavior, HbA1c, visual-related quality of life: performing activities dimension, and family satisfaction than the comparison group at Week 16. However, no significant differences in perceived security, self-management behavior, functional ability, and overall visual-related quality of life were found between the two groups at Week 8. This program be further tested before being implemented into practice. However, it has a potential for healthcare providers to create an intervention program encompassing disease control and skill training for older people with diabetic retinopathy and visual impairment and encourage their families to support them.

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Introduction

Diabetic retinopathy (DR) is one of the most frequent microvascular complications of diabetes, resulting in visual impairment (VI).¹ Globally, the prevalence of visual impairment related to diabetic retinopathy is projected to increase from 37.3 million in 2011 to 56.3 million by 2030 following the number of diabetes and the aging population.² In Thailand, a population-based study revealed that 5.1% of Thai people aged 50 years or older experienced VI and blindness due to DR³ and VI substantially impacts many aspects of daily life among older people, such as perceived insecurity in performing activities,⁴ functional ability,⁵ and quality of life.⁶

To prevent further VI and blindness among people with DR, it is imperative to control blood glucose levels through appropriate lifestyle changes and adhere to medications and medical appointments regularly to preserve their functions and quality of life.^{7,8} Systematic reviews^{9,10} demonstrated the effectiveness of the self-management program in improving knowledge, glycemic control, and complications among people with diabetes. However, for older people with diabetic retinopathy and visual impairment (DRVI), self-management of various tasks and skills such as managing medications, maintaining proper diet and exercise and performing daily activities might not be accomplished because of their functional decline, visual function limitation,¹¹ and lack of knowledge.¹² Therefore, support from other people, particularly family members, is necessary for older people with DRVI in self-management to achieve health outcomes. A literature review illustrated that social support from family members could help people with chronic diseases better manage their conditions and improve health behavior and outcomes.¹³⁻¹⁶

Caring for older people with DRVI should focus on controlling the disease progression and living with the eye condition as holistic care. Although there are several studies about self-management in people with

either DR or VI, few studies explored this strategy in those with diabetes and this chronic condition. Moreover, limited studies included family member involvement and self-management in the older people. Therefore, this study sought to determine whether the Self- and Family Management Support Program (SFMSP) among older people with DRVI could improve the outcomes, including perceived security, self-management behavior, glycated hemoglobin (HbA1c), functional ability, and visual-related quality of life. Moreover, family satisfaction would be evaluated by family members' perception of care delivered by the nurse.

Conceptual Framework and Review of Literature

This study used Grey and colleagues' Self- and Family Management Framework¹⁴ for chronic conditions and the literature review on DR and VI to develop an intervention program, namely the Self- and Family Management Support Program (SFMSP) for older people with DRVI. This framework depicts the relationships of the four constructs: facilitators and barriers, self-management processes, proximal outcomes, and distal outcomes. It illustrates that facilitators and barriers can influence self-management processes, which contribute to proximal and distal outcomes. The family member is a significant socio-cultural environment that involves an individual's self-management, such as assistance in daily life, understanding of treatment goals, and decision-making in healthcare.¹⁴

In the context of older people with DRVI, their crucial management tasks are to take responsibility for controlling the disease progression through lifestyle modification and adhere to treatments and medical check-ups regularly.^{7,8} Literature reviews demonstrate the effectiveness of the self-management program on improved diabetes knowledge,^{9,10} self-management in medication adherence,⁹ blood glucose monitoring,

diet, exercise and glycemic control.^{9,10} However, they may have difficulty controlling diabetes and require support from other people.¹⁵ Evidence reveals that family members are essential in strengthening self-management in people with chronic diseases and conditions,¹³ providing instrumental and emotional support to people with visual impairment and serving as the communicator and coordinator with vision-related health care providers.¹⁶

Self-management programs have a diverse range of components to improve physical health status, knowledge, laboratory tests, and self-management behavior among people with chronic diseases.¹⁷ Providing knowledge is one of the effective strategies to control HbA1c levels in people with DR,¹⁸ and DM,¹⁹ but may not be sufficient. In addition, self-monitoring is one such significant component of self-management. In the context of chronic illness, self-monitoring is defined as the people undertaking one or more activities, such as self-measurement and interpretation of the clinical data, self-adjustment of symptoms and medications.²⁰ Previous studies demonstrated that self-monitoring is positively associated with disease control.²¹ Maintaining a normal blood glucose level is necessary for people with DR to prevent visual impairment and blindness. However, health behavior change is challenging for older people with multiple chronic diseases. Goal setting is another strategy that patients and providers discuss and agree on their health goals.²² To perform their daily activities of living and disease self-management that may be complex and challenging for older people with VI, which impacts their quality of life. Also, skill training is one of the effective methods in guiding and strengthening people with VI to live with their condition and increase their quality of life.^{23,24}

The SFMSP provides knowledge about diabetic control and diabetic retinopathy and skill training for living with visual impairment. According to the theory utilization,¹⁴ the self-management processes include three principles: 1) focusing on illness needs, 2) activating resources, and 3) living with the conditions. The strategies in this study comprised goal setting, teaching for

controlling diabetes, encouraging to perform tasks (e.g., diet control, exercise, taking medications, and follow-up), and self-monitoring signs and symptoms. This included not only the processes of strengthening the family to assist older people in need and mobilizing resources to improve visual functions, but also the program provides information about visual aids, coaching to modify the home environment, and demonstrating and practicing daily tasks (e.g., eating, mobility, toileting, medication management) for the safety of older people with DRVI. In this study, perceived security and self-management behavior were proposed as the proximal outcomes, while HbA1c, functional ability, and visual-related quality of life were proposed as the distal outcomes.

