Effect of a self-care promoting program on engagement in self-care behaviors and health-related outcomes among persons with type 2 diabetes and diabetic retinopathy: A single-blind randomized controlled trial

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Abstract

Background: Diabetic retinopathy (DR) is the most common microvascular complication of diabetes, leading to visual impairment and eventual blindness. Promoting self-care behaviors is crucial in controlling DR progression and preventing blindness.

Objective: This study aimed to investigate the effects of a Self-Care Promoting Program (SCPP) on engagement in self-care behaviors, HbA1c levels, visual acuity (VA), severity of DR, and vision-related quality of life (VRQoL) among individuals with type 2 diabetes and DR.

Methods: This study employed a single-blind randomized controlled trial design to compare SCPP with conventional diabetic care interventions (standard care). The SCPP was based on the Self-Care of Chronic Illness Theory, Self-efficacy theory, and the Association of Diabetic Care and Education Specialist (ADCES) guidelines incorporating health education, self-care maintenance, monitoring, and management skills training over 12 weeks. Ninety-eight participants were randomly allocated to the experimental or control group (n = 49 per group). While the experimental group received SCPP alongside standard care, the control group received standard care alone. Data collection occurred between May 2022 and March 2023 and included demographic information, the Self-Care of Diabetes Index questionnaire (SCODI), the self-care for diabetes eye care questionnaire (SCFDE), the impact of visual impairment questionnaire (IVI-Thai version), and retinal images for DR severity grading. Data analysis utilized descriptive statistics, Chi-Square tests, t-tests, and MANOVA.

Results: Following 8 and 16 weeks of SCPP, the experimental group had significantly higher mean scores in engagement with self-care and eye-care behaviors compared to the control group (p <0.001). The highest scores were observed in self-care and eye-care confidence behaviors, followed by maintenance, monitoring, and management. Furthermore, HbA1c levels and VRQoL significantly decreased and were lower than those of the control group at week 16 (p <0.001 and p <0.05, respectively). However, there were no significant differences in VA, and DR severity increased in both groups by week 16.

Conclusion: SCPP benefits individuals with DR, enhancing their confidence and ability to perform, monitor, and manage self-care behaviors. These strategies contribute to improved diabetes management, enhanced quality of life, and reduced DR-related blindness. Integrating SCPP into routine DR management is recommended, with nurses playing a pivotal role in overseeing and driving this integration, highlighting the critical role of nurses in managing this widespread global disease.

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Keywords

Background

Diabetic retinopathy (DR) is a significant microvascular complication among type 2 diabetes patients, the prevalence of which increased by 25% between 1990 and 2015 (World Health Organization, 2020). According to the International Diabetes Federation (IDF) estimates, in 2019, 87.6 million people in Southeast Asia had diabetes, while 30.6 million and 9.6 million people had DR and sight-threatening DR, respectively (World Health Organization, 2020). In Thailand, the prevalence of DR in adults with type 2 DM increased from 24% in 2007 to 31% in 2013 (Silpa-archa & Ruamviboonsuk, 2017), and DR is the second leading cause of blindness in people aged 50 or older after 15 years of the disease (Isipradit et al., 2014).

DR is classified into non-proliferative diabetic retinopathy (NPDR) and proliferative diabetic retinopathy (PDR) (Thomas et al., 2019). Early-stage DR may be asymptomatic until blurred vision and dark string-like scotomata occur (Silpa-archa & Ruamviboonsuk, 2017). Disease progression can result in visual loss (Fenwick et al., 2012). The major risk factors for the development and progression of DR include HbA1c >7% and a duration of diabetes exceeding ten years. Conversely, intensive glycemic control (HbA1c <7%) has been shown to reduce the incidence of DR by 76% (Flaxel et al., 2020; Thomas et al., 2019). Furthermore, poor understanding of DM and DR additionally leads to poorer health-related outcomes (American Diabetes Association, 2018; Kim et al., 2014; Lee et al., 2015; Raman et al., 2017; Solomon et al., 2017).

The burden that DR, as a chronic illness, creates for the public health system is enormous, as DR is a major cause of global blindness and is associated with poor health outcomes (Flaxel et al., 2020; International Diabetes Federation & The Fred Hollows Foundation, 2015). The benefits of educating patients to maintain their own self-care have been borne out in several studies, and this form of intervention is a widely recommended method for maintaining and improving the health status of chronically ill patients (Ausili et al., 2017; Baiuomy et al., 2021; Kato et al., 2014). Nurses lead these educational efforts, including preventative strategies that improve diabetes self-care and prevent or slow DR progression. These strategies include lifestyle modification, patient education to enable an understanding of how glycemic control affects DR progression and regular ophthalmologic screenings. In addition, promoting patient engagement in self-care behaviors and increasing patients' awareness of adherence to behavioral modification are essential strategies for improving diabetes self-care to prevent or slow DR progression. Again, nurses are optimally placed in the healthcare framework to effect these beneficial strategies (Duangkaew et al., 2016; Flaxel et al., 2020; Jitkui, 2020; Wong & Sabanayagam, 2019).

Self-care is a process for maintaining health through various determined practices and is performed in both healthy and ill states (Riegel et al., 2012). The three components of self-care are maintenance, monitoring, and management. Self-care maintenance refers to behaviors that maintain health physical and emotional stability, and improve well-being. Self-care monitoring involves observing and consciously checking for signs and symptoms. Self-care management means adopting behaviors to manage signs and symptoms as they occur (Riegel et al., 2012).

Furthermore, previous studies have supported that self-care confidence or self-efficacy is a factor that strongly influences self-care maintenance, monitoring, and management. Self-care confidence is conceptualized as an individual's perception or judgment of their confidence in their capabilities to perform specific health behaviors to prevent or treat health conditions (Bandura, 1997). Self-care confidence consists of two components: perceived self-efficacy and outcome expectation. Expectations about one's self-efficacy can be enhanced through mastery experience, vicarious experience, verbal persuasion, and physiological and affective states (Bandura, 1997; Riegel et al., 2012). DSME/T practice is a strategy to foster optimal self-monitoring of blood glucose, self-reported dietary behaviors, glycemic control, and reduce hospitalizations for DM-related health problems (Tachanivate et al., 2019; Wattana, 2006). Additionally, effectively performing self-care behaviors to promote health and manage chronic illness is crucial. These methods require self-care knowledge, skills, confidence, and motivation to engage in these activities routinely. Individuals also need the capability to cope with multiple individual barriers that obstruct self-care, including poor self-efficacy, cognitive decline, multi-comorbidity, lack of social support, and depression (Bandura, 1997; Riegel et al., 2012).

In chronic diseases such as DR, self-care is a fundamental and integral part of treatment, and patients who engage in self-care have significantly improved clinical outcomes and a better quality of life. However, supporting literature is limited, both from Thailand and abroad. The current study thus aims to evaluate a self-care promoting program that was developed based principally on the Self-Care of Chronic Illness Theory (Riegel et al., 2012), Self-Efficacy Theory (Bandura, 1997), and the Association of Diabetes Care and Education Specialist (ADCES, formerly the American Association of Diabetes Educators, AADED) (American Association of Diabetes Educators, 2009, 2020) guidelines recommendations. This program incorporates nursing interventions that utilize available technologies to support patient efforts and facilitate communication with caregivers.

