The effect of the primary care-based chronic disease management program on health care utilization outcomes and mortality among patients with type 2 diabetes mellitus

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This certifies that the dissertation of ***Dong-Woo Choi*** is approved.

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Dong-Woo Choi

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ABSTRACT

The effect of the primary care-based chronic disease management program on health care utilization outcomes and mortality among patients with type 2 diabetes mellitus

Background: The incidence of chronic diseases is rapidly increasing worldwide due to aging population, thereby causing a burden because of higher life expectancy, advances in medical technology, and changes in lifestyle. Primary care is required to optimize the management of chronic diseases and improve patients' outcomes. Although the primary care-based management program (PCDMP) can change and improve the behaviors of diabetes patients, it is not clear whether it is directly effective in improving diabetes-related health outcomes. This study investigated the effect of PCDMP on mortality and healthcare utilization outcomes among patients with newly diagnosed type 2 diabetes mellitus.

Methods: We included 31,368 participants after propensity score matching with time-dependent covariates at a 1:5 ratio using age, sex, Charlson comorbidity index, insulin use, hospitalization due to diabetes complications, and onset of diabetes complications. We investigated the effect of the PCDMP on continuity of care

(COC), medication possession ratio (MPR), health care utilization outcomes, and mortality using multiple linear regression, negative binomial (NB) Poisson regression, stratified Cox proportional hazard model, and stratified Cox proportional cause-specific hazard model.

Results: Of 31,368 participants, 16.67% (n = 5,228) were allocated to the intervention group, while 83.33% (n = 26,140) were allocated to the control group. The intervention group had higher log-transformed COC than the control group (Exp(β): 1.15, 95% confidence interval (CI): 1.14-1.16). The intervention group's log-transformed MPR was higher than that of the control group (Exp(β): 1.12, 95% CI: 1.12-1.13). The intervention group had a higher risk ratio (RR) for outpatient visits than the control group (RR: 1.64, 95% CI: 1.58-1.71). In contrast, the intervention group had a lower RR for hospitalization than the control group (RR: 0.84, 95% CI: 0.79-0.90). The RR for length of stay (RR: 0.79, 95% CI: 0.72-0.87) of the intervention group was lower than that of the control group. However, emergency department visits did not show significant differences. The proportion of all-cause mortality was 3.18% (n = 999). The intervention group had a lower hazard ratio (HR) for all-cause mortality than the control group (HR: 0.62, 95% CI: 0.51-0.77). Finally, PCDMP reduced diabetes complication-specific hospitalization (RR: 0.82, 95% CI: 0.76-0.88) and mortality (HR: 0.63, 95% CI: 0.42-0.93). However, there was no significant association regarding length of stay (RR: 0.92, 95% CI: 0.83-1.02) and emergency department visits (RR: 0.94, 95% CI: 0.87-1.01).

Conclusions: This study found that PCDMP had positive and desirable effects on all-cause and diabetes complication-specific healthcare utilization outcomes and mortality. PCDMP was associated with an increase in COC and MPR and a reduction in all-cause mortality and hospitalization and length of stay after controlling for covariates. Moreover, participation in the program was associated with a reduction in diabetes complication-specific mortality, hospitalization, and length of stay outcomes. Although we observed a positive impact of the PCDMP, the effect was for a short term, hence warranting further studies to investigate whether the short-term effects could be sustained over a longer duration of the program.

Key words: Primary care-based management program, Type 2 diabetes mellitus, Mortality, Healthcare utilization, Propensity score matching with time-dependent covariates

I. Introduction

1. Background

Treatment of chronic diseases has emerged as a major global policy agenda, with the United Nations (UN) holding a high-level summit in September 2011 to discuss ways to strengthen national capabilities and promote international cooperation in the prevention and management of chronic diseases worldwide [1]. The global burden of chronic diseases is rapidly increasing due to the aging population, evolving medical technology, and changing lifestyles. Consequently, the population is battling complications triggered by chronic diseases and increased medical expenses [1].

In 2014, Korea's average life expectancy was 82.2 years, 1.4 years longer than the Organization for Economic Co-operation and Development (OECD) average of 80.8 years, but its health life span was 65.4 years [2]. This could mean that the population spends 17 years of life battling different types of diseases and disabilities. The increase in life expectancy reflects an increase in the size of the

elderly population. The number of senior citizens aged 65 years or older in Korea was 730,000 (2.9%) in 1960, 3.38 million (7.3%) in 1990, and 7.69 million (14.9%) in 2019. The proportion of those aged 65 years or older is expected to reach 15.7% in 2020 and expand to 33.9% by 2040 [3]. Approximately 57% of all deaths in Korea are caused by six major chronic diseases: malignant neuropathy, heart disease, cerebrovascular disease, diabetes, chronic heart disease, and hypertension. Korea's diabetes-related mortality rate is 32.3 per 100,000 people, which is 1.4 times higher than the OECD average of 22.8 per 100,000 people, ranking fifth among 34 OECD countries. In addition, because of chronic diseases such as stroke and heart disease from hypertension and diabetes complications are twice as many as those in the hospital, and the mortality rate from chronic diseases accounts for more than a quarter of all deaths [4]. The rate of hospitalization due to chronic diseases in Korea is also more than twice as high as the OECD average [5]. The total medical expenditure in Korea was 54.55 trillion won in 2014, of which 19.4 trillion won was used to treat chronic diseases, accounting for 35.6% of the total medical expenditure. This cost represents a 3.5-fold increase from 5.55 trillion won in 2003 and is expected to increase further [6].

With increasing burden of chronic diseases, focus has shifted to the provision of high-quality primary care to help the population cope with the health problem.[7] Primary healthcare is well organized to improve the treatment and management outcomes for patients with chronic diseases [8]. However, there are notable alterations in providing chronic care programs and services in primary care settings [9]. The way chronic disease management is communicated in common practice is greatly influenced by organizational factors [10, 11]. Moreover, financial incentives, capitation payment, improved health information, communication, and technology infrastructure and extensive use of non-medical healthcare professionals could promote high-quality chronic disease management [12-14]. It is desirable to have a functional chronic disease management system; however, the role of primary healthcare continues to decline in Korea's medical delivery system. Furthermore, public health centers that would be expected to vitalize chronic disease management for the entire population focus mainly on the visiting services for vulnerable groups [4].

The primary care-based chronic disease management program (PCDMP) has been promoted since April 2012 to improve the health of patients with chronic diseases. This program also seeks to avoid overreliance on large hospitals for

chronic conditions by activating primary healthcare care for hypertension and diabetes at local clinics [15]. Patients with hypertension and diabetes are treated at designated local clinics by specific doctors who ensure continuity of care. In effect, there is reduced fragmentation of chronic disease management that lowers the self-payment rate for patients' re-examination fees by 10% (from 30% to 20%) and enhances access to health support services such as notification service (SMS), health counseling, blood pressure measuring instrument and blood glucose measuring device rental, and booklet provision. This chronic care model is committed to the continuous improvement of the medical care efforts of physicians through the provision of incentives to physicians with positive clinical outcomes for hypertension and diabetes. In 2015, a total of 7,935 medical institutions participated in a program to provide health support services to 130,000 people a year, of which 13,000 people participated in education services, which improved the continuity of care (1.6 to 9.7 times) and the medication adherence (1.1 to 1.3 times) [4, 16].

Although PCDMP has changed and improved the behaviors of diabetes patients, it is unclear whether this chronic care program is directly effective in improving diabetes-related health outcomes.

In this study, we investigated the effect of PCDMP on mortality and healthcare utilization outcomes among patients with newly developed type 2 diabetes mellitus.

2. Study objectives

The purpose of this study was to examine the effect of PCDMP on health outcomes related to diabetes complications among patients with type 2 diabetes mellitus.

Details of the study objectives are as follows:

(1) To investigate the effect of PCDMP on diabetes patient's continuity of care.

(2) To investigate the effect of PCDMP on diabetes patient's healthcare utilization.

(3) To investigate the effect of PCDMP on diabetes-related all-cause mortality.

II. Literature Review

1. Conceptual framework for chronic illness management

(1) Chronic Care Model

The chronic care model (CCM), developed by Wagner *et al.*, is a guideline for high-quality chronic disease management within primary care settings [14, 17]. The CCM considers the healthcare system part of a large community of both medical and non-medical players who combine their efforts to transform the daily care of patients with chronic conditions. Effective chronic disease management requires a properly organized delivery system linked to complementary community resources. The CCM is designed to improve interactions between the provider and the patient for integrated decision support. This model describes the elements essential to improve the primary care services for patients with chronic conditions [14]. The CCM aims to create a well-informed patient population and a healthcare system that is adequately prepared to address the patients' needs.