Study Aim and Hypothesis

This study aimed to examine the effectiveness of the SFMSP on perceived security, self-management behavior, HbA1c, functional ability, and visual-related quality of life in older people with DRVI and family satisfaction. The hypotheses were 1) the mean scores of perceived security, self-management behavior, functional ability, and visual-related quality of life of the experimental group would be higher than those of the comparison group at Week 8 and Week 16 from baseline (or immediately and eight weeks after completion of the program, respectively), 2) the mean level of HbA1c of the experimental group would be lower, whereas the mean score of family satisfaction would be higher than that of the comparison group at Week 16 from baseline.

Methods

Design: This study used a randomized controlled trial with a two-group random assignment repeated measure design. The CONSORT (CONsolidated Standards of Reporting Trials) 2010 checklist was used to guide writing of this study.

Research setting: This study was conducted at an eye specialty hospital in the central region of Thailand.

Sample: The samples consisted of two groups: older people with DRVI who received services at the ophthalmology outpatient department and their family members who regularly cared for older people with DRVI. Inclusion criteria for older people with DRVI were 60 years and older, diagnosed with DR, having visual acuity worse than 20/70 in the better eye, having family members who cared for them, able to communicate in Thai, and being cognitively intact. Exclusion criteria included having visual acuity as no light perception in both eyes and being unwilling to participate in the study. Inclusion criteria for the family members were 18 years and older, a family member who provided routine care, able to communicate in Thai, and willing to participate in the study.

The sample size was calculated based on the means and variances in a previous study related to people with DR¹⁸ using Rosner's formula²⁵ to achieve a power of .80

at a significance level of .05. The required sample size was 41 per group. Due to the possible dropout rate, this study determined an attrition rate of 20%. Thus, the total number of participants was 50 per group.

The block randomization technique with a block size of 4 and a ratio of 1:1 was used to randomly assign the participants to either the experimental group (n = 50) or the comparison group (n = 50). The randomization generation was performed by a statistician who was not involved with data collection. Stata, a statistical software package, was used for the generation with the setting of a seed number. The generated random sequence was kept confidential using sealed envelopes.

During the study, eight participants in the experimental group and eight in the comparison group withdrew because of a stroke, lower-extremity amputation, postponed appointment during the COVID-19 pandemic, referral to another hospital, or loss of follow-up. Therefore, 84 participants completed the study, with 42 in the experimental group and 42 in the comparison group (Figure 1).

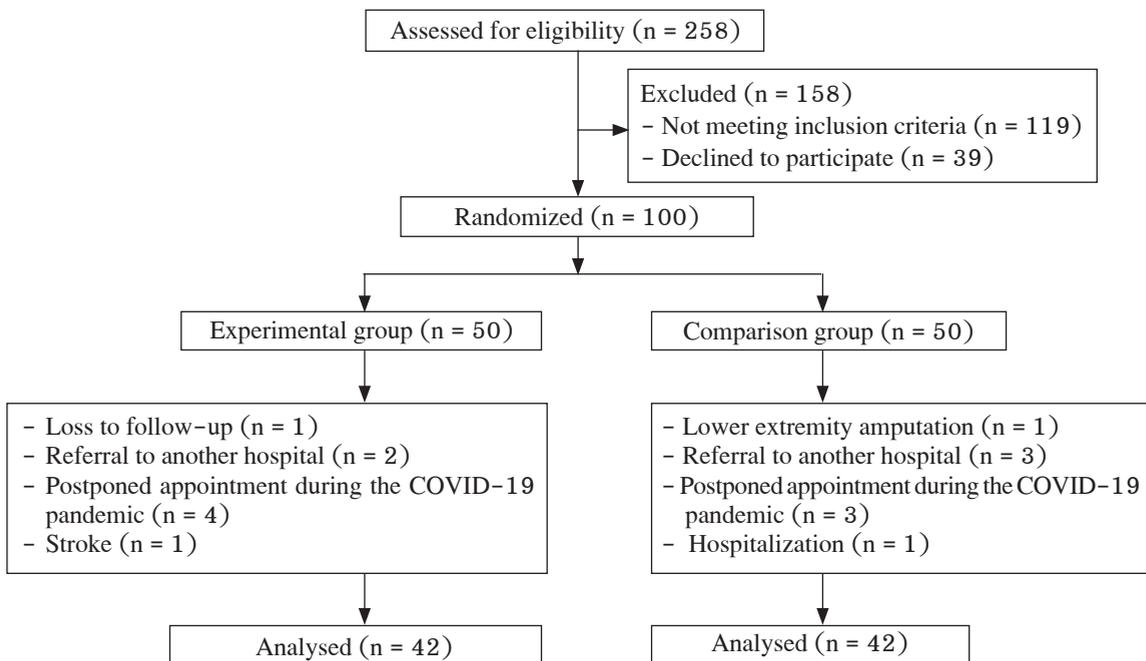


Figure 1. Flowchart of selecting the participants in a randomized controlled trial