Methods

Study Design

This randomized controlled trial (RCT) was performed in accordance with the Consolidated Standards of Reporting Trials (CONSORT) guidelines (Schulz et al., 2010). Participants were randomly allocated into an experimental group (SCPP plus standard care) and a control group (standard care only). Single masking was used to reduce or eliminate the Hawthorne effect. The blind assessor was concealed by the research assistants as the evaluator.

Samples/Participants

The study population consisted of patients with type 2 DM and DR registered at the retina center of a government super-tertiary eye hospital. Enrolled patients met all the inclusion criteria: 1) type 2 DM; 2) NPDR in either eye; 3) aged 30-69 years; 4) HbA1c ≥7%; 5) VA ≥ 20/70 in the better eye; 6) able to use the LINE mobile application; and 7) literacy in the Thai

language. Patients were excluded if they had diabetic macular edema (DME) or PDR in both eyes or mature cataracts in both eyes.

The sample size was calculated by power analysis using G*Power software version 3.1. The effect size, calculated from a previous study by Kuntawee. (2007), was 0.546. The power analysis was set at 0.80, and the significance level was α = 0.05, with two treatment groups and two repeated measures. MANOVA was used to assess the group differences of dependent variable changes for repeated measures between subjects. The sample size calculated by this method was 82 persons. An additional 16 participants were recruited to account for 20% of expected attrition (Miller & Smith, 1983, as cited in Srisatidnarakul, 2012), totaling 98 participants, divided evenly into the experimental and control groups.

Medical files of people with DR were screened, and individuals who met the eligibility criteria were approached. Eligibility was confirmed by a registered nurse at the retinal clinic of the research setting. Interested patients were referred to the researcher, and written consent was obtained before enrollment. Randomization was conducted by a third party (unrelated to this study) in permuted blocks of four (ratio of 1:1) using SPSS version 21 to generate the random allocation sequence, and these were distributed in serially numbered, sealed envelopes. Ninety-eight envelopes were thus provided, each indicating either "standard care" or "SCPP plus standard care" (**Figure 1**).
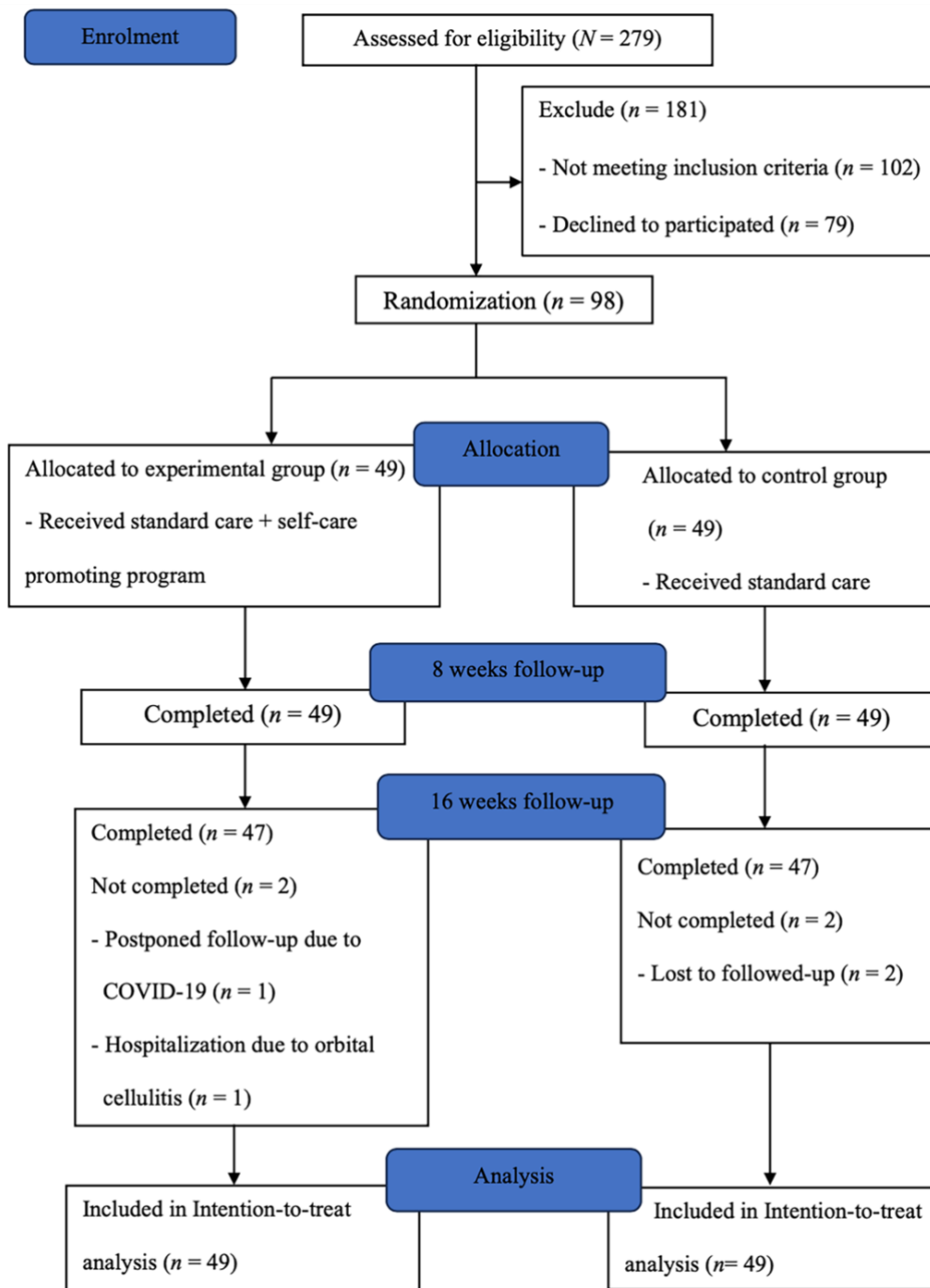

Figure 1 A CONSORT flow diagram of selecting the participants in this study

Instruments

Two types of research instruments were deployed: one for data collection and the other for intervention. Content validity (CVI) was evaluated by eight experts: an endocrinologist, a nursing science professor, a retinal specialist ophthalmologist, a doctor of nurse practitioner for diabetes (DPN), an ophthalmic nurse practitioner, an informatics nurse, an informatics professor, and an ophthalmologist specializing in digital informatics technology. The following data collection instruments were used in this study:

The Sociodemographic and Clinical Characteristics Questionnaire was developed by the researchers to gather details on age, gender, marital status, education level, received DR education, body mass index (BMI), duration of diabetes and DR, HbA1c, systemic and eye comorbidities, VA in the better eye, and DR severity in both eyes and the better eye.