The CCM model comprises six components: health care organization, delivery system design, decision support, clinical information system, self-management support, and community resources and policies.

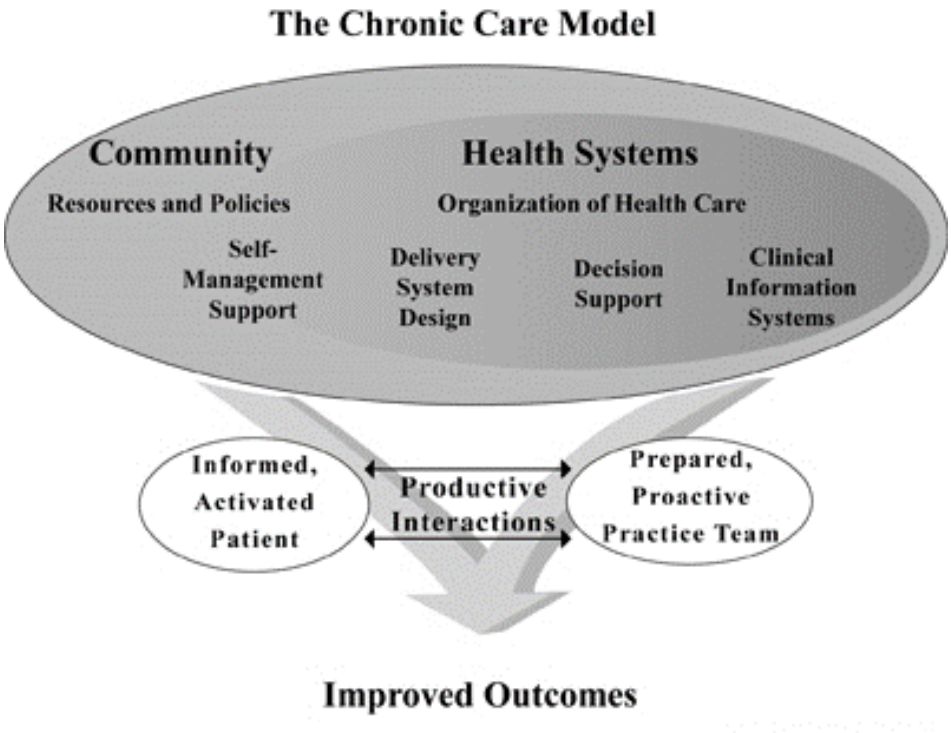

Figure 1. Chronic care model

Source: Wagner EH, Austin BT, Davis C, et al. Improving chronic illness care: translating evidence into action. Health affairs 2001;20(6):64-78

First, the community resources and policy element emphasizes the linkage between community organizations and hospitals to provide patient care and improve population health. The health system creates partnerships with

community-based resources such as exercise programs, self-help groups, and senior centers to improve the wellbeing of the people. Second, the healthcare organization encompasses the structure, goals, and values of the provider organization. Its relationship with the purchaser, insurers, and healthcare stakeholders underpins this model. There are four elements in the healthcare organization. Third, self-management support involves a collaborative approach to help patients and their families acquire the requisite skills and confidence to manage their condition. It provides self-management tools, referrals to community resources, and routine assessment of progress in addition to a sense of responsibility for the patients' health. Fourth, decision support integrates evidence-based clinical guidelines into patient care and reminder systems. Health professionals undergo continuous education to be acquainted with emerging evidence for the provision of quality and patient-centered care. Fifth, clinical information systems ensure access to patient data through a reminder system, feedback on performance measures, and registries. This element of CCM promotes patient care planning and performance monitoring for continuous quality improvement.

The effects of CCM on the outcome of chronic diseases and the impact of its elements have been evaluated. The results indicated that including one or more

aspects of the CCM in chronic disease treatment would improve patient or process outcomes.

(2) Innovative Care for Chronic Conditions

The Innovative Care for Chronic Conditions (ICCC) Framework developed by the World Health Organization (WHO) provides a health systems roadmap to meet the increasing needs of chronic disease care (Figure 2) [18]. The framework integrates community, patient, healthcare and policy environmental perspectives, and can be used to create or redesign healthcare systems. It also provides a global framework to harmonies initiatives aimed at improving chronic patient care.

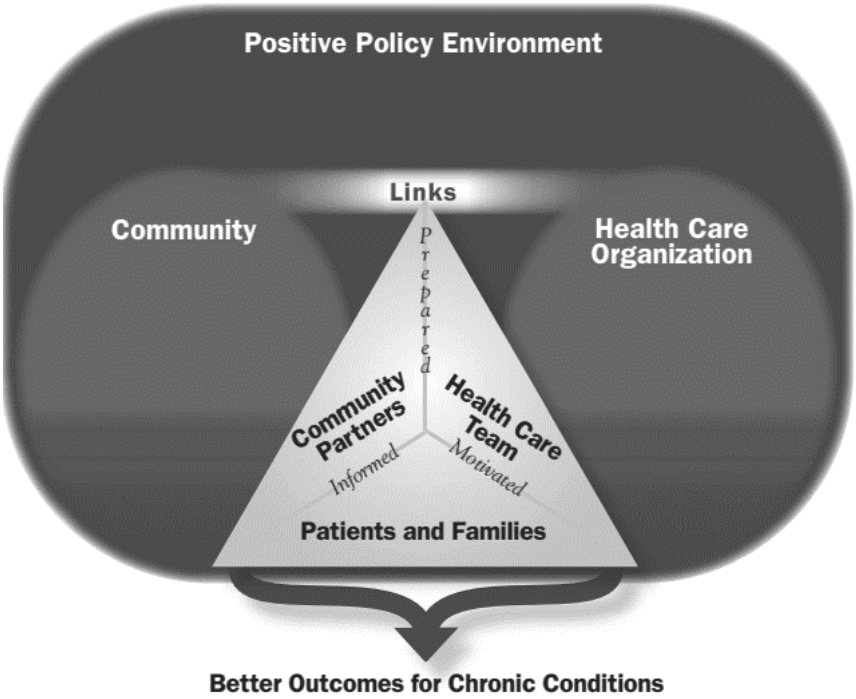

Figure 2. Innovative care for chronic conditions framework

Source: World Health Organization. Innovative care for chronic conditions: building blocks for actions: global report: World Health Organization, 2002.

A key feature of the ICCC framework is the incorporation of health policy perspectives. It can be used as a reference for a comparative analysis of systems and for the identification of best practices. This framework emphasizes the need to optimize the use of available healthcare resources in a specific population/geographical context. The development of an integrated care strategy and the establishment of a health service network are essential for the health care system to successfully address the challenges of chronic conditions. To support

successful changes to respond more effectively to the increasing burden of chronic diseases, the WHO has proposed six factors as areas of activity essential to decision-makers: Evidence-based decision making, population focus, prevention focus, quality focus, integration, and flexibility/adaptability. These principles are fundamental to the micro-, meso-, and macro-levels of the health care system (Figure 3) [18]. The micro-, meso-, and macro-levels provide a reasonable framework for quality care and refer to the patient interaction level, the healthcare organization and community level, and the policy level, respectively. All three levels interact and dynamically affect each other. They are linked through an interactive feedback loop that affects actions and events at another level. In this plan, patients respond to the care-taking system, and health care institutions and communities react to policies that affect the patient, hence creating a network of feedback that is repeated permanently.

Figure 3. Micro-, meso-. and macro-level of the health care system

Source: World Health Organization. Innovative care for chronic conditions: building blocks for actions: global report: World Health Organization, 2002.

2. Primary care-based management program

(1) Registration and management of hypertension and diabetes mellitus

In Korea, the program for registration and management of hypertension and diabetes mellitus was launched in 2007 as part of a comprehensive plan for cardiovascular disease [19]. The establishment of a collaborative system among the Korea Centers for Disease Control and Prevention, public health centers, and private medical institutions aimed at improving the continuous treatment rate of patients with hypertension and diabetes and change their health behavior to delay the onset of severe diseases and reduce the socioeconomic burden [19]. The target population for the high blood pressure and diabetes registration management program is patients over 30 years of age who live in the area and receive recall and remind services that inform the charges, registration fees, and treatment schedules and counseling services for disease and nutrition education. In addition, the government can support various health programs to encourage healthy behavior and ensure early and timely detection of severe complications (eye disease, chronic kidney disease, etc.).

(2) Primary care based chronic disease management program

The PCDMP was implemented in April 2012 to promote the health of patients with high blood pressure and diabetes, which are typical chronic diseases, and enhance the utilization of primary care services [20]. Through this program, patients with high blood pressure and diabetes are encouraged to consistently seek care at specific clinics to qualify for incentives that accrue to both the patients and the health care providers [14, 21]. Patients with essential hypertension (I10) and insulin-non-dependent diabetes (E11), disease codes based on the International Classification of Diseases (ICD)-10, benefit from a reduction in copayment fees. PCDMP provides self-burden incentives to induce patients to self-care of chronic diseases [19].