Ethical considerations: Approval for this study was obtained from the Institutional Review Board on Research Ethics, Faculty of Medicine Ramathibodi Hospital, Mahidol University (COA. MURA2019/1215) and an eye-specialized hospital in one central province of Thailand (COA No. 002/2563). All participants were informed about the study's purpose, research procedures, length of time to complete the questionnaires, risks and benefits, and their right to confidentiality and to join or refuse. They were asked to sign the informed consent form before the study was conducted.

Research instruments: The research instruments consisted of two parts: the instruments for data collection and those for intervention. The content validity of all instruments was evaluated by five experts: an ophthalmologist, two ophthalmic nurse instructors, a gerontological nurse instructor, and a diabetes advanced practice nurse. All instruments except demographic data were used with permission from the developers.

The Demographic Data Form was developed by the primary investigator (PI) to gather details on age, gender, marital status, level of education, healthcare payment, income, and the primary caregiver.

The Health Data Form included health history regarding diabetes mellitus (DM), DR, comorbidity, tobacco smoking, and alcohol drinking. The clinical data were collected from the medical records consisting of the visual acuity, DR stages, blood pressure, and HbA1c level.

The Perceived Security in Performance of Daily Life Activities Questionnaire was used to measure the feeling of being safe in daily activities of older people with DRVI. The original version, "the ADL instrument," was developed by Dahlin-Ivanoff and colleagues.²⁶ It was translated and modified for some wordings with permission from the developers into Thai by the PI. It was then back-translated by a bilingual person, and an English native speaker compared the meaning of the two versions, following Brislin's method.²⁷ It consists of 30 items divided into seven performance areas: meals,

self-care and clothing care, cleaning, mobility, communication, shopping, and financial management. The participants are asked to rate their feeling of being safe in the daily activities (e.g., How secure do you feel when finding things on the table while eating?). Each item was rated on a 4-point scale from 1 (very insecure) to 4 (secure). The range of total scores is 30–120, with higher scores indicating a more perceived feeling of being safe in performing daily activities. The instrument was tested for its content validity by five experts. The result of CVI was 0.93. Cronbach's alpha coefficients were 0.91 in the pilot study among 20 older people with DRVI and 0.95 in the main study.

The Self-Management Behavior Questionnaire was adapted from the original version of self-care behavior developed by Duangkaew and colleagues²⁸ to be suitable for older people with DRVI and fit with the theoretical framework in this study. It was used to measure self-management behavior in controlling blood glucose and preventing disease progression (e.g., "You immediately stop eating sweet foods when your eyes feel burring"). It has 30 items with five aspects of self-management behavior, including general health, diet, exercise, medication, and eye care. Each item is rated on a 5-point scale from 1 (never do) to 5 (always). The possible range of total scores is 30–150, with higher scores indicating more self-management behavior. The instrument was tested for its content validity by five experts. The result of CVI was 0.90. Cronbach's alpha coefficients were 0.78 in the pilot study and 0.78 in the main study.

The Sirindhorn National Medical Rehabilitation Center Functional Assessment was developed by Suwapan and colleagues.²⁹ It was used to evaluate the functional ability of older people with DRVI. There are 35 items with ten dimensions, including feeding, grooming, cleaning, dressing, bowel and bladder management, mobility, walking, communication, social and cognition, and instrumental activity of daily living. Each item is rated on a 5-point rating scale from 1 (dependent) to 5 (complete independent). The possible range of total

scores is 35–175, with higher scores indicating more independence. The same five experts evaluated the validation of this instrument, and the CVI was 0.89. Cronbach’s alpha coefficients were 0.95 in the pilot study and 0.91 in the main study.

The Thai Visual Function Questionnaire 28 (VFQ-28) was developed by Chaiyasong and colleagues.³⁰ It is used to evaluate the quality of life in Thai people with general eye diseases. The total 28 items consist of one question on general health and 27 questions on the general visual-related quality of life. There are three dimensions: general health and eye health, performing activities, and the impact of visual impairment. Each item is rated on a 5 or 6 Likert scale and translated into 100 points. The possible range of total scores is 0–100, with a higher score indicating a better quality of life. The CVI of VFQ-28 Thai was 0.98. Cronbach alpha’s coefficient for overall visual-related quality of life in the pilot study were 0.86, and 0.84 in the main study.

The Personal Demographic Data of Family Form elicited the demographic characteristics of family members, including gender, age, marital status, education, occupation, and the role of family members in caring for older people with DRVI.