The Self-Care For Diabetic Eye Care (SCFDE) questionnaire was employed to assess the level of patient engagement in eye care behaviors. This instrument was developed by the researcher based on the self-care of chronic illness theory (Riegel et al., 2012), the Royal College of Ophthalmology of Thailand clinical guidelines for DR (Cheewariamgrpk & Rattanapakorn, 2016), and previously published studies (Baiuomy et al., 2021; Beaser et al., 2018; Cho & Kim, 2021; Duangkaew et al., 2016; Flaxel et al., 2020; Wannasiri et al., 2021; Wong & Sabanayagam, 2019). The SCFDE was adapted and constructed following the original SCODI questionnaire, which was based on the Self-Care of Chronic Illness Theory (Riegel et al., 2012), including self-care maintenance, monitoring, management, as well as based on the self-care confidence or Self-Efficacy Theory (Bandura, 1997).

This instrument was adapted following a series of steps based on questionnaire principles to enhance its efficacy (Gunawan et al., 2021; Srisatidnarakul, 2012). These steps were: 1) Define the concept of the variable, 2) Define operational definitions, 3) Design the scale based on the original SCODI questionnaire, 4) Draft and sequence the items, 5) Seek content experts, 6) Tabulate content validity judgments by these experts, 7) Pilot pretest the instrument with 30 DR patients, 8) Conduct item analysis and reliability assessment. It was initially planned to perform a confirmatory factor analysis (CFA) to verify that the variables as defined correlated with their associated underlying constructs (patient behaviors, impressions, and disease indicators). However, after specifying a model, determining its identification, and collecting data, it was apparent that the sample size of patients with diabetic retinopathy was insufficient to enable a meaningful analysis. For this reason, CFA was not performed.

During content validity assessments by eight experts, one item from eye care maintenance was eliminated and deemed irrelevant due to the concept definition. Twenty-eight items were analyzed after the items were tested with 30 DR patients to determine item correlation. All these items had an inter-item correlation of 0.30-0.70, more than 50 percent of the acceptable values (Jacobsen et al., 1988, as cited in Srisatidnarakul, 2012). Next, 28 questions in four categories were included in the instrument: nine questions on eye care maintenance, six questions on eye care monitoring, six questions on eye care management, and seven questions on eye care confidence. A 5-point Likert scale for eye care maintenance, monitoring, management, and eye care confidence was used, scoring from 1 (not at all) to 5 (always) for items 1-13 and 16-28. Scoring for items 14-15 used a 6-point Likert scale from 0 (do not recognize symptoms) to 5 (very quickly). For each scale, scores were standardized as 0-100, with a higher SCFDE score (≥70) indicating better engagement in eye care behaviors. The content validity (CVI) results were 0.96, and reliability (Cronbach's alpha coefficient) was 0.86 in the pilot study among 30 DR patients and 0.88 in the current study.

The Self-Care of Diabetes Index (SCODI) questionnaire (Thai version) was used to measure engagement in diabetes self-care behaviors. The original version, developed by Ausili et al. (2017) for diabetes patients, was translated into Thai by a researcher, and its validity was verified by seven experts using a forward-backward translation technique as determined by the instrument owner (Ausili et al., 2017). The author's translation was used for a final check. This tool consists of 40 items divided into four dimensions: 12 questions on self-care maintenance, eight questions on self-care monitoring, nine questions on self-care management, and 11 questions on self-care confidence. Scoring used a 5-point Likert scale. Self-care maintenance, monitoring, and management are scored from 1 (not at all) to 5 (always). For self-care confidence, a score of 1 indicated "not confident at all," and 5 indicated "confident in everything." Scoring for items 19-20 used a 6-point Likert scale from 0 (do not recognize symptoms) to 5 (very quickly). Participants who received insulin injections had their scores converted based on 40 questions, while those who did not had their scores converted based on 39 questions. For each scale, scores were standardized from 0-100, with higher SCODI scores (≥70) indicating better engagement in diabetes self-care behaviors (Ausili et al., 2017). Eight experts tested the instrument for its content validity (CVI). The results of CVI were 0.92, and the Cronbach's alpha reliability coefficient was 0.90 in the pilot study among 30 DR patients and 0.88 in the current study.

The Impact of Visual Impairment Questionnaire (IVI-Thai version) was translated by Ratanasukon et al. (2016), and the authors permitted the researcher to use it to assess VRQoL. This instrument contains 28 items divided into three sub-scales: (i) reading and accessing information (VR) (items 1-9), (ii) mobility and independence (VM) (items 11-20), and (iii) emotional well-being (VE) (items 21-28) to evaluate the impact of vision impairment on the quality of life of DR patients. The active response options of each item are expressed on a scale ranging from 0 (not at all), 1 (a little), 2 (moderately) to 3 (a lot), and items 1 to 15 have an additional response for not applicable (do not do this activity for other reasons). The range of total scores is 0-84, with a higher score indicating a more greatly reduced vision-related quality of life. The internal consistencies (Cronbach's alpha) of the IVI questionnaires (Thai version) were reported in the previous study, ranging from 0.787 to 0.849. Additionally, in this study, the reliability of the pilot study (Cronbach's alpha coefficient) among 30 DR patients was 0.92. In the main study, it was 0.89.

The clinical outcomes assessment consisted of the following:

The level of DR severity was measured using the DR patient's retinal images, which were obtained from Ultra-

widefield fundus photographs (Nikon group company, Thailand) and graded by three ophthalmologists based on the Early Treatment Diabetic Retinopathy Study (ETDRS). Grading classified findings into no DR, mild, moderate, severe NPDR, and PDR.

HbA1c was assessed using DR patients' blood, which was collected by laboratory technicians and analyzed via pathology service for HbA1c. The goal for the HbA1c level in patients with type 2 DM was less than 7% (American Diabetes Association, 2018).

Visual acuity (VA) was measured using The Early Treatment Diabetic Retinopathy Study (ETDRS) LogMAR chart at a distance of 4 meters. The researcher collected VA data from the medical records. The International Classification of Diseases (ICD-11) (World Health Organization, 2022) classifies the level of distance vision impairment into mild, presenting VA worse than 6/12 (≤ 20/50); moderate, presenting VA worse than 6/18 (≤ 20/63); severe, presenting VA worse than 6/60 (≤ 20/200), and blindness, presenting VA worse than 3/60 (≤ 20/400).

Interventions
The experimental group received standard care along with the SCPP for 12 weeks, provided by the researcher, while the control group only received standard care. The SCPP was developed based on the Self-Care of Chronic Illness Theory (Riegel et al., 2012), the Self-Efficacy Theory (Bandura, 1997), the ADCES Guidelines (American Association of Diabetes Educators, 2009, 2020), and additional supporting literature. The SCPP content was based on related literature reviews, which suggested that a successful nursing intervention program to control diabetes and prevent diabetic retinopathy progression included standards of diabetes care and patient engagement and adherence to performing self-care and eye care behaviors (American Association of Diabetes Educators, 2009, 2020; Ausili et al., 2017; Baiuomy et al., 2021; Beaser et al., 2018; Cho & Kim, 2021; Chrvala et al., 2016; Fabrizi et al., 2020; Flaxel et al., 2020; International Diabetes Federation, 2019; Riegel et al., 2012; Tachanivate et al., 2019). Furthermore, previous studies demonstrated that all effective aspects of self-care, including self-care maintenance, monitoring, and management behaviors, are strongly influenced by self-care confidence or self-efficacy, which is defined as a person's belief in their ability to perform self-care at each stage of the self-care process (Bandura, 1997; Beaser et al., 2018; Kong & Cho, 2020; Riegel et al., 2012; Riegel et al., 2021). Moreover, essential digital technology such as smartphone applications can promote preventive self-care, patient clinical consultations, and individualized feedback to provide real-time self-care and empower patients to engage in personal problem-solving to change behaviors, as well as reminders to improve health outcomes (Cho & Kim, 2021; Riegel et al., 2021; Wong & Sabanayagam, 2020).