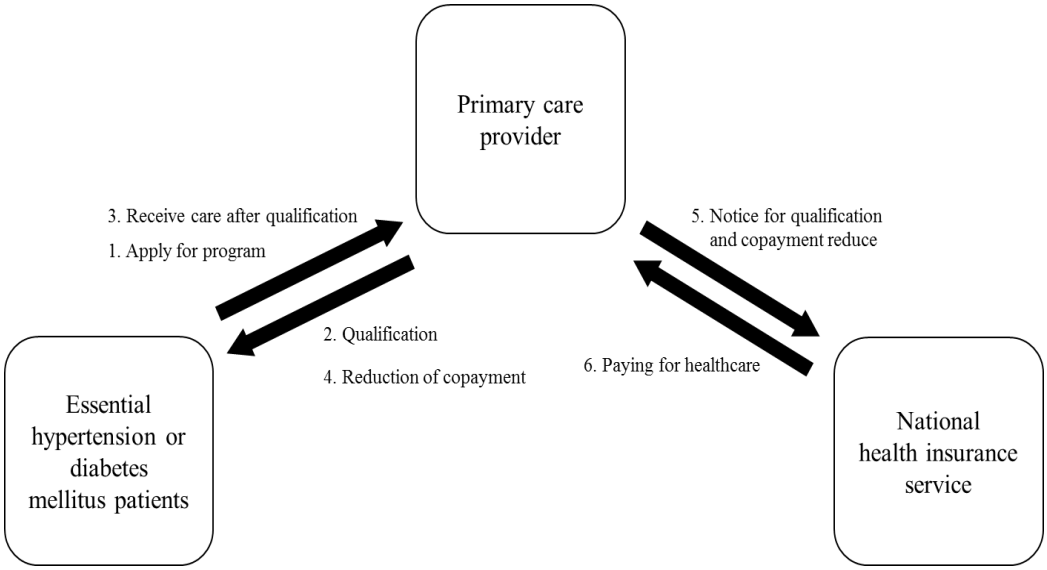

Figure 4. Primary care-based chronic disease management program framework

Source: Jung Y, Ko S-J, Kim E-J. A study on the effective chronic disease management. *Seoul: Korea Institute for Health and Social Affairs* 2013;12

The patient who continues to use a particular primary care clinic enjoys a reduced burden of the outpatient examination fee from 30% to 20%, and the personal burden of the patient reduces by 920 won. These cost benefits accrue to patients who develop a sense of responsibility for the chronic disease and collaborate with the caregivers to manage the condition. In addition, health support services (health partners) from the National Health Insurance Corporation are provided to augment the self-care practice of patients.

(3) Community-based primary health care program

To enhance the quality of primary care, the medical institution introduced the education and counseling fees for chronic disease management to ensure sufficient medical hours. It also established the comprehensive management plans and linkage of community health resources for the systematic management of chronic diseases [22]. Approximately 101,000 clinics from 741 cities, counties, and districts have been participating in the pilot project, operated with state subsidies since 2014, which was converted into a health insurance pilot project in November 2017. Doctors establish an annual management plan by comprehensively evaluating the patients' conditions and their lifestyles to inform health education and counseling (nutrition, exercise, smoking, etc.). The healthcare providers, in collaboration with community health centers, offer health education and counseling interventions to improve the lifestyle of the patients and alleviate the risk of disease complications [23].

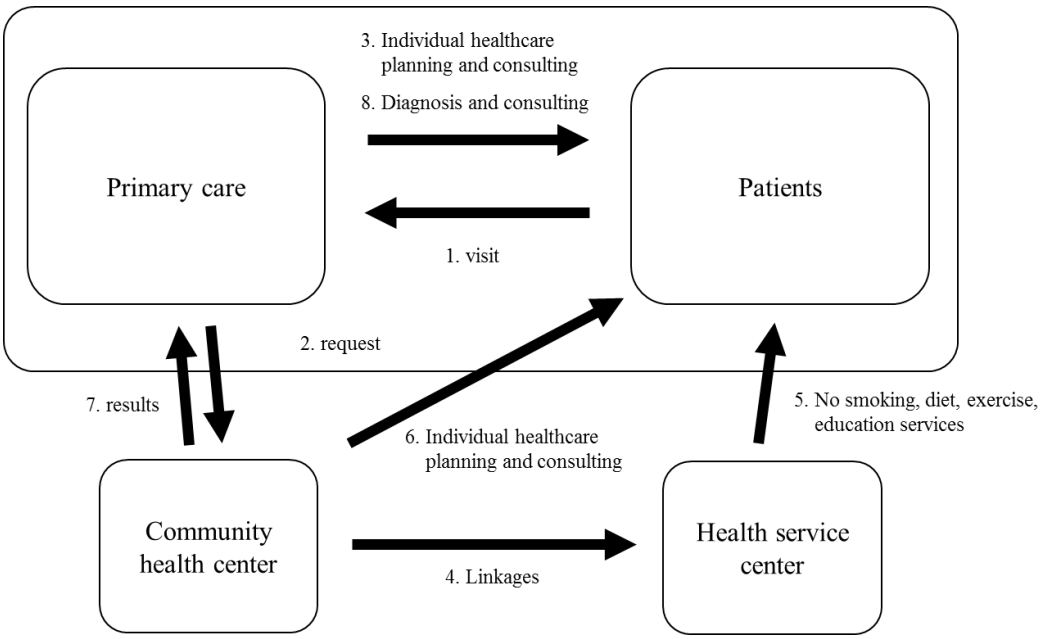

Figure 5. Community-based primary care program framework

Source: Kim HS, Yoo B-N, Lee EW. Evaluation of the national chronic diseases management policy: performance and future directions. Public Health Aff 2018;2(1):105-20. doi: 10.29339/pha.2.1.105

The community-based primary health care program selects participating areas through a public contest for local communities. It establishes a collaborative system with primary medical institutions in the region based on the autonomous participation of local communities. Additionally, it provides 25 standardized educational materials and medical educational manuals recognized by the WHO to improve the competencies of the primary medical doctors for further enhancement of care quality [24]. In addition, the health and behavior centers focus on personalized

education and counseling to improve the lifestyle of the patients, hence allowing doctors to focus on the clinical aspects of disease management [23].

III. Material and Methods

1. The framework of the study

This study aimed to investigate the effect of PCDMP on continuity of care, health care utilization, and mortality among patients with newly diagnosed type 2 diabetes mellitus (Figure 6).