The Family Satisfaction Questionnaire was adapted with permission from the original Patient

Satisfaction with Nursing Care Questionnaire (PSNQ) developed by Suwisith and Hanucharumkul.³¹ It is used to evaluate family members’ perception of care delivered by the nurse. There are 15 items rated on a 5–point Likert scale ranging from 1 (highly dissatisfied) to 5 (highly satisfied). Higher scores mean more family members’ satisfaction. Cronbach’s alpha coefficient of this questionnaire in the pilot study was .91 and in the main study was 0.93.

Self- and Family Management Support Program (SF MSP)

The SF MSP is an 8–week health education program and skills training based on the revised Self- and Family Management Framework.¹⁴ It aimed to guide older people with DRVI on living with visual impairment and promote them to control the disease progression in conjunction with family involvement. The SF MSP is an individual intervention given by the PI. There are two main sessions in the SF MSP: 1) health education for older people with DRVI, including the knowledge about DM, DR, diabetic complications, and how to manage them, and 2) information and skills training for older people living with DRVI. The five experts, as mentioned earlier, validated the contents. The detail and implementation of the program are shown in **Table 1**.

Table 1. Schedule and contents of the SF MSP

Time schedule	Topic	Method/Strategies	Media
At hospital Week 1 60 mins	Part 1: Health education for older people with DRVI <i>Topic 1:</i> Visual impairment related to diabetic retinopathy	Introduction: Explaining the objective and details of the SF MSP to older people with DRVI and their family members Teaching: Providing knowledge of DM and its complications Strengthening: Empowering older people to live with their conditions and strengthening family members to assist and support older people in performing their tasks Providing: Providing information regarding tools and techniques for living with visual impairment and giving	The Booklet: “Self–management for older people with visual impairment due to diabetic retinopathy and family” The Brochures: – “The thing to know about diabetes” – “The dangers of diabetes”

Table 1. Schedule and contents of the SFMSP (Cont.)

Time schedule	Topic	Method/Strategies	Media
		examples of low vision aids: non-optical and optical devices, electronic devices, and applications to family members	
	<i>Topic 2: Self-management tasks for older people with diabetic retinopathy</i>	<p>Encouraging: Encouraging older people to take responsibility and ownership in their self-management in diet control, exercise, and medication adherence to control the DR progression</p> <p>Goal setting: Empowering to set the goal of HbA1c, fasting blood glucose, blood pressure, and body weight under the treatment guidelines</p> <p>Advising: Demonstrating older people regarding types and methods of exercise</p> <p>Self-monitoring, observing, and problem-solving: regarding abnormal signs and symptoms of DM and DR</p> <p>Diary log usage: for self-regulation in self-management for controlling blood glucose, self-observation, monitoring signs and symptoms of abnormal eyes, and problem-solving by family members</p> <p>To strengthen and support self-management: Discussing and supporting self-management</p>	<p>The Booklet: “Self-management for older people with visual impairment related to diabetic retinopathy and the family”</p> <p>The brochures:</p> <ul style="list-style-type: none"> - “Principles of diet control for diabetes” - “Diabetes and exercise” - “Exercise posture for elderly people” - “Hypoglycemia related to the use of diabetes”
Telephone follow-up			
Week 2, 3, 4			
10-15 mins			
Home visiting	Part 2:		
Week 5	Information and skills training for older people living with DRVI	<p>Providing: Providing non-optical aids (adjusting contrast and using large prints to increase visual resolution) and optical aids (a hand-held magnifier and reading glasses)</p> <p>Strengthening and coaching: Discussing with older people and family members about the impact of VI, barriers, and facilitators in performing daily activities and coaching them for home adjustment</p> <p>Demonstrations and return demonstrations: Demonstrating basic skills in daily living, e.g., table setting for eating and sighted guide techniques</p>	
60 mins			

Table 1. Schedule and contents of the SFMSP (Cont.)

Time schedule	Topic	Method/Strategies	Media
Telephone follow-up Week 6, 7, 8 10-15 mins		Strengthening and supporting self-management: Discussing and supporting self-management	

Usual care: At each visit, older people with DR received the usual care including eye assessment, examination, treatment, and advice from the medical staff. These activities included 1) measurement of blood pressure, visual acuity, and intraocular pressure, 2) specific eye examination before seeing the ophthalmologist, such as dilatation pupil or retina imaging from the previous doctor's order, 3) arranging patients to see the doctor for an eye examination, and 4) giving the prescription and an appointment card from nurses for the next visit or some specific treatment, such as laser therapy or intravitreal injection by the ophthalmologist.

Data collection: Data were collected from March 2020 to December 2020. After each participant signed the informed consent, baseline data, including demographic data, health history, and clinical data, and all expected outcomes in this study were collected. Then, the participants were randomly assigned to either the experimental or the comparison groups by a statistician who was not involved with data collection. The experimental group received an 8-week SFMSP provided by the PI plus usual care, while the comparison group received the usual care only at the ophthalmology outpatient department of the research setting. Older people with DRVI were evaluated using the questionnaires three times at baseline, Week 8, and Week 16 from baseline and HbA1c and family satisfaction were measured with the questionnaires twice at baseline and Week 16 in both groups. Data collection was done by a trained research assistant RA before starting the study, the RA received the information regarding the study protocol, the contents of questionnaires, data

collection procedures, and the follow-up schedule, but was blinded regarding the participants' group status.