The SCPP process was delivered in five steps: (1) Assessing patients' needs, barriers, and abilities to perform self-care for glycemic control; (2) Gaining knowledge and skill mastery training to build confidence; (3) Goal setting and plan formulation; (4) Self-care skills practice and implementation; and (5) Evaluating and monitoring performance. The SCPP employs several strategies related to diabetes and diabetic retinopathy knowledge and skills training for diabetic control

and maintaining or delaying the progression of DR. These include individualized assessment, small group education and discussions, and skills mastery training. All SCPP materials were provided to participants. These included the DR self-care manual, the DR booklet, the near card Snellen VA, the Amsler grid document, and the DR health education mobile application. They included the SCPP information and instructions for practicing, covering the five steps of self-care.

Steps 1-4 were performed during participants' first week in the study. During step 1, all individuals participated in a discussion with the researcher for 30 minutes. In the other three steps, participants were divided into nine small groups of 5-10 people for 60-90 minutes per session (totaling 330 minutes) of education, discussion, and training. Step 5 was performed in weeks 4 and 8 and included online group discussions for 2-3 hours of sharing and evaluation using the LINE mobile application. Telephone follow-up discussions lasting 10-15 minutes were completed in weeks 2, 3, 5, 6, 7, and 12 (6 phone calls total) to reinforce patients' DR self-care engagement. Then, the participants were requested to follow up within four weeks of completing the SCPP, usually with their next ophthalmologist appointment. During the follow-up visit, they met with the researcher to discuss their objective successes and evaluate any barriers. The researcher proceeded to empower and motivate individuals to make any additional behavioral adjustments that were necessary, as well as to maintain their self-care and eye care routines (**Table 1**).

The participants were assessed for engagement in self-care and eye-care behaviors, vision-related quality of life, visual acuity, fundus photography, and HbA1c in week 1 as baseline, week 8, and week 16 as comparison data. Both groups also received DR standard care provided by medical staff at the retinal clinic each visit, consisting of 1) measurement of blood pressure, VA, and intraocular pressure (IOP); 2) eye examination, such as pupil dilation, retinal photographs, or optical coherence tomography (OCT); 3) scheduling examination by an ophthalmologist, and 4) individual DM and DR health education. Additionally, appointments were made as necessary for specific treatments, such as laser treatment, intravitreal injection by an ophthalmologist.

Data Collection
Data were collected from May 2022 to March 2023. All data were collected by three registered nurses with experience caring for DR patients who were trained as research assistants (RA) and blinded to allocation. After the first RA invited each interested participant who met the inclusion criteria to participate, the participants were randomly assigned to either the experimental or control groups by a statistician who was not involved with data collection. The researcher then provided a verbal informal consent explanation, and the participants obtained and signed the informed consent form. Baseline data, including sociodemographic and clinical data, and all expected outcomes of this study in the experimental group were collected by the second RA, and the control group data were completed by the third RA.

The experimental group received 12 weeks of the SCPP plus standard care provided by the researcher, while the control group received only standard care provided by registered nurses at the retina center of the ophthalmology

outpatient department. Participants in both groups were evaluated for engagement in eye care and self-care behaviors using the SCFDE (Thai version) and the SCODI (Thai version) three times: at baseline, week 8, and week 16. Additionally, clinical outcomes included the level of DR severity, HbA1c, and VA, which were assessed at baseline and week 16. Moreover, the vision-related quality of life (VRQoL) was also evaluated using the IVI questionnaire (Thai version) at baseline and week 16.

Table 1 Components of Self-Care Promoting Program (SCPP)

Components of Theory	Strategies	Description of Intervention
Self-Care of Chronic Illness Theory		
Self-care maintenance	Health education Skills training	Individual health education regarding self-care, including diet, physical activities and exercise, medication and treatment adherence, and stress management (based on ADCES guidelines)
Self-care monitoring	Skills training Diary log record	Monitoring DM control, observing and recording blurred vision symptoms (based on ADCES guidelines) of DR related to poorly controlled DM
Self-care management	Health education	The nurse taught the patient how to manage symptoms autonomously or through consultation when the symptoms occur (based on ADCES guidelines)
Self-Efficacy (Self-Care Confidence)		
Mastery experience	Patient-nurse interaction	Discussion regarding success at self-care skills for glycemic control
	Self-monitoring	Teaching patients to observe and record in a diary their performance and identify problems performing self-care
	Goal setting	The researchers discussed the patient's goal for self-care behaviors and clinical outcomes (HbA1c, VA, VRQoL, Severity of DR)
Vicarious experience	Observation with Successful Model	The successful model was presented to demonstrate how to perform self-care actions to control DM and its complications The patients observed and discussed the successful model regarding techniques to control DM and overcoming barriers to achieving their goals
Verbal persuasion	Education and discussion	The researcher encouraged patients that they had the capability to undertake more activities than they had performed and supported them as they began making a lifestyle change
Physiological and emotional states	Education, discussion, and training	The researcher discussed physical and emotional barriers impacting patients' confidence and performance and re-interpreted their symptoms and emotions, such as fatigue, blurred vision, fear of falling, or blindness, and suggested ways to overcome these barriers
ADCES Guidelines for DSME/T Implementation Process		
Applying and integrating the five steps of the ADCES Guidelines with the theory of Self-Care of Chronic Illness, Self-Efficacy, and related literature reviews to be the major strategies of the Self-Care Promoting Program (SCPP)		
Assessment	Assessing patients' needs, barriers, and strengths	The researcher performed an individual face-to-face discussion aimed at assessing the patient's needs and symptoms (e.g., eye pain, blurred vision, hypo/hyperglycemia) using specific instruments such as the near card Snellen VA, Amsler grid, or self-monitoring blood glucose instrument
Goal setting and planning	Setting the goal and formulating the plan	The desired behavioral goal and specific strategic planning were set in mutual agreement with each participant. These goals and strategic plans were based on the patient's problems, needs, and strengths. The plan was developed to increase the patient's knowledge and skills required for self-management and the confidence to perform appropriate self-care and eye-care behaviors
Implementation	Self-care skills practice and implementation Education, discussion and training	The researcher educated and trained the patients regarding self-care maintenance, monitoring, and management The participants were encouraged to maintain and continuously perform self-care skills and monitor symptoms for controlling illness from the hospital to their home
Evaluation/Monitoring	Evaluating and monitoring performance	The researcher evaluated the participants' self-care and eye-care behaviors, gave feedback, and empowered them to sustain their performance of new self-care and eye-care behaviors to prevent the complications of DR The results of participants' health outcomes were evaluated to ensure that the goals were met as expected

Data Analysis

Intention-to-treat (ITT) analysis was conducted using imputed ITT for primary analysis, employing the Last Observation Carried Forward (LOCF) method to impute missing data (Polit & Gillespie, 2010). Participants were considered to have dropped out if they were not reachable by phone or did not respond to calls during the follow-up period, and they were included in the analysis. After participating in the program at week 8, the total number of dropped-out participants was four (4.08%) (n = 2 in each group).