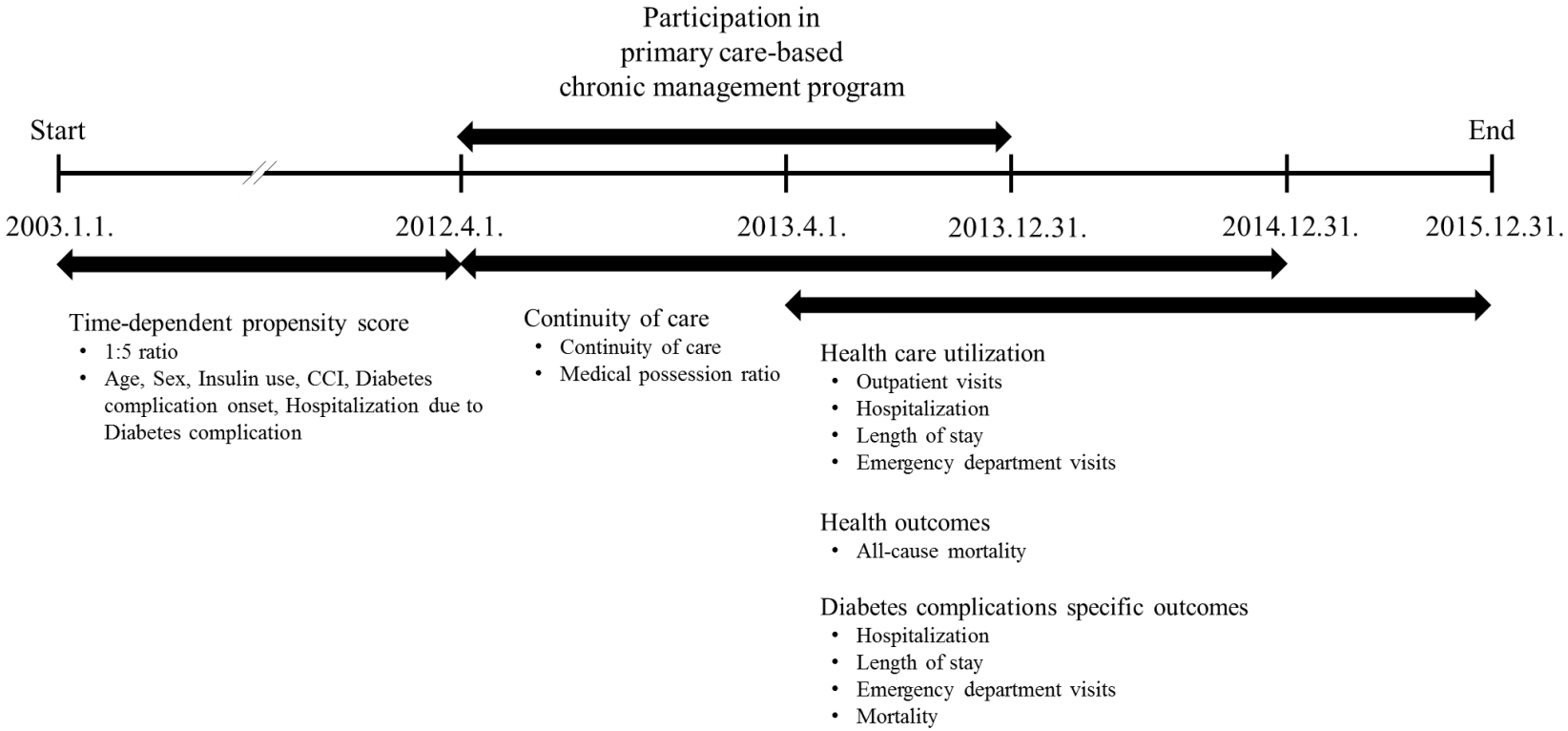

Figure 6. Study design

2. Data sources and study subjects

This study used the Korean National Health Insurance Services National Sample Cohort (NHIS-NSC) data collected from 2002 to 2015. This database of the Korean population was established by the National Health Insurance Service to provide representative information about health care use for policymakers and public health research [25]. The NHIS-NSC records patients' claim data in four categories, namely, insurance eligibility, medical institutions' data, health examination data, and medical treatments, which include diagnosis code, medication, and treatment. Among the 46,605,433 Korean individuals who were covered by insurance under the National Health Insurance or Medical aid in the baseline year 2002, 1,025,340 participants, representing approximately 2.2% of the Korean population in 2002, were randomly selected.

This cohort included 215,064 participants with type 2 diabetes mellitus, but 59,774 patients with onset of type 2 diabetes mellitus in 2002 and 2014-2015 or who were enrolled for the program in 2014-2015, were excluded. Additionally, 32,386 participants were also excluded based on the following criteria: missing covariates, death before April 1, 2012, which was the start date of PCDMP, age

below 30, and the onset of type 2 diabetes mellitus before one year of enrollment for the program.

Among the remaining 122,904 participants, 31,368 were finally included in this study after propensity score matching with time-dependent covariates in 1:5 ratios using age, sex, Charlson comorbidity index (CCI), insulin use, hospitalization due to diabetes complications, and onset of diabetes complications (Figure 7).

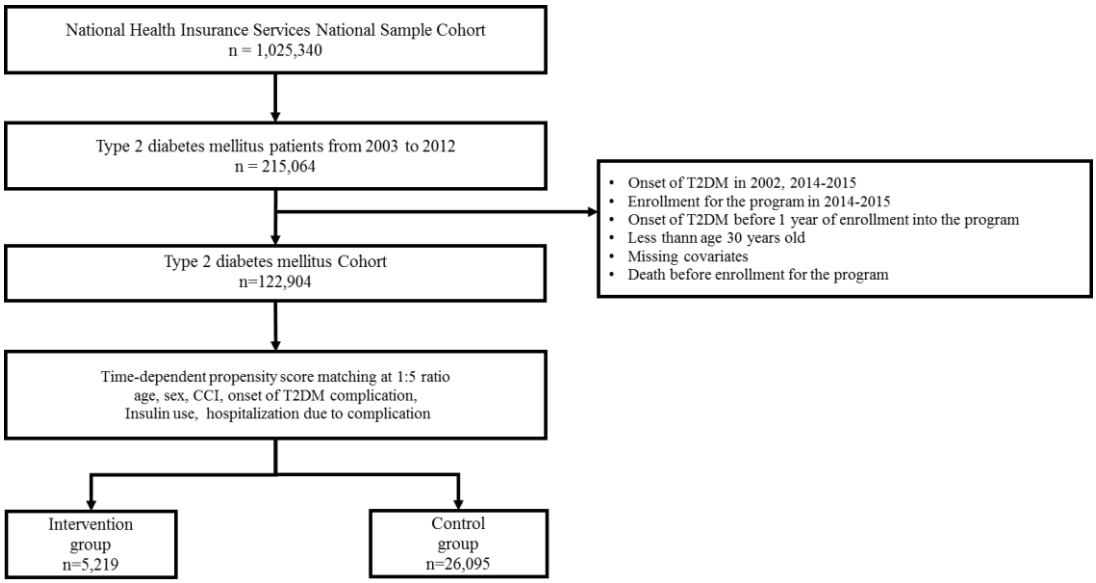

Figure 7. Flowchart of the patient selection

3. Variables

(1) Dependent variables

The dependent variable in our study is healthcare utilization, which encompasses continuity of care (COC), medication possession ratio (MPR), number of outpatient department visits, diabetes complications-specific and all-cause hospitalization, and diabetes complication specific and all-cause mortality.

Considering the variation and higher frequency of physician visits in clinics, this study used the COC index developed by Bice and Boxerman, which is the common measure used in COC-related studies [26-28]. The index was calculated only for the COC score based on outpatient physician visits. The COC index reflects the distribution of visits to different physicians and the number of visits to each physician. The formula of the COC index is as follows:

$$\mathrm{COC} = \frac{\sum_{j=1}^{M} n_j^2 - N}{N(N-1)},$$

W where N is the total number of physician visits, n_j is the number of visits to the j_{th} physician, and M is the number of physicians. The COC index value ranges from 0 to 1, with a higher value corresponding to better COC. A COC score of 1 represents the patient visits to the same physician.

The MPR assesses the number of days a drug is prescribed in relation to the prescribing period and is a measure of overall diabetes medication availability. The length of the most recent gap may be more visible to prescribing physicians than a period assessment like the MPR. The MPR, however, may better reflect chronic suboptimal adherence [29]. We calculated MPR using the following formula for an observation period of 1 year after start date of primary care based chronic management program:

$$\text{MPR} = \frac{Days\ \ supply\ \ of\ \ medication}{365\ \ days}$$

The number of outpatient department visits, hospitalizations, and emergency department visits and length of stay was defined based on patient visits to clinics or hospitals during one year after enrollment in the PCDMP. All-cause mortality and diabetes complications-specific mortality were defined as the occurrence of death of any cause or due to diabetes complications after one year of enrollment in the PCDMP. Diabetes complications were retinopathy, neurological, peripheral circulatory, renal, myocardial infarction, cerebrovascular disease, and diabetic foot as defined by the ICD-10.

Table 1. Definition of diabetes complications

Complications	ICD-10 codes
Retinopathy complications	E11.3, E12.3, E13.3, E14.3, H28.x, H33.x, H34.x, H35.x, H36.x, H54.x
Neurological complications	E11.4, E12.4, E13.4, E14.4, G60.9, G62.9,G32.2, G90.0, G90.8, G90.9, G99.0, G99.1, G53.8, K31.8, N31.9, M14.6, G56.x, G57.x, G58.x, G59.x, G64.x, H49.x, S04.x
Peripheral circulatory complications	E11.5, E12.5, E13.5, I72.4, I73.8, I73.9, I74.3, I77.1, I79.0, I79.2, I79.8
Myocardial infarction	I20.x-I24.x, I46.x-I50.x, I70.x
Cerebrovascular disease	I60.x-I67.x, G45
Renal complications	N04.9, N05.9, N08.3, N17.x, N18.x, N19.x, N26.x, N28.9, T86.1, Z49.x, Z99.2, Z94.0, E11.2
Diabetic foot	R02.x, S80.7, S80.8, S80.9, S81.7, S90.7, S90.8, S90.9, Z89.4, Z89.8, E11.7, L97.x

(2) Main independent variable

The primary independent variable in this study is enrollment in the PCDMP. Patients who were enrolled in PCDMP from April 1, 2012, to December 31, 2013, were defined by claims code “AA250”.