Data analysis: The SPSS Version 18.0 (SPSS Inc., Chicago, IL, USA) was used for data analysis. Descriptive statistics of mean, standard deviation, median, interquartile range, and percentage were used to describe the characteristics of older people with DRVI and their family members. To compare the differences between the two groups at baseline (and Week 16), the chi-square test and Fisher's exact test were tested for categorical data, while independent t-test, and Mann-Whitney U test were employed for continuous data. Two-way repeated measures ANOVA was performed to assess the mean difference in perceived security, self-management behavior, functional ability, and visual-related quality of life between the two groups at each time point and changes over time. An analysis of covariance (ANCOVA) was used to test the differences in mean HbA1c between the two groups.

Results

Of the total, 84 older participants with DRVI and 84 family members completed the study, with 42 dyads in the experimental group and 42 dyads in the comparison group. As shown in **Table 2**, all characteristics between two groups were not significantly different, except that the comparison group had more cataracts, but less severe visual impairment compared to those in experimental group.

Table 2. Characteristics of older people with diabetic retinopathy and visual impairment

Characteristics	Experimental group (n = 42)	Comparison group (n = 42)	Statistic values	p-value
Age (years), median (IQR)	64 (5)	65 (6)	-.79 ^a	.472
Gender , n (%)			.47	.491
Male	13 (31.0)	16 (38.1)		
Female	29 (69.0)	26 (61.9)		
Marital status , n (%)			.23	.629
Married	31 (73.8)	29 (69.0)		
Other (single, widowed, divorced)	11 (26.2)	13 (31.0)		
Education , n (%)			2.58	.108
Primary	31 (73.8)	24 (57.1)		
Secondary or higher	11 (26.2)	18 (42.9)		
Living with , n (%)			.21	.643
Spouse	29 (69.0)	27 (64.3)		
Other (children, grandchild)	13 (31.0)	15 (35.7)		
Family member , n (%)			.76	.382
Children	18 (42.9)	22 (52.4)		
Spouse and others	24 (57.1)	20 (47.6)		
Cataract , n (%)			6.92	.009
Yes	13 (31.0)	25 (59.5)		
No	29 (69.0)	17 (40.5)		
Visual acuity , n (%)			3.91	.048
Moderate visual impairment	19 (45.2)	28 (66.7)		
Severe visual impairment	23 (54.8)	14 (33.3)		
Diabetic retinopathy stage , n (%)			.39	.533
Non-proliferative DR	5 (11.9)	7 (16.7)		
Proliferative DR	37 (88.1)	35 (83.3)		
Duration of diabetic retinopathy (years), median (IQR)	3 (5)	2 (4)	-.93 ^a	.351
Duration of diabetes (years), mean (SD)	15.76 (8.61)	14.86 (8.56)	.48 ^b	.631

Note. IQR = Interquartile range, DR = Diabetic retinopathy, ^b Independent t-test, ^a Mann-Whitney U Test

All characteristics of the family members between the two groups were not significantly different. Most family members in the experimental and comparison groups were female (59.5% and 64.3%, respectively). The average ages of family members in the experimental

and comparison groups were 47.83 (SD = 14.31) and 46.74 (SD = 13.86) years, respectively. The prominent roles of family members in caring for older people with DRVI in both groups were similar, including taking them to the hospital, preparing food, preparing medicines, giving

Effectiveness of a Self- and Family Management Support Program

money, and taking a shower. They also had specific roles regarding DR and VI, such as testing blood glucose, assisting with basic ADLs, adjusting for a safe home environment, and eye care and drop administration.

Before testing the study's hypotheses, the between-group comparisons of the baseline outcome

measurements were performed by the independent t-test. The results revealed that the mean scores on perceived security, self-management behavior, antilog HbA1c, functional ability, visual-related quality of life, and family satisfaction were not significantly different at baseline (**Table 3**).

Table 3. Comparison of outcome variables of older participants and family satisfaction between groups at baseline

Dependent variables	Experimental group (n = 42)		Comparison group (n = 42)		t-value	p-value
	Mean	SD	Mean	SD		
Perceived security	67.05	11.56	67.48	7.81	-.19	.843
Self-management behavior	118.88	10.37	114.81	8.69	1.95	.055
HbA1c*	7.44	1.24	7.66	1.18	-.71	.481
Functional ability	129.05	12.88	128.86	7.89	.08	.935
Visual-related quality of life	37.21	7.73	37.30	7.39	-.06	.953
Family satisfaction	60.05	6.59	60.10	6.74	-.03	.974

Note. HbA1c = glycated hemoglobin, * Mean of antilog

When performing two-way repeated measures ANOVA, the results showed a significant interaction between the time and group on perceived security, self-management behavior, functional ability, overall visual-related quality of life (VRQoL), and VRQoL: performing activities dimension (**Table 4**). Therefore, Bonferroni correction was used to assess post hoc

comparisons at each time point between groups. The result demonstrated that the mean perceived security, self-management behavior, and VRQoL: performing activities dimension scores were statistically significantly higher in the experimental group only at Week 16 than in the comparison group (**Table 5**).