Data were analyzed using SPSS version 21.0 (SPSS Inc., Chicago, IL, USA). The data were checked for multivariate normality distribution, linearity of dependent variables, and homoscedasticity before being subjected to parametric tests. Mahalanobis distance was performed to assess the multivariate normality distribution of the dependent variables, and the data matched the appropriate test accordingly.

Descriptive statistics were used to analyze participants' characteristics. The Chi-squared and Fisher's exact tests were employed for categorical data, while an independent t-test was used for continuous data. Additionally, the chi-square test was utilized to compare the severity of DR. Multivariate Analysis of Variance (MANOVA) and repeated measures MANOVA were performed to assess the mean difference in engagement in self-care behavior, HbA1c, VA, and VRQoL between the two groups at each time point and the change over time (Tabachnick & Fidell, 2007).

Ethical Considerations

This research obtained approval from the Human Research Ethics Committee of Thammasat University (Science) (COA No.017/2565) and the Ethical Committee of Mettapracharak (Wat Rai Khing) Hospital (COA No.014/2565). Additionally, it was registered with the Thai Clinical Trials Registry (TCTR20230302002).

Results

Sociodemographic Data

Fifty-six participants (57%) were male. The mean age of the participants was 55.45 years (range 32-69, SD 8.326), and 74 participants (75.5%) were aged between 50 and 69 years. Seventy-eight patients (79.6%) were married. All participants had at least a primary school education level and had undergone DR screening in the past year. Fifty-five patients (56%) reported never having received any information about

diabetic retinopathy. The mean body mass index (BMI) of participants in both groups was 27.37 kg/m² (SD = 5.057).

Clinical Data

The mean time since diagnosis of type 2 DM was 11.8 years (range 1 –35 years, SD = 7.699), with most participants (52, 53.06 %) having been diagnosed ten or fewer years prior. The mean time since diagnosis of DR was 21 months (range one month -12 years, SD = 2.766), and the majority of participants (44, 44.9%) had been diagnosed less than one year prior. HbA1c levels in 40 (40.8%) patients were less than 8.0, in 32 (32.7%) patients between 8.1 and 9.0, and in 26 (26.5%) participants over 9.0. HbA1c levels were statistically similar between the control and experimental groups. The duration of DR was similar between the groups.

DR severity was evaluated for each eye separately, and patients were grouped according to the severity in the better eye for subsequent analysis. Ninety-four participants (95.92%) had VA = 0.00-0.40 LogMAR, and VA was similar between the control and experimental groups. Thirty-five patients (35.7%) had mild NPDR, 51 (52.1%) had moderate NPDR, and 12 (12.2%) had severe NPDR in the better eye. The degree of DR severity was similar between the control and experimental groups. Most of the participants (59, 60.2%) presented with cataracts. After applying Chi-Square, Fisher's exact test, and independent t-test methods, the sociodemographic and medical history data comparison between the experimental and control groups indicated no significant statistical differences (p >0.05). The details are shown in **Table 2**.

Table 2 Characteristics of persons with type 2 diabetes and DR

Characteristics	Total (N = 98) f (%)	Control (n = 49) f (%)	Experiment (n = 49) f (%)	Statistical value	p
Gender				0.667[a]	0.414
Male	56 (57.1)	30 (61.2)	26 (53.1)		
Female	42 (42.9)	19 (38.8)	23 (46.9)		
Age (years)	Mean =55.45, SD = 8.33 (range = 32-69)	Mean = 55.35, SD = 8.91 (range = 32-69)	Mean = 55.55, SD = 7.79 (range = 42-69)	-0.121[t]	0.904
30-49	24 (24.5)	11 (22.4)	13 (26.5)	0.221[a]	0.638
50-69	74 (75.51)	38 (77.6)	36 (73.5)		
Marital status				2.262[a]	0.133
Married	78 (79.6)	42 (85.7)	36 (73.5)		
Single/ divorced	20 (20.4)	7 (14.3)	13 (26.5)		
Education				4.690[a]	0.096
Primary/Secondary	39 (39.8)	24 (49.0)	15 (30.6)		
Vocational/High Vocational	28 (28.6)	14 (28.6)	14 (28.6)		
Bachelor/ Postgraduate	31 (31.6)	11 (22.4)	20 (40.8)		
Received DR education				373[a]	0.41
No	55 (56.1)	29 (59.2)	26 (53.1)		
Yes	43 (43.9)	20 (40.8)	23 (46.9)		
Body Mass Index (BMI) (Kg/m2)	Mean = 27.37, SD = 5.056 (range = 32-69)	Mean = 26.72, SD = 5.26 (range = 32-69)	Mean = 28.02, SD = 4.82 (range = 32-69)	-1.276[t]	0.205
18.5 -22.9	18 (18.4)	12 (24.5)	6 (12.2)	2.721[a]	0.437
23-24.9	16 (16.3)	8 (16.3)	8 (16.3)		
25-29.9	38 (38.8)	18 (36.7)	20 (40.8)		
≥30	26 (26.5)	11 (22.4)	15 (30.6)		
Duration of diabetes (years)	Mean =11.80, SD = 7.69 (range = 1-35)	Mean = 12.99, SD = 8.27 (range = 1-35)	Mean = 10.62, SD = 6.96 (range = 1-35)	1.534[t]	0.128
1-5	29 (29.6)	12 (24.5)	17 (34.7)	3.231[a]	0.52
6-10	23 (23.5)	12 (24.5)	11 (22.4)		
11-15	19 (19.4)	9 (18.4)	10 (20.4)		
16-20	16 (16.3)	8 (16.3)	8 (16.3)		
>20	11 (11.2)	8 (16.3)	3 (6.1)		