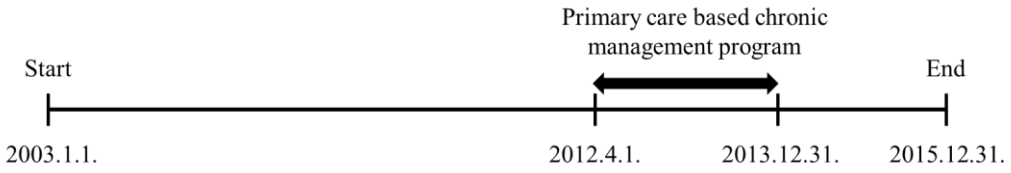

Figure 8. Primary care-based chronic disease management program periods

(3) Other independent variables

Other independent variables included include age, sex, household income, region, type of insurance, CCI, onset of hypertension, use of insulin, disability status, onset of diabetes complications, and hospitalization due to diabetes complications.

4. Statistical methods

(1) Propensity score matching with time-dependent covariates

Propensity score matching with time-dependent covariates involves the use of hazards as a propensity score to create a matched sample of subjects who experience the exposure event and those who never experience this event [30]. In observational studies with time-dependent therapy and covariates, it is desirable to balance the distribution of covariates at each point of time. A time-dependent score based on the Cox proportional hazard model is proposed and used for risk set matching. The Cox proportional hazards model with time-varying covariates is used to estimate the hazard of being treated at a particular time point for each patient. The hazard of receiving the treatment will be modeled using a proportional hazards model with time-varying covariates [31] as follows:

$$h_m(t) = h_0(t)\exp\left\{\beta^T X_m(t)\right\},$$

$h_m(t)$: the hazard for patient m at time t.

The matching takes place within a set of hazards consisting of all patients at risk of treatment at each point. Sequential matching is performed in the chronological order for each set of hazards. If there is only one patient in the risk

set, matching is simple and consists of selecting the closest control in terms of propensity score over time.

The matching algorithm requires distance metrics in which distance is defined as forcing a newly treated patient to match a patient who has not yet been treated. The distance between two controls, or between two patients, is defined as an infinity that is treated simultaneously. For other patients, the distance between any patient pairs (m_p, m_q) is calculated as follows:

$$\delta_t(m_p, m_q) = \left(\hat{\beta}^T X_p(t) - \hat{\beta}^T X_q(t)\right)^2$$

We conducted propensity score-matching with time-dependent covariates for matching between the PCDMP group and the control group. Study subjects were evaluated at enrollment into the study and at intervals of approximately every three months for up to nine years. The time-varying covariates in our study included the use of insulin, hospitalization due to diabetes complications, CCI, and onset of diabetes complications, while baseline covariates were sex and age. After matching the case and the control, we conducted the Mantel-Haenszel test for each covariate (Table 2).

Table 2. Results of propensity score matching with time-dependent covariates

Variables	Time-dependent propensity score matching									
	Before				*p*	After				*p*
	Intervention		Control			Intervention		Control		
	n	%	n	%		n	%	n	%	
Sex					<0.001					1.000
Men	5,507	52.55	54,993	48.92		2,951	56.45	14,755	56.45	
Women	4,973	47.45	57,431	51.08		2,277	43.55	11,385	43.55	
Age					<0.001					0.523
30- 49	1,647	15.72	23,044	20.50		897	17.16	4,476	17.12	
50 - 59	4,013	38.29	27,087	24.09		2,062	39.44	10,215	39.08	
60 - 69	3,082	29.41	26,739	23.78		1,474	28.19	7,362	28.16	
70 - 79	1,380	13.17	23,552	20.95		649	12.41	3,431	13.13	
80+	358	3.42	12,002	10.68		146	2.79	656	2.51	
Charlson comorbidity index					<0.001					<0.001
0	6,027	57.51	62,189	55.32		3,237	61.92	16,949	64.84	
1	3,016	28.78	31,350	27.89		1,370	26.21	6,815	26.07	
2+	1,437	13.71	18,885	16.80		621	11.88	2,376	9.09	
Insulin use					0.028					0.088
Yes	1,479	14.11	16,771	14.92		1,008	19.28	5,314	20.33	
No	9,001	85.89	95,653	85.08		4,220	80.72	20,826	79.67	
Diabetes complications					<0.001					0.171
Yes	7,901	75.39	82,890	73.73		4,156	79.50	20,999	80.33	
No	2,579	24.61	29,534	26.27		1,072	20.50	5,141	19.67	
Hospitalization due to diabetes complications					<0.001					0.529
Yes	1,133	10.81	23,776	21.15		634	12.13	3,281	12.55	1,133
No	9,347	89.19	88,648	78.85		4,594	87.87	22,859	87.45	9,347
Total	**10,480**	**100.00**	**112,424**	**100.00**		**5,228**	**100.00**	**26,140**	**100.00**	**10,480**

(2) Negative binomial Poisson regression

Negative binomial (NB) Poisson regression was used for modeling count variables; it is usually used for over-dispersed outcome count variables [32]. NB Poisson regression is a generalization of Poisson regression, which loosens the restrictive assumption that the variance is equal to the mean created by the Poisson model. The traditional NB regression model is based on the Poisson-gamma mixture distribution. This formula is popular because it allows modeling of Poisson heterogeneity using gamma distribution [33].

We conduct NB Poisson regression for healthcare utilization outcomes following: number of outpatient visit, hospitalization, length of stay, emergency department visit, and diabetes cause-specific healthcare utilization outcomes.

(3) Cause-specific cox-proportional hazard model

The method of defining a set of risks in a standard survival analysis can be modified to enable competitive events [34]. In the standard survival analysis, the risk set is defined as a group of individuals who have not experienced results, and therefore, they are at risk of events of interest in time t. Individuals with competition events may be excluded from the subsequent set of hazards for events of interest. A proportional hazards model can be constructed for the cause-specific hazard as follows:

$$h_{\mathrm{ev}}(t|x) = h_{\mathrm{ev0}}(t)\mathrm{e}^{\sum_{l=1}^{k} \beta_l x_l}$$

where h_{ev0} is the arbitrary baseline cause-specific hazard, and β_l is the corresponding regression coefficients, where $exp(\beta_j) = {}_{cs}RH_j$ is interpretable as the relative change in the cause-specific hazard for the jth event corresponding to a 1-unit increase in the corresponding covariate [35].

We conducted survival analyses using a stratified Cox proportional hazard model that helped analyze the main models for all-cause mortality. Kaplan-Meier survival curves were performed using the log-rank test between the intervention group and the control group (log-rank test: $p < 0.001$). When analyzing mortality related to diabetes complications, cause-specific methods were considered to account for competing risk. Mortality event was excluded if it occurred within one year of enrollment in the PCDMP.

(4) Descriptive statistics

We used a t-test, analysis of variance, and chi-square test to examine the distribution of the general characteristics of the study population according to all outcomes. All statistical analyses were performed using SAS 9.4 software (SAS, Cary, NC, USA).

5. Ethics statement

This study was approved by the Institutional Review Board, Yonsei University Health System (IRB number: Y-2020-1390).

IV. Results

1. Continuity of care and medication adherence

(1) General characteristics of the study population

Table 3 shows the general characteristics of the study population according to the continuity of care and medication adherence. Of the 31,368 participants, 16.67% (n=5,228) were allocated to the intervention group and 83.33% (n = 26,140) to the control group. The mean values of COC in the intervention and control groups were 0.81 (standard deviation (SD): ±0.32) and 0.61 (SD: ±0.45), respectively. The mean of MPR in the intervention group was 0.75 (SD: ±0.31), while that of the control group was 0.59 (SD: ±0.42). There were significant differences in the mean values of COC and MPR between the intervention and control groups.

Table 3. Characteristics of the study population for continuity of care and medication possession ratios

Variables	Total		Continuity of care			Medication possession ratio		
	n	%	mean	±SD	*p*	mean	±SD	*p*
Primary care-based chronic disease management program					<0.001			<0.001
Intervention	5,228	16.67	0.81	0.32		0.75	0.31	
Control	26,140	83.33	0.61	0.45		0.59	0.42	
Sex					0.435			<0.001
Men	17,706	56.45	0.64	0.44		0.59	0.41	
Women	13,662	43.55	0.64	0.44		0.64	0.41	
Age					<0.001			<0.001
30 - 49	5,373	17.13	0.61	0.46		0.53	0.40	
50 - 59	12,277	39.14	0.67	0.43		0.63	0.40	
60 - 69	8,836	28.17	0.66	0.43		0.65	0.41	
70 - 79	4,080	13.01	0.59	0.44		0.62	0.43	
80+	802	2.56	0.41	0.45		0.49	0.44	
Household income					<0.001			<0.001
1st quintile	4,615	14.71	0.64	0.44		0.60	0.42	
2nd quintile	4,572	14.58	0.65	0.44		0.63	0.41	
3rd quintile	5,494	17.51	0.62	0.45		0.59	0.41	
4th quintile	7,165	22.84	0.66	0.43		0.64	0.40	
5th quintile	9,522	30.36	0.64	0.44		0.61	0.41	