Table 4. Comparison of mean scores from two-way repeated measures ANOVA on outcome variables over time

Outcome variables	Baseline	Week 8	Week 16	Group		Time		Group x Time		
	Mean (SD)	Mean (SD)	Mean (SD)	F-value	p-value	F-value	p-value	F-value	p-value	
Perceived security										
Experimental	67.05 (11.57)	71.69 (9.75)	78.38 (8.80)	4.27	.042	127.14	<.001	59.31	<.001	
Comparison	67.48 (7.82)	68.62 (7.22)	69.64 (5.95)							
Self-management behavior										
Experimental	118.88 (10.38)	119.95 (8.07)	123.81 (6.28)	5.90	.017	29.07	<.001	11.74	<.001	
Comparison	114.81 (8.69)	117.50 (10.05)	116.93 (8.56)							
Functional ability										
Experimental	129.05 (12.88)	132.00 (13.39)	134.69 (13.50)	.73	.395	57.75	<.001	10.86	.001	
Comparison	128.86 (7.89)	129.86 (7.69)	131.10 (6.85)							
Visual-related Quality of Life										
Experimental	37.21 (7.74)	39.52 (6.02)	41.26 (5.32)	.26	.610	56.29	<.001	4.00	.038	
Comparison	37.30 (7.39)	39.00 (5.45)	39.66 (5.24)							
General health and eye health dimension										
Experimental	50.03 (12.26)	54.17 (8.14)	61.01 (6.53)	.72	.397	74.09	<.001	.09	.855	
Comparison	48.63 (10.55)	53.33 (5.83)	59.43 (6.68)							

Table 4. Comparison of mean scores from two-way repeated measures ANOVA on outcome variables over time (Cont.)

Outcome variables	Baseline	Week 8	Week 16	Group		Time		Group x Time		
	Mean (SD)	Mean (SD)	Mean (SD)	F-value	p-value	F-value	p-value	F-value	p-value	
Performing activities dimension										
Experimental	30.73 (8.59)	32.74 (6.82)	34.08 (5.88)	.72	.397	11.57	<.001	11.42	<.001	
Comparison	31.25 (6.50)	31.59 (5.69)	31.21 (5.26)							
Impact of visual impairment dimension										
Experimental	43.75 (12.54)	45.76 (10.64)	45.76 (10.64)	.06	.810	24.94	<.001	.82	.366	
Comparison	43.75 (13.09)	46.65 (10.86)	46.65 (10.86)							

Table 5. Post-hoc comparison of outcome variables on different time points between the experimental group (n = 42) and the comparison group (n = 42)

Time/Outcome variables	Group	Mean difference	SE	p-value	95% CI for difference	
					Lower	Upper
Perceived security						
Baseline	Experimental Comparison	-.43	2.15	.843	-4.71	3.85
Week 8	Experimental Comparison	3.07	1.87	.105	-.65	6.79
Week 16	Experimental Comparison	8.74	1.64	<.001	5.47	11.99
Self-management behavior						
Baseline	Experimental Comparison	4.07	2.09	.055	-0.08	8.22
Week 8	Experimental Comparison	2.45	1.99	.221	-1.50	6.41
Week 16	Experimental Comparison	6.88	1.64	<.001	3.62	10.13
Functional ability						
Baseline	Experimental Comparison	.19	2.33	.935	-4.44	4.82
Week 8	Experimental Comparison	2.14	2.38	.371	-2.59	6.88
Week 16	Experimental Comparison	3.59	2.34	.128	-1.05	8.24
Visual-related quality of life (VRQoL)						
Baseline	Experimental Comparison	-.09	1.65	.953	-3.38	3.19
Week 8	Experimental Comparison	.52	1.25	.678	-1.97	3.02
Week 16	Experimental Comparison	1.61	1.15	.167	-.68	3.89
VRQoL: Performing activities dimension						
Baseline	Experimental Comparison	-.52	1.66	.755	-3.83	2.79
Week 8	Experimental Comparison	1.15	1.37	.403	-1.57	3.88
Week 16	Experimental Comparison	2.86	1.22	.021	.44	5.28

ANCOVA testing aims to control the possible effect of the factor covarying with the dependent variable (covariate). The result showed a significant effect of the SFMSP on HbA1c after controlling for the duration of diabetes (M = 7.1 and M = 7.9, respectively) ($F_{(1,80)} = 6.45, p = .013$). For family members, the result showed that the mean score of family satisfaction in the experimental group (M = 70.33, SD = 2.11) was statistically significantly higher than that in the

comparison group (M = 60.67, SD = 2.63; $p < .001$) at Week 16 from baseline.