Table 2 *(Cont.)*

HbA1c (%)	Mean = 9.067, SD = 2.06 (range = 7-15.3)	Mean = 8.92, SD = 2.004 (range= 7-15.3)	Mean = 9.26, SD = 2.13 (range=7-15.3)	-0.713[t]	0.478
7.0-8.0	40 (40.8)	21 (42.9)	19 (38.8)	0.754[a]	0.686
8.1-9.0	32 (32.7)	14 (28.6)	18 (36.7)		
>9.0	26 (26.5)	14 (28.6)	12 (24.5)		
Systemic Comorbidities				0.344[a]	0.558
No	3 (3.1)	1 (2.0)	2 (4.1)		
Yes	95 (96.9)	48 (98.0)	47(95.9)		
Cataract				0.043[a]	0.836
No	39 (39.8)	19 (38.8)	20 (40.8)		
Yes	59 (60.2)	30 (61.2)	29 (59.2)		
Duration of DR (years)	Mean = 1.913, SD = 2.76 (range = 0.01-12)	Mean = 1.96, SD = 2.84 (range = 0.01-12)	Mean = 1.869, SD = 2.72 (range = 0.01-12)	0.153[t]	0.879
<1	44 (44.9)	21 (42.9)	23 (46.9)	0.424[a]	0.809
1-5	42 (42.9)	21 42.9)	21 (42.9)		
>5	12 (12.2)	7 (14.3)	5 (10.2)		
DR severity: Right Eye				2.381[b]	0.702
No DR	-	-	-		
Mild NPDR	31 (31.6)	17 (34.7)	14 (28.6)		
Moderate NPDR	47 (48.0)	22 (44.9)	25 (51.0)		
Severe NPDR	9 (9.2)	3 (6.1)	6 (12.2)		
PDR	6 (6.1)	4 (8.2)	2 (4.1)		
Non-specified due to CRVO	5 (5.1)	3 (6.1)	2 (4.1)		
DR severity: Left Eye				3.793[b]	0.624
No DR	1 (1.02)	1 (2.1)	-		
Mild NPDR	28 (28.6)	16 (32.7)	12 (24.5)		
Moderate NPDR	48 (49.0)	20 (40.8)	28 (57.1)		
Severe NPDR	10 (10.2)	5 (10.2)	5 (10.2)		
PDR	8 (8.2)	5 (10.2)	3 (6.1)		
Non-specified due to CRVO	3 (3.1)	2 (4.1)	1 (2.0)		
DR severity in the better eye				0.887[a]	0.642
Mild NPDR	35 (35.7)	20 (40.8)	15 (30.2)		
Moderate NPDR	51 (52.1)	24 (49.0)	27 (55.1)		
Severe NPDR	2 (12.2)	5 (10.2)	7 (14.3)		
VA in the better eye (LogMAR)	Mean = 0.96, SD = 0.120 (range = 0.00-0.60)	Mean = 0.108, SD = 0.133 (range = 0.00-0.60)	Mean = 0.83, SD = 0.104 (range = 0.00-0.50)	1.010[t]	0.315
None (0.00-0.40)	96 (97.96)	48 (97.96)	48 (97.96)	4.718[b]	0.635
Mild-moderate VI (0.50 - <1.0)	2 (4.08)	1 (2.04)	1 (2.04)		

Comparisons of the Mean Scores of the Outcome Measurements

The MANOVA analysis results indicated that the mean scores on engagement in self-care behaviors, HbA1c, VA, severity of DR, and VRQoL were not significantly different at baseline. Additionally, MANOVA analysis showed that the mean scores for engagement in SM1, EM1, SM2, EM2, SM3, EM3, SC, EC, HbA1c, VA, and total VRQoL were not significantly different between the experimental and control groups at baseline (p >0.05) (**Figure 2**).

Comparison of the mean score of engagement in self-care behaviors between the experimental and control groups at all time points

Self-care behavior includes diabetes management and diabetic eye care, categorized as self-care and eye-care maintenance (SM1, EM1), self-care and eye-care monitoring (SM2, EM2), self-care and eye-care management (SM3, EM3), and self-care and eye-care confidence (SC, EC).

After performing repeated measures MANOVA, the results showed a significant interaction between time and group on SM1, SM2, SM3, and SC [F (8, 89) = 16.393, p <0.001], and EM1, EM2, EM3, and EC [F (8, 89) = 16.132, p <0.001]. Table 3 illustrates the results of the post-hoc comparison of mean scores for self-care and eye-care behaviors. Bonferroni correction was used to assess post-hoc comparisons between groups at each time point. The results showed that the mean self-care maintenance, monitoring, management, and confidence behavior scores were statistically significantly higher in the experimental group than in the control group at weeks 8 and 16. The pairwise comparison revealed that within the experimental group, mean SM1, SM2, and SM3 score differences between all three-time points (e.g., Time 1 vs. Time 2, etc.) were statistically significant (p <0.001). In the control group, mean SM1, SM2, and SM3 score differences varied between some time points but fewer than in the experimental group.

Scores for engagement in eye-care behaviors showed a similar pattern. In the experimental group, mean scores increased over time for EM1, EM2, EM3, and EC. In contrast, in the control group, these comparisons showed fewer differences (**Table 3**).

Comparison of mean scores for HbA1C, VA, total VRQoL, and sub-scales (VR, VM, VE) over time and between groups

The MANOVA results indicated that the participants in the SCPP group showed improvement in HbA1c, total VRQoL, VR, and VM, but not in VA and VE at 16 weeks (see **Table 4** and **Figure 2**).

Table 3 Post-hoc comparison of the mean scores of engagement in self-care and eye-care behaviors between the two groups at different time points by time and by group ($N = 98$)

Variables/ Time	Between Group				Within Group (Bonferroni)		
	Group	Mean (SD)	SE	*p*	Mean difference		
					Time 1	Time 2	Time3
SM1							
Baseline	Control	77.4658 (14.46)	1.829	0.023		-2.934*	-4.507*
	Experimental	77.1257 (10.89)	1.829	0.000		-12.925**	-17.177**
Eight weeks	Control	80.3995 (12.37)	1.601	0.001			-1.573
	Experimental	90.0510 (9.91)	1.601	0.000			-4.252**
16 weeks	Control	81.9726 (11.83)	1.408	0.157			
	Experimental	94.3027 (7.36)	1.408	0.000			
SM2							
Baseline	Control	50.4201 (23.93)	3.384	0.024		-6.302*	-11.104**
	Experimental	59.4237 (23.43)	3.384	0.000		-24.490**	-33.674**
Eight weeks	Control	56.7225 (21.83)	2.969	0.000			-4.802*
	Experimental	83.9136 (19.68)	2.969	0.000			-9.184**
16 weeks	Control	61.5245 (20.25)	2.478	0.016			
	Experimental	93.0972 (13.84)	2.478	0.000			
SM3							
Baseline	Control	28.8265 (20.02)	3.095	0.011		-7.426*	-4.989
	Experimental	32.0011 (23.19)	3.095	0.000		-40.625**	-48.165**
Eight weeks	Control	36.2528 (19.89)	2.906	0.112			2.438
	Experimental	72.6263 (20.79)	2.906	0.000			-7.540**
16 weeks	Control	33.8152 (19.23)	2.977	0.243			
	Experimental	80.1659 (22.33)	2.977	0.000			
SC							
Baseline	Control	64.5638 (18.53)	2.807	0.031		-5.566*	-8.859*
	Experimental	66.0946 (20.72)	2.807	0.000		23.238**	-28.572**
Eight weeks	Control	70.1298 (16.25)	2.073	0.001			3.293*
	Experimental	89.3322 (12.53)	2.073	0.000			-5.334**
16 weeks	Control	73.4229 (15.23)	1.787	0.021			
	Experimental	94.6661 (9.00)	1.787	0.000			
EM1							
Baseline	Control	67.9210 (15.06)	2.123	0.000		-7.972**	-6.059*
	Experimental	69.4516 (14.65)	2.123	0.000		-9.515**	-23.533**
Eight weeks	Control	75.8929 (13.81)	1.661	0.004			1.913
	Experimental	88.9670 (8.90)	1.661	0.000			-4.018*
16 weeks	Control	73.9796 (14.92)	1.688	0.217			
	Experimental	92.9849 (7.51)	1.688	0.011			
EM2							
Baseline	Control	32.6793 (30.56)	3.922	0.000		-15.293**	-13.762*
	Experimental	35.2237 (23.94)	3.922	0.000		-48.810**	-59.439**
Eight weeks	Control	47.9723 (29.24)	3.289	0.001			1.531
	Experimental	84.0332 (14.32)	3.289	0.000			-10.629**
16 weeks	Control	46.4417 (25.66)	2.838	0.578			
	Experimental	94.6624 (11.43)	2.838	0.000			
EM3							
Baseline	Control	30.3572 (25.94)	3.418	0.000		-17.517**	-15.221**
	Experimental	28.6566 (21.73)	3.418	0.000		-58.333**	-66.581**
Eight weeks	Control	47.8741 (30.61)	3.513	0.000			2.296
	Experimental	86.9898 (16.51)	3.513	0.000			-8.248*
16 weeks	Control	45.5782 (32.59)	3.434	0.451			
	Experimental	95.2381 (9.66)	3.434	0.008			
EC							
Baseline	Control	53.1339 (22.09)	3.107	0.004		-8.528*	-10.350**
	Experimental	53.1340 (21.40)	3.107	0.000		-36.808**	-43.295**
Eight weeks	Control	61.6616 (20.72)	2.550	0.000			-1.822
	Experimental	89.9417 (14.43)	2.550	0.000			-6.487*
16 weeks	Control	63.4837 (18.26)	2.030	0.379			
	Experimental	96.4286 (8.41)	2.030	0.002			