Table 3. Characteristics of the study population for continuity of care and medication possession ratios (continued)

Variables	Total		Continuity of care			Medication possession ratio		
	n	%	Mean	SD	*p*	Mean	SD	*p*
Types of insurance					<0.001			<0.001
Employee insured	11,167	35.60	0.63	0.44		0.60	0.41	
Self-employed insured	20,201	64.40	0.65	0.44		0.62	0.41	
Region					<0.001			0.005
Metropolitan	6,313	20.13	0.65	0.44		0.62	0.41	
City	8,035	25.62	0.66	0.44		0.62	0.41	
Rural	17,020	54.26	0.63	0.44		0.61	0.41	
Charlson comorbidity index					<0.001			<0.001
0	20,186	64.35	0.65	0.44		0.63	0.40	
1	8,185	26.09	0.64	0.44		0.61	0.42	
2+	2,997	9.55	0.57	0.45		0.56	0.43	
Hypertension					<0.001			<0.001
Yes	16,203	51.65	0.67	0.43		0.66	0.40	
No	15,165	48.35	0.61	0.45		0.57	0.41	
Insulin use					0.099			0.665
Yes	6,322	20.15	0.62	0.44		0.61	0.42	
No	25,046	79.85	0.65	0.44		0.62	0.41	
Disability					<0.001			<0.001
Yes	3,323	10.59	0.57	0.45		0.54	0.44	
No	28,045	89.41	0.65	0.44		0.62	0.41	

Table 3. Characteristics of the study population for continuity of care and medication possession ratios (continued)

Variables	Total		Continuity of care			Medication possession ratio		
	n	%	Mean	SD	*p*	Mean	SD	*p*
Diabetes complications					<0.001			<0.001
Yes	25,155	80.19	0.66	0.43		0.64	0.40	
No	6,213	19.81	0.57	0.47		0.50	0.43	
Hospitalization due to diabetes complications					<0.001			<0.001
Yes	3,915	12.48	0.60	0.44		0.60	0.42	
No	27,453	87.52	0.65	0.44		0.62	0.41	
Total	**31,368**	**100.00**	**0.64**	**0.44**		**0.61**	**0.61**	

(2) Multiple linear regression for log-transformed COC and MPR

Table 4 showed results of multiple linear regression for log-transformed continuity of care and medication possession ratio. The intervention group had higher log-transformed COC compared to control group (Exp(β): 1.15, 95% confidence interval (CI): 1.14-1.16). For Log-transformed MPR, the intervention group's MPR was higher than control group (Exp(β): 1.12, 95% CI: 1.12-1.13). These associations were significant statistically.

Table 4. Results of multiple linear regression for log-transformed continuity of care and medication possession ratio

Variables	Log-transformed continuity of care		Log-transformed medication possession ratio	
	Exp(β)	95% CI	Exp(β)	95% CI
Primary care-based chronic disease management program				
Case	1.15	(1.14 - 1.16)	1.12	(1.12 - 1.13)
Control	1.00		1.00	
Sex				
Men	1.00	(0.99 - 1.00)	0.98	(0.97 - 0.98)
Women	1.00		1.00	
Age				
30 - 49	1.00	(1.02 - 1.04)	1.06	(1.05 - 1.07)
50 - 59	1.03	(1.01 - 1.03)	1.05	(1.04 - 1.06)
60 - 69	1.02	(0.96 - 0.99)	1.03	(1.02 - 1.06)
70 - 79	0.97	(0.83 - 0.87)	0.94	(0.92 - 0.96)
80+	0.85			
Household income				
1st quintile	0.99	(0.98 - 1.00)	0.98	(0.97 - 0.99)
2nd quintile	0.99	(0.98 - 1.01)	1.01	(1.00 - 1.02)
3rd quintile	0.98	(0.97 - 0.99)	0.98	(0.97 - 0.99)
4th quintile	1.01	(1.00 - 1.01)	1.01	(1.00 - 1.02)
5th quintile	1.00		1.00	
Types of insurance				
Employee insured	0.98	(0.98 - 0.99)	0.99	(0.98 - 0.99)
Self-employed insured	1.00		1.00	
Region				
Metropolitan	1.00		1.00	
City	1.01	(1.00 - 1.02)	1.01	(1.00 - 1.02)
Rural	0.99	(0.98 - 1.00)	0.99	(0.99 - 1.00)
Charlson comorbidity index				
0	1.00		1.00	
1	0.99	(0.98 - 0.99)	0.98	(0.97 - 0.98)
2+	0.95	(0.93 - 0.96)	0.94	(0.93 - 0.95)

Table4. Results of multiple linear regression for log-transformed continuity of care and medication possession ratio

Variables	Log-transformed continuity of care		Log-transformed medication possession ratio	
	Exp(β)	95% CI	Exp(β)	95% CI
Hypertension				
Yes	1.04	(1.04 - 1.05)	1.04	(1.04 - 1.05)
No	1.00		1.00	
Insulin use				
Yes	1.00	(0.99 - 1.01)	1.00	(0.99 - 1.01)
No	1.00		1.00	
Disability				
Yes	0.96	(0.95 - 0.97)	0.95	(0.94 - 0.96)
No	1.00		1.00	
Diabetes complications				
Yes	1.07	(1.06 - 1.08)	1.11	(1.10 - 1.12)
No	1.00		1.00	
Hospitalization due to diabetes complications				
Yes	0.97	(0.96 - 0.98)	0.97	(0.96 - 0.98)
No	1.00		1.00	

(3) Multiple linear regression for log-transformed COC and MPR according to subgroups

Table 5 shows the results of multiple linear regression for log-transformed COC and MPR, according to subgroups.

For COC, participants who were men (exp(β): 1.16, 95% CI: 1.15-1.17), aged 30-49 years (exp(β): 1.21, 95% CI: 1.18-1.23), aged above 80 years (exp(β): 1.19, 95% CI: 1.13-1.26), had 3rd quintile of household income (exp(β): 1.18, 95% CI: 1.15-1.20), and living in a metropolitan region (exp(β): 1.16, 95% CI: 1.14-1.18) had stronger effects of PCDMP. Likewise, participants who were men (exp(β): 1.14, 95% CI: 1.13-1.15), aged 30-49 years (exp(β): 1.18, 95% CI: 1.15-1.20), had 1st quintile (exp(β): 1.14, 95% CI: 1.11-1.16) and 3rd quintile (exp(β): 1.15, 95% CI: 1.12-1.17) of household income, and living in the city (exp(β): 1.14, 95% CI: 1.12-1.16) had stronger effects of PCDMP for MPR.

Table 5. Results of multiple linear regression for log-transformed continuity of care and medication possession ratio according to subgroups

Variables	Log-transformed continuity of care		Log-transformed medication possession ratio	
	Exp(β)	95% CI	Exp(β)	95% CI
Sex				
Men	1.16	(1.15 - 1.17)	1.14	(1.13 - 1.15)
Women	1.15	(1.13 - 1.16)	1.11	(1.09 - 1.12)
Age				
30 - 49	1.21	(1.18 - 1.23)	1.18	(1.15 - 1.20)
50 - 59	1.14	(1.13 - 1.16)	1.12	(1.10 - 1.13)
60 - 69	1.14	(1.12 - 1.16)	1.11	(1.09 - 1.13)
70 - 79	1.14	(1.11 - 1.17)	1.12	(1.09 - 1.15)
80+	1.19	(1.13 - 1.26)	1.09	(1.03 - 1.15)
Household income				
1st quintile	1.15	(1.13 - 1.18)	1.14	(1.11 - 1.16)
2nd quintile	1.15	(1.12 - 1.17)	1.11	(1.09 - 1.14)
3rd quintile	1.18	(1.15 - 1.20)	1.15	(1.12 - 1.17)
4th quintile	1.14	(1.12 - 1.16)	1.12	(1.10 - 1.13)
5th quintile	1.15	(1.13 - 1.17)	1.11	(1.10 - 1.13)
Region				
Metropolitan	1.16	(1.14 - 1.18)	1.12	(1.10 - 1.14)
City	1.15	(1.13 - 1.17)	1.14	(1.12 - 1.16)
Rural	1.15	(1.14 - 1.16)	1.12	(1.11 - 1.13)

2. Health care utilization outcomes

(1) General characteristics of the study population

Table 6 shows the general characteristics of the study population according to health care utilization outcomes. The mean values of outpatient visits in the intervention and control groups were 10.70 (SD: ±7.55) and 6.64 (SD: ±8.04), respectively. The mean of hospitalization in the intervention group was 0.14 (SD: ±0.70), while that of the control group was 0.20 (SD: ±1.11). The mean values of the length of stay in the intervention and control groups were 1.77 days (SD: ±12.62) and 3.16 days (SD: ±24.66), respectively. We noted significant differences in the mean values of outpatient visits, hospitalization, and length of stay between the intervention and control groups (p: <0.001). However, the mean values of emergency department visits were not significantly different between the two study groups (p: 0.154).