Discussion

The results revealed that participants receiving the SFMSP plus usual care had significantly better perceived security, self-management behavior, HbA1c, visual-related quality of life (performing activities

dimension), and family satisfaction at Week 16 from baseline than those receiving only usual care. The findings confirmed the beneficial effects of the SFMSP, which included individual health education and skills training guided by the revised Self-and Family Management Framework.¹⁴ The intervention program used several strategies, such as goal setting, teaching, strengthening, material instruments, telephone follow-up, home visiting, and family support. Perceived security is regarded as a proximal outcome in this study. The result showed that older people with DRVI in the experimental group had better perceived security than the comparison group at Week 16. One explanation is that the findings might result from the process of the SFMSP, which provided the information for caring for people with VI, coached family members to modify the home environment, and trained essential skills in daily living activities for safety.

This finding is congruent with a previous study that a health education program improved perceived security in older people with VI related to age-related macular degeneration at 16 weeks after completing the program.⁴ Health education with several strategies, such as providing knowledge and materials (booklets, brochures, and diary logs), goal setting and advising, self-monitoring, self-observing, and problem-solving, were used in this SFMSP for enhancing self-management behavior in older people with DRVI. Previous studies revealed that telephone follow-up was another strategy for strengthening and supporting self-management behavior in people with DM.³² In addition, family members are supporters of helping people with chronic illnesses to improve their self-management.³³

In this study, the HbA1c in the experimental group had decreased and was lower than the comparison group at Week 16 from baseline. This finding demonstrates that the SFMSP could improve glycemic control. Consistently, a self-management program in a prior study is an effective strategy for controlling glucose among people with diabetes and decreasing HbA1c levels.³⁴ Also, a previous study revealed that self-management behaviors were negatively associated with HbA1c levels, indicating better diabetes control.³⁵

However, our findings revealed no significant difference in the overall visual-related quality of life between the two groups at Week 8 and Week 16 from the baseline, which is consistent with previous studies in older persons with visual impairment.³⁶ However, when the subscales of visual-related quality of life were further analyzed, it revealed that the experimental group had better scores on the performing activities dimension than the comparison group at Week 16. This result may be from the process of the SFMSP, such as providing information regarding the tool and techniques for living with visual impairment and advising about useful resources to improve visual functions at the right time. Moreover, telephone follow-up and home visiting are the program's components to strengthen and support the participants in self-management. In contrast, the general health and eye health dimension and the impact of the visual impairment dimension were not found to be different between the two groups because the participants in this study had chronically moderate to severe visual impairment. Thus, these two dimensions might not be sensitive to the intervention.

Furthermore, this study did not find a significant difference in functional ability between the two groups at Week 8 and Week 16 from the baseline. This result is congruent with a previous study.³⁷ It is possible that older people with VI had adapted to their environment in the physiologic mode and could perform self-care themselves.³⁸ They might be familiar with their surroundings and remember where things were placed. Another reason, which may explain the non-significant difference in functional ability between the two groups in this study, is that older participants in both groups received support in activities of daily living from their families.

Family members are a vital social support integrated into this program. The SFMSP also provided health education and skill training to family members who had several roles in helping older people with DRVI accomplish tasks. In a previous study,³⁹ family

satisfaction was used to reflect the quality of care in diverse settings and contexts. Our finding revealed that family members receiving the SFMSP plus usual care had more satisfaction with care than those receiving only usual care at Week 16 from the baseline. This result is consistent with a previous study that family members in the intervention group had greater satisfaction with communication with healthcare providers.⁴⁰ In this study, family members expressed that they learned and understood the disease and conditions of their older relatives more. They were interested in the content of the techniques to care for older people with VI, such as the sighted guide techniques, low visual aids, home adjusting, eating, and pouring liquid techniques. Telephone follow-up and home visiting by the researcher were other components that the participants perceived satisfaction with. In brief, they expressed satisfaction with the interventions provided for older people with DRVI.

In summary, this study revealed the effectiveness of the SFMSP on perceived security, self-management behavior, HbA1c, visual-related quality of life: performing activities dimension, and family satisfaction. However, these findings only partially supported the hypotheses in this study. It could be explained that some outcome variables need a particular time of interventions, at least eight weeks after receiving the intervention, to change. Therefore, the evaluation of outcome variables should be extended after completing the program.

Limitations

According to age-related changes, senile cataracts are inevitable, resulting in some degree of vision impairment. It is less likely to have older people without cataracts. This factor may affect some outcomes of the intervention program. In addition, this study was conducted at an ophthalmology outpatient department with a 16% attrition rate related to the participants' health problems and being postponed during the COVID-19 pandemic. Therefore, the generalizability may be limited.

Conclusions and Implications for Nursing Practice

The Self- and Family Management Support Program can enhance perceived security in performing tasks, self-management behavior, diabetes control, and visual-related quality of life in performing activities. Thus, healthcare providers should use the SFMSP components to strengthen older people with DRVI to accomplish their desired outcomes. Nurses should create a care program encompassing knowledge about the disease and its control and skill training for older people with DRVI to perform daily activities using visual and age-friendly media. However, nurses should be trained in knowledge and techniques for developing the care program. The family members should be included in the program to learn essential techniques and help persons with DRVI to manage tasks and communicate with healthcare professionals. Moreover, the program should be tested with other groups of older people with chronic diseases or conditions before being implemented into practice.