Notes: * *p*-value < 0.05, ** *p*-value <0.001

Comparison of the severity of DR at baseline and 16 weeks between the experimental and control groups

The Chi-Square results showed that overall patients' DR severity remained unchanged between groups over 16 weeks ($p >0.05$; right eye $p = 0.358$, left eye $p = 0.475$). However, the experimental group showed a decrease in DR severity progression more than before participating in the program, whereas the control group did not.

Table 4 Pairwise comparisons of the mean scores of HbA1C, Visual Acuity (VA), and total VRQoL with three subscales (VR, VM, VE) between the two groups at baseline and 16 weeks (*N* = 98)

Variables	Group	Baseline	16 weeks	Within Group (Bonferroni)		
		Mean ± SD	Mean ± SD	Mean difference	SE	Sig.
HbA1C	Control	8.92 ± 2.004	8.81 ± 2.003	0.100	0.183	0.587
	Experimental	9.22 ± 2.130	7.92 ± 1.71	1.292**	0.183	<0.001
VA	Control	0.108 ± 0.134	0.098 ± 0.135	0.010	0.019	0.587
	Experimental	0.083± 0.105	0.089 ± 0.133	-0.006	0.019	0.745
VR	Control	6.22 ± 6.273	5.33 ± 6.266	0.898	0.831	0.282
	Experimental	4.73 ± 4.974	2.57 ± 4.153	2.163*	0.831	0.011
VM	Control	6.00 ± 8.193	7.31 ± 8.583	-1.306	0.845	0.125
	Experimental	5.53 ± 6.465	2.82 ± 4.671	2.714*	0.845	0.002
VE	Control	2.96 ± 3.297	3.35 ± 4.635	-0.388	0.495	0.435
	Experimental	3.29 ± 4.397	2.47 ± 3.703	0.816	0.495	0.102
Total VRQoL	Control	15.18 ± 15.34	15.98 ± 16.71	-0.796	1.77	0.654
	Experimental	13.55 ± 14.61	7.86 ± 11.07	5.694*	1.77	0.002

*Notes: **p <0.001, *p <0.05*

Changes in mean score of self-care maintenance (SM1), monitoring (SM2), management (SM3), and confidence (SC) behaviors between the two groups at baseline, week 8 and week 16

Changes in mean score of eye-care maintenance (EM1), monitoring (EM2), management (EM3), and confidence (EC) behaviors between the two groups at baseline, week 8 and week 16

Changes in mean score of HbA1C and visual acuity (VA) in the better eye between the two groups at baseline and 16 weeks

Changes in mean total scores of impact of visual impairment (total vision-related quality of life; VRQoL) with three subscales; VR, VM, and VE between the two groups at baseline and 16 weeks
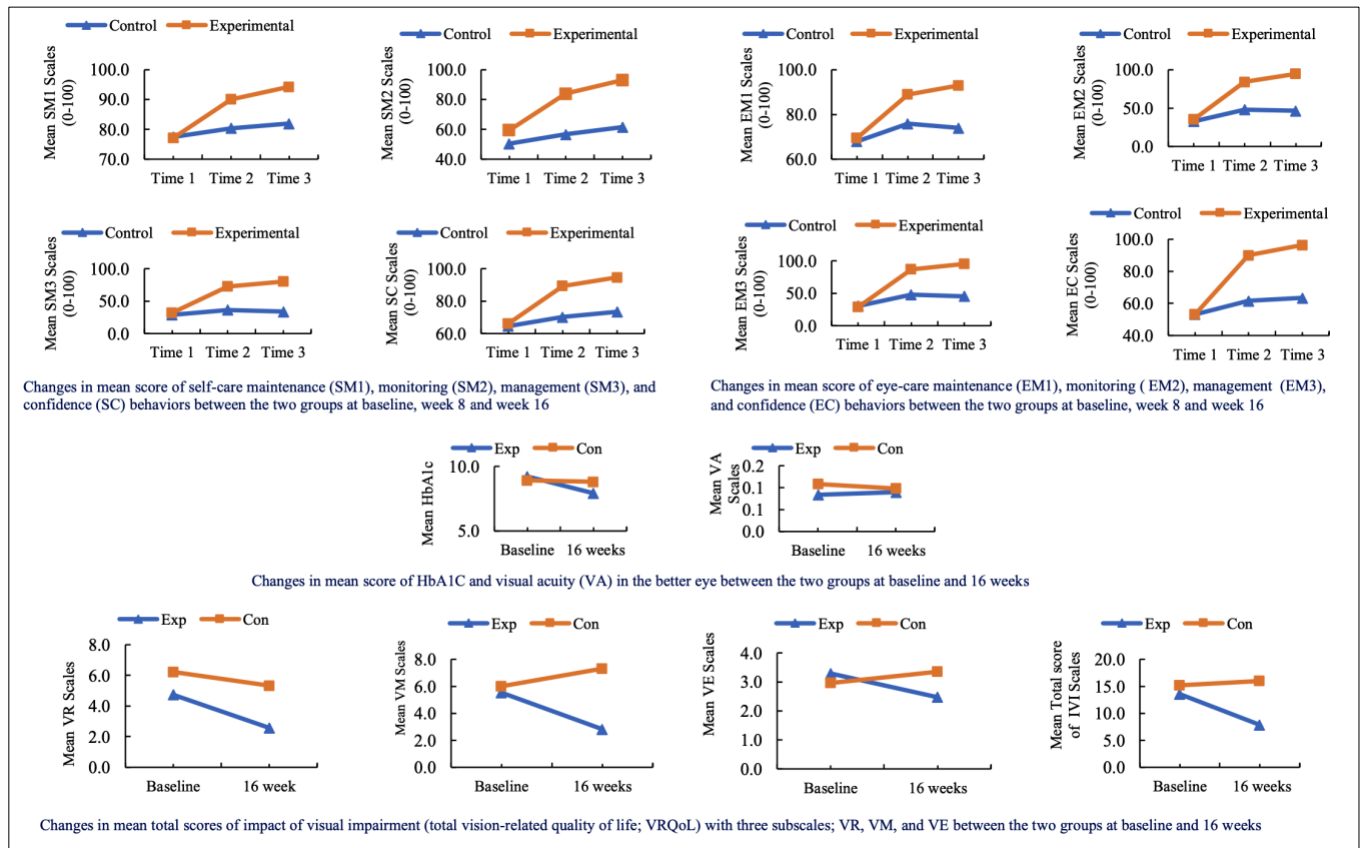
Figure 2 Changes in the mean score of outcome variables between the two groups at different time points