Table 6. Characteristics of the study population for health care utilization

Variables	Outpatient visits			Hospitalization			Length of stay			Emergency department visits		
	Mean	**±SD**	***p***	**Mean**	**±SD**	***p***	**Mean**	**±SD**	***p***	**Mean**	**±SD**	***p***
Primary care-based chronic disease management program			<0.001			<0.001			<0.001			0.239
Intervention	10.70	7.55		0.14	0.70		1.77	12.62		0.03	0.23	
Control	6.64	8.04		0.20	1.11		3.16	24.66		0.03	0.28	
Sex			<0.001			<0.001			<0.001			0.333
Men	6.77	7.25		0.17	1.05		2.44	20.85		0.03	0.26	
Women	8.03	9.03		0.21	1.05		3.56	25.72		0.03	0.28	
Age			<0.001			<0.001			<0.001			<0.001
30 - 49	5.92	5.95		0.10	0.64		1.25	13.37		0.02	0.22	
50 - 59	7.09	7.47		0.15	0.84		1.93	15.72		0.02	0.20	
60 - 69	7.88	7.96		0.18	0.95		2.61	20.65		0.04	0.31	
70 - 79	8.95	11.45		0.36	1.60		6.46	37.07		0.06	0.35	
80+	5.85	8.68		0.66	2.45		15.00	63.01		0.07	0.45	
Household income			<0.001			0.019			0.0519			0.007
1st quintile	7.32	7.85		0.18	1.00		2.98	23.22		0.02	0.17	
2nd quintile	7.39	7.78		0.19	1.13		2.79	22.43		0.03	0.23	
3rd quintile	7.02	7.12		0.19	0.99		3.02	23.79		0.04	0.27	
4th quintile	7.79	9.45		0.20	1.14		3.13	24.26		0.04	0.35	
5th quintile	7.11	7.78		0.18	1.00		2.77	22.05		0.03	0.26	

Table 6. Characteristics of the study population for health care utilization (continued)

Variables	Outpatient visits			Hospitalization			Length of stay			Emergency department visits		
	Mean	±SD	*p*	Mean	±SD	*p*	Mean	±SD	*p*	Mean	±SD	*p*
Types of insurance			0.138			0.013			0.0217			0.0445
Employee insured	7.34	8.24		0.20	1.08		3.09	23.71		0.04	0.30	
Self-employed insured	7.31	8.02		0.18	1.03		2.84	22.76		0.03	0.25	
Region			0.005			<0.001			<0.001			0.017
Metropolitan	6.70	7.33		0.15	1.06		1.88	17.46		0.03	0.27	
City	7.50	7.44		0.17	0.96		2.97	24.59		0.03	0.25	
Rural	7.47	8.64		0.21	1.09		3.30	24.18		0.04	0.28	
Charlson comorbidity index			0.635			0.0010			<0.001			0.381
0	7.18	7.98		0.19	1.12		3.07	24.34		0.03	0.27	
1	7.51	8.03		0.16	0.84		2.35	18.17		0.03	0.26	
2+	7.73	9.03		0.21	1.08		3.54	26.33		0.03	0.25	
Hypertension			<0.001			0.086			0.1425			0.017
Yes	8.15	8.88		0.20	1.06		3.15	23.88		0.03	0.25	
No	6.43	7.06		0.18	1.04		2.69	22.24		0.03	0.29	
Insulin use			0.665			<0.001			<0.001			<0.001
Yes	8.09	11.13		0.30	1.48		4.91	30.60		0.06	0.39	
No	7.13	7.12		0.16	0.91		2.43	20.76		0.02	0.23	

Table 6. Characteristics of the study population for health care utilization (continued)

Variables	Outpatient visits			Hospitalization			Length of stay			Emergency department visits		
	Mean	±SD	*p*	Mean	±SD	*p*	Mean	±SD	*p*	Mean	±SD	*p*
Disability			0.086			<0.001			<0.001			<0.001
Yes	7.84	13.23		0.38	1.77		7.53	42.27		0.06	0.39	
No	7.26	7.25		0.16	0.93		2.39	19.56		0.03	0.25	
Diabetes complications			<0.001			<0.001			0.002			0.002
Yes	7.65	8.48		0.21	1.13		3.32	24.86		0.04	0.29	
No	6.00	6.17		0.10	0.62		1.37	13.73		0.02	0.15	
Hospitalization due to diabetes complications			0.400			<0.001			<0.001			0.003
Yes	7.97	12.97		0.42	1.88		7.34	40.39		0.06	0.39	
No	7.23	7.13		0.15	0.86		2.30	19.34		0.03	0.25	
Total	7.30	8.04		0.19	1.05		2.93	23.09		0.03	0.27	

(2) Results of the negative binomial Poisson model for health care utilization.

Table 7 shows the results of the NB Poisson regression model for health care utilization. The intervention group had a higher rate ratio (RR) for outpatient visits than the control group (RR: 1.64, 95% CI: 1.58-1.71 vs. RR: 1.00). In contrast, the intervention group had a lower RR for hospitalization than the control group (RR: 0.84, 95% CI: 0.79-0.90 vs. RR: 1.00). The RR for length of stay of the intervention group was lower than that of the control group (RR: 0.79, 95% CI: 0.72-0.87 vs. RR: 1.00). However, emergency department visits did not show any significant difference.

Table 7. Results of the negative binomial Poisson model for health care utilization

Variables	Outpatient visits		Hospitalization		Length of stay		Emergency department visits	
	RR	95% CI	RR	95% CI	RR	95% CI	RR	95% CI
Primary care-based chronic disease management program								
Case	1.64	(1.58 - 1.71)	0.84	(0.79 - 0.90)	0.79	(0.72 - 0.87)	0.95	(0.88 - 1.02)
Control	1.00		1.00		1.00		1.00	
Sex								
Men	0.89	(0.86 - 0.91)	0.87	(0.82 - 0.91)	0.72	(0.67 - 0.78)	1.39	(1.32 - 1.47)
Women	1.00		1.00		1.00		1.00	
Age								
30 - 49	1.00		1.00		1.00		1.00	
50 - 59	1.14	(1.10 - 1.19)	1.44	(1.33 - 1.55)	1.42	(1.27 - 1.58)	1.24	(1.13 - 1.35)
60 - 69	1.23	(1.17 - 1.28)	1.76	(1.62 - 1.91)	1.98	(1.76 - 2.22)	2.17	(1.99 - 2.37)
70 - 79	1.33	(1.25 - 1.40)	3.38	(3.07 - 3.72)	5.05	(4.37 - 5.84)	3.36	(3.04 - 3.70)
80+	0.81	(0.74 - 0.90)	6.89	(5.93 - 8.01)	15.00	(11.76 - 19.13)	4.49	(3.86 - 5.22)
Household income		-		-		-		-
1st quintile	1.01	(0.96 - 1.05)	1.14	(1.05 - 1.23)	1.44	(1.29 - 1.62)	0.69	(0.63 - 0.75)
2nd quintile	1.04	(0.99 - 1.09)	1.26	(1.17 - 1.37)	1.40	(1.24 - 1.57)	0.96	(0.88 - 1.04)
3rd quintile	0.97	(0.93 - 1.01)	1.33	(1.24 - 1.43)	1.66	(1.49 - 1.85)	1.23	(1.14 - 1.32)
4th quintile	1.07	(1.03 - 1.12)	1.27	(1.19 - 1.36)	1.46	(1.32 - 1.62)	1.17	(1.09 - 1.25)
5th quintile	1.00		1.00		1.00		1.00	

Table 7. Results of the negative binomial Poisson model for health care utilization (continued)