For further study, an evaluation of the long-term effect of the program on study outcomes should be explored. Additionally, digital health technologies, such as mobile health with the application, may be added to the program to provide health education and information to patients and family members. Also, patients and family members may need to repeat the information. Therefore, developing a technology-based education program for older people with DRVI and family should be explored in future studies.

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ผลของโปรแกรมการสนับสนุนการจัดการตนเองของบุคคลและครอบครัว ในผู้สูงอายุที่เป็นโรคเบาหวานขึ้นจอประสาทตาและมีความบกพร่องใน การมองเห็น: การทดลองแบบสุ่มและมีกลุ่มควบคุม

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บทคัดย่อ: เบาหวานขึ้นจอประสาทตาเป็นภาวะแทรกซ้อนจากโรคเบาหวานส่งผลทำให้เกิดความบกพร่องในการมองเห็น การควบคุมความก้าวหน้าของโรค และการจัดการกับอาการ การรักษา และวิถีชีวิตเป็นภารกิจและทักษะที่สำคัญสำหรับผู้สูงอายุที่เป็นโรคเบาหวานขึ้นจอประสาทตาและมีความบกพร่องในการมองเห็น วัตถุประสงค์ของการวิจัยเชิงทดลองแบบสุ่มและมีกลุ่มควบคุมนี้ เพื่อทดสอบผลของโปรแกรมการสนับสนุนการจัดการตนเองของบุคคลและครอบครัวในผู้สูงอายุที่เป็นโรคเบาหวานขึ้นจอประสาทตาและมีความบกพร่องในการมองเห็นและความพึงพอใจของสมาชิกในครอบครัว กลุ่มตัวอย่างจำนวน 84 คน ได้รับการสุ่มเข้ากลุ่มทดลอง ($n = 42$) และกลุ่มเปรียบเทียบ ($n = 42$) กลุ่มทดลองได้รับโปรแกรมความรู้และการฝึกทักษะจำนวน 8 สัปดาห์ร่วมกับการดูแลตามปกติ กลุ่มเปรียบเทียบได้รับการดูแลแบบปกติเท่านั้น เครื่องมือที่ใช้ในการเก็บรวบรวมข้อมูลประกอบด้วย แบบบันทึกข้อมูลส่วนบุคคล แบบประเมินความรู้สึกมั่นคงปลอดภัยในการปฏิบัติกิจกรรม แบบสอบถามพฤติกรรมกรรมการจัดการตนเอง แบบประเมินความสามารถในการทำกิจกรรม แบบวัดคุณภาพชีวิต และแบบสอบถามความพึงพอใจของสมาชิกในครอบครัว วิเคราะห์ข้อมูลโดยใช้สถิติเชิงพรรณนา t-test, chi-square, two-way repeated measures ANOVA, และ ANCOVA

ผลการศึกษาพบว่ากลุ่มทดลองที่ได้รับโปรแกรมมีความรู้สึกปลอดภัยในการปฏิบัติกิจกรรม พฤติกรรมการจัดการตนเอง น้ำตาลสะสมในเลือด คุณภาพชีวิตที่เกี่ยวข้องกับการมองเห็น: มิติการทำกิจกรรมและความพึงพอใจของสมาชิกในครอบครัวดีขึ้นกว่ากลุ่มเปรียบเทียบอย่างมีนัยสำคัญทางสถิติในสัปดาห์ที่ 16 อย่างไรก็ตาม ไม่พบความแตกต่างของความรู้สึกปลอดภัยในการปฏิบัติกิจกรรม พฤติกรรมการจัดการตนเอง ความสามารถในการทำกิจกรรม และคุณภาพชีวิตโดยรวมระหว่างกลุ่มทดลองและกลุ่มเปรียบเทียบในสัปดาห์ที่ 8 โปรแกรมนี้ควรได้รับการทดสอบต่อไปก่อนนำไปใช้ในการปฏิบัติ อย่างไรก็ตาม บุคลากรด้านสุขภาพสามารถนำข้อมูลเหล่านี้ไปใช้เป็นแนวทางในการพัฒนาโปรแกรมการดูแลผู้สูงอายุที่เป็นโรคเบาหวานขึ้นจอประสาทตาและมีความบกพร่องในการมองเห็นเพื่อควบคุมโรคและพัฒนาทักษะการจัดการตนเองและสนับสนุนสมาชิกในครอบครัวในการดูแลผู้สูงอายุที่มีปัญหาสุขภาพดังกล่าว

Pacific Rim Int J Nurs Res 2023; 27(1) 105-120

คำสำคัญ: เบาหวานขึ้นจอประสาทตา การสนับสนุนจากครอบครัว โปรแกรมการจัดการ ผู้สูงอายุ การทดลองแบบสุ่มและมีกลุ่มควบคุม ความบกพร่องในการมองเห็น

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