Discussion

Summary of the Findings

This study suggests that SCPP is beneficial. Participants receiving SCPP showed improvement in self-care and eye-care behavior, HbA1c, and VRQoL and maintained VA and DR compared with participants who received only standard care over 16 weeks. For participants in SCPP, engagement in self-care and eye-care confidence behaviors scores showed the most notable improvement of all self-care parameters, including self-care maintenance, monitoring, and self-care management over the duration of the study, suggesting that SCPP effectively instilled a degree of belief in patients' own ability to manage their illness. Therefore, integrating self-care confidence into the intervention program could affect the patient with DR in terms of adequate engagement in self-care behaviors. Congruence with previous studies' results showed that higher engagement in self-care was associated with higher self-care confidence or self-efficacy (Kong & Cho, 2020).

SCPP incorporates numerous innovative strategies, and it is difficult to know which of these is operative in enhancing self-care behaviors in people with type 2 DM and DR (Riegel et al., 2012; Tachanivate et al., 2019; Thongyost et al., 2023; Wannasiri et al., 2021). It seems reasonable to suspect that information about ophthalmic complications—how exactly DR happens and how people lose vision—generates a simple "fear factor" pushing patients to be diligent in managing their disease. This would include increased awareness of how high blood sugar leads to DR and lens-related vision changes. It is not surprising that participants in SCPP reported significantly higher adequate engagement in self-care and eye-care behaviors, which showed a clearer understanding of the link between diabetes management, the development, and the progression of DR (Beaser et al., 2018; Wong & Sabanayagam, 2019; Wong & Sabanayagam, 2020).

SCPP participants showed improvement in HbA1C over time, an extremely encouraging finding that correlates with earlier studies and highlights the benefits of self-care behavior promotion in people with diabetes (Cho & Kim, 2021; Fabrizi et al., 2020; Jitkui, 2020; Lee et al., 2015; Thongyost et al., 2023). The link between educational interventions and dietary intake, as well as exercise, has additionally been shown and illustrates the benefits of interventions similar to SCPP (Baiuomy et al., 2021).

No improvement in VA was noted throughout this study. This is not surprising, as diabetes-induced visual deficits are extremely stubborn and take a long time to improve, far more than the 16 weeks duration of this study (Altomare et al., 2018; Beaser et al., 2018; Flaxel et al., 2020). A proper investigation of the actual visual benefits of SCPP would require a longer study with an evaluation of more specific parameters related to vision (e.g., macular thickness, degree of cataract). Similarly, DR severity did not change over the course of the study, almost certainly for the same reasons: diabetes-related eye disease takes a long time to reverse, and this current study was not designed to show improvement, being only 16 weeks long (Flaxel et al., 2020; Jitkui, 2020; McLauchlan, 2014; Perais et al., 2023). A longer study with more detailed parameters would be needed to study whether SCPP correlates with such improvement.

Participants in the SCPP experimental group showed more VRQoL improvement than control group patients over time. This contrasts with previous studies by Rees et al. (2013) and Thongyost et al. (2023), who found that VRQoL in older persons with DR with visual impairment after implementation of the self-management educational program did not generally improve over 16 weeks. The most obvious implication is that quality of life is more difficult to change as people age, although the question requires further explanation.

To sum up, a self-care promoting program assembled through a combination of the Self-Care of Chronic Illness Theory, the Self-Efficacy Theory, and the ADCES guidelines for diabetes self-management approaches could effectively promote adequate engagement in self-care and eye-care behaviors, reduce HbA1c, and increase VRQoL in people with diabetes. It seems reasonable to suspect that SCPP could improve vision and reduce DR severity if applied over a sufficient period of time.

Limitations of the Study

This study was conducted at a single clinical site, a tertiary care referral center. Its generalizability to the Thai—or global—population is presumed, although it may be limited by cultural or other factors. Moreover, the duration of this study was only 16 weeks, which is too short to expect an improvement in vision or diabetic retinopathy severity. In addition, performing confirmatory factor analysis (CFA) on the Self-Care for Diabetic Eye Care (SCFDE) questionnaire is necessary to verify the construct validity of the scale in future studies.

Implications of the Study for Nursing Practice

This self-care promoting program represents a hybrid intervention that, if integrated into routine nursing care for individuals with DM and DR soon after diagnosis, could potentially prevent visual impairment caused by DR. A cost analysis of this benefit would likely demonstrate it as the optimal approach to preventing blindness from DR. The educational components within the SCPP are effective in assisting patients in modifying their diabetes self-care behaviors. These findings hold significant relevance for nursing, as SCPP interventions necessitate a strong understanding of diabetes as a condition and are quite labor-intensive, involving extensive communication and dialogue with patients—a considerable amount of interaction to achieve the goal of modifying self-care. Nurses are the logical focal point of the SCPP, as they typically possess the optimal combination of medical knowledge regarding diabetes and a practical understanding of its day-to-day impacts. Additionally, as primary care providers, they have the most natural rapport and refined communication skills with patients. Therefore, nurses are ideally positioned to integrate SCPP into clinical eye care services, and incorporating these interventions into routine nursing practice is likely to enhance diabetes outcomes and prevent or delay the progression of DR.

Conclusion

SCPP comprises educational interventions designed for patients with DR, aiming to enhance their disease awareness and facilitate monitoring of key parameters in DM management to detect DR deterioration early, thereby reducing vision loss. The SCPP evaluated in this study proves beneficial for patients with DR, as it leads to improved self-care and eye-care behaviors, lowered HbA1c levels, and enhanced VRQoL. Integrating SCPP components into standard practice for type 2 DM management is highly likely to decrease DR severity, accompanied by improvements in these metrics and subsequent disease impact indicators. The potential societal benefits would be significant. Nurses are the natural leaders overseeing SCPP and its integration into standard practice. This intervention underscores the pivotal role of nurses in diabetes management, positioning them at the forefront of efforts to address this increasingly prevalent public health issue. It is in the interest of Thailand and global society that public health planners acknowledge this crucial nursing role and support it through educational initiatives and resource allocation policies.

Declaration of Conflicting Interest

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Authors' Contributions

WM contributed to the study's conceptualization, literature review, research design, data collection, data analysis, and conclusions, including manuscript writing. TH contributed to providing key concepts of the study, research methodology, sample selection, data analysis, and manuscript writing. DH contributed to the sample selection and critical analysis of the study. PAG contributed to the clinical analysis of the study. All authors approved the final version to be published.

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Data Availability

The datasets generated during and/or analyzed are available from the corresponding author upon reasonable request.

Declaration of Use of AI in Scientific Writing

There is nothing to declare.

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