Variables	Outpatient visits		Hospitalization		Length of stay		Emergency department visits	
	RR	95% CI	RR	95% CI	RR	95% CI	RR	95% CI
Types of insurance								
Employee insured	1.02	(0.99 - 1.05)	1.21	(1.15 - 1.27)	1.36	(1.26 - 1.47)	1.23	(1.17 - 1.30)
Self-employed insured	1.00		1.00		1.00		1.00	
Region								
Metropolitan	1.00		1.00		1.00		1.00	
City	1.13	(1.09 - 1.18)	1.25	(1.16 - 1.35)	1.34	(1.20 - 1.49)	0.82	(0.76 - 0.89)
Rural	1.13	(1.08 - 1.17)	1.58	(1.48 - 1.69)	1.93	(1.76 - 2.13)	1.10	(1.03 - 1.17)
Charlson comorbidity index								
0	1.00		1.00		1.00		1.00	
1	1.00	(0.97 - 1.04)	0.81	(0.77 - 0.86)	0.74	(0.68 - 0.81)	1.02	(0.96 - 1.08)
2+	0.95	(0.91 - 1.00)	0.88	(0.80 - 0.95)	0.86	(0.76 - 0.97)	0.77	(0.71 - 0.85)
Hypertension								
Yes	1.20	(1.17 - 1.24)	0.80	(0.76 - 0.84)	0.71	(0.66 - 0.77)	0.78	(0.74 - 0.82)
No	1.00		1.00		1.00		1.00	
Insulin use								
Yes	1.09	(1.05 - 1.13)	1.33	(1.25 - 1.41)	1.43	(1.29 - 1.58)	2.10	(1.98 - 2.23)
No	1.00		1.00		1.00		1.00	
Disability								
Yes	1.02	(0.97 - 1.07)	1.73	(1.60 - 1.86)	2.46	(2.19 - 2.77)	1.63	(1.51 - 1.75)
No	1.00		1.00		1.00		1.00	

Table 7. Results of the negative binomial Poisson model for health care utilization (continued)

Variables	Outpatient visits		Hospitalization		Length of stay		Emergency department visits	
	RR	95% CI	RR	95% CI	RR	95% CI	RR	95% CI
Diabetes complications								
Yes	1.21	(1.16 - 1.25)	1.28	(1.20 - 1.37)	1.22	(1.11 - 1.34)	1.59	(1.47 - 1.72)
No	1.00		1.00		1.00		1.00	
Hospitalization due to diabetes complications								
Yes	0.98	(0.94 - 0.1.03	1.93	(1.79 - 2.08)	2.00	(1.78 - 2.25)	1.43	(1.33 - 1.53)
No	1.00		1.00		1.00		1.00	

(3) Negative binomial Poisson model for health care utilization, according to subgroups.

Table 8 shows the results of the NB Poisson model for health care utilization, according to subgroups. For outpatient visits, participants who were men (RR: 1.68, 95% CI: 1.60-1.77), aged 30-49 years (RR: 1.95, 95% CI: 1.78-2.14), aged above 80 years (RR: 2.47, 95% CI: 1.77-3.47), had 1st quintile (RR: 1.68, 95% CI: 1.52-1.85) and 3rd quintile (RR: 1.74, 95% CI: 1.58-1.90) of household income, and living in the metropolitan region (RR: 1.74, 95% CI: 1.60-1.89) showed a stronger association with PCDMP. Likewise, PCDMP was strongly associated with hospitalization among participants who were aged 60-69 years (RR: 0.68, 95% CI: 0.60-0.77), 70-79 years (RR: 0.82, 95% CI: 0.67-0.99) and above 80 years (RR: 0.54, 95% CI: 0.32-0.91), had 4th quintile (RR: 0.65, 95% CI: 0.56-0.76) of household income, and living in the rural region (RR: 0.75, 95% CI: 0.68-0.82). The RR for LOS and ED visits also showed similar trends for PCDMP.

Table 8. Results of the negative binomial Poisson model for health care utilization according to subgroups

Variables	Outpatient visits		Hospitalization		Length of stay		Emergency department visits	
	RR	95% CI	RR	95% CI	RR	95% CI	RR	95% CI
Sex								
Men	1.68	1.60 - 1.77	0.90	0.82 - 0.99	0.86	0.76 - 0.98	0.83	0.74 - 0.93
Women	1.60	1.51 - 1.69	0.85	0.76 - 0.94	0.96	0.82 - 1.12	1.15	1.03 - 1.27
Age								
30 - 49	1.95	1.78 - 2.14	0.99	0.84 - 1.17	1.39	1.06 - 1.81	0.44	0.35 - 0.55
50 - 59	1.62	1.54 - 1.72	1.03	0.93 - 1.14	1.08	0.93 - 1.26	1.06	0.95 - 1.18
60 - 69	1.50	1.40 - 1.61	0.68	0.60 - 0.77	0.52	0.43 - 0.63	0.98	0.86 - 1.12
70 - 79	1.64	1.38 - 1.77	0.82	0.67 - 0.99	0.80	0.59 - 1.06	1.24	1.03 - 1.49
80+	2.47	1.77 - 3.47	0.54	0.32 - 0.91	0.38	0.16 - 0.90	1.01	0.68 - 1.50
Household income								
1st quintile	1.68	1.52 - 1.85	1.16	0.98 - 1.39	1.64	1.25 - 2.14	1.50	1.26 - 1.79
2nd quintile	1.63	1.47 - 1.79	0.86	0.72 - 1.02	0.92	0.71 - 1.20	1.29	1.07 - 1.54
3rd quintile	1.74	1.58 - 1.90	0.96	0.82 - 1.13	0.86	0.68 - 1.09	0.81	0.68 - 0.96
4th quintile	1.58	1.47 - 1.71	0.65	0.56 - 0.76	0.53	0.43 - 0.66	0.91	0.78 - 1.06
5th quintile	1.64	1.52 - 1.76	0.99	0.87 - 1.12	1.08	0.90 - 1.29	0.87	0.76 - 0.99
Region								
Metropolitan	1.74	1.60 - 1.89	1.14	0.98 - 1.33	1.58	1.26 - 1.97	1.23	1.05 - 1.43
City	1.63	1.52 - 1.74	1.01	0.89 - 1.15	1.05	0.87 - 1.26	0.86	0.75 - 0.99
Rural	1.63	1.54 - 1.71	0.75	0.68 - 0.82	0.67	0.59 - 0.77	0.95	0.86 - 1.05

3. All-cause mortality

(1) General characteristics of the study population

Table 9 shows the general characteristics of the study population for all-cause death. Of the 31,368 participants, the proportion of all-cause mortality was 3.18% (n = 999). The proportions of death in the intervention and control groups were 2.12% (n=111) and 3.40% (n=888), respectively. We observed a significant difference between the intervention and control groups for all-cause mortality (p: <0.001).

Table 9. General characteristics of the study population for all-cause death

Variables	Total	Survival		All-cause death		*p*
	n	n	%	n	%	
Primary care-based chronic disease management program						<0.001
Intervention	5,228	5,117	97.88	111	2.12	
Control	26,140	25,252	96.60	888	3.40	
Sex						
Men	17,706	17,098	96.57	608	3.43	
Women	13,662	13,271	97.14	391	2.86	
Age						0.005
30- 49	5,373	5,317	98.96	56	1.04	
50 - 59	12,277	12,058	98.22	219	1.78	
60 - 69	8,836	8,603	97.36	233	2.64	
70 - 79	4,080	3,732	91.47	348	8.53	
80+	802	659	82.17	143	17.83	
Household income						<0.001
1st quintile	4,615	4,413	95.62	202	4.38	
2nd quintile	4,572	4,459	97.53	113	2.47	
3rd quintile	5,494	5,294	96.36	200	3.64	
4th quintile	7,165	6,967	97.24	198	2.76	
5th quintile	9,522	9,236	97.00	286	3.00	
Types of insurance						0.309
Employee insured	11,167	10,827	96.96	340	3.04	
Self-employed insured	20,201	19,542	96.74	659	3.26	
Region						<0.001
Metropolitan	6,313	6,152	97.45	161	2.55	
City	8,035	7,813	97.24	222	2.76	
Rural	17,020	16,404	96.38	616	3.62	
Charlson comorbidity index						<0.001
0	20,186	19,584	97.02	602	2.98	
1	8,185	7,934	96.93	251	3.07	
2+	2,997	2,851	95.13	146	4.87	
Hypertension						0.002
Yes	16,203	15,638	96.51	565	3.49	
No	15,165	14,731	97.14	434	2.86	

Table 9. General characteristics of the study population for all-cause mortality (continued)

Variables	Total	Survival		All-cause mortality		*p*
	n	n	%	n	%	
Insulin use						<0.001
Yes	6,322	5,965	94.35	357	5.65	
No	25,046	24,404	97.44	642	2.56	
Disability						<0.001
Yes	3,323	3,124	94.01	199	5.99	
No	28,045	27,245	97.15	800	2.85	
Diabetes complications						<0.001
Yes	25,155	24,295	96.58	860	3.42	
No	6,213	6,074	97.76	139	2.24	
Hospitalization due to diabetes complications						<0.001
Yes	3,915	3,640	92.98	275	7.02	
No	27,453	26,729	97.36	724	2.64	
Total	31,368	30,369	96.82	999	3.18	

(2) Kaplan-Meier survival curves

Figure 5 shows the results of Kaplan-Meier survival curves with the log-rank test. The intervention group showed a higher survival probability than the control group. The log-rank test showed a significant difference ($p<0.001$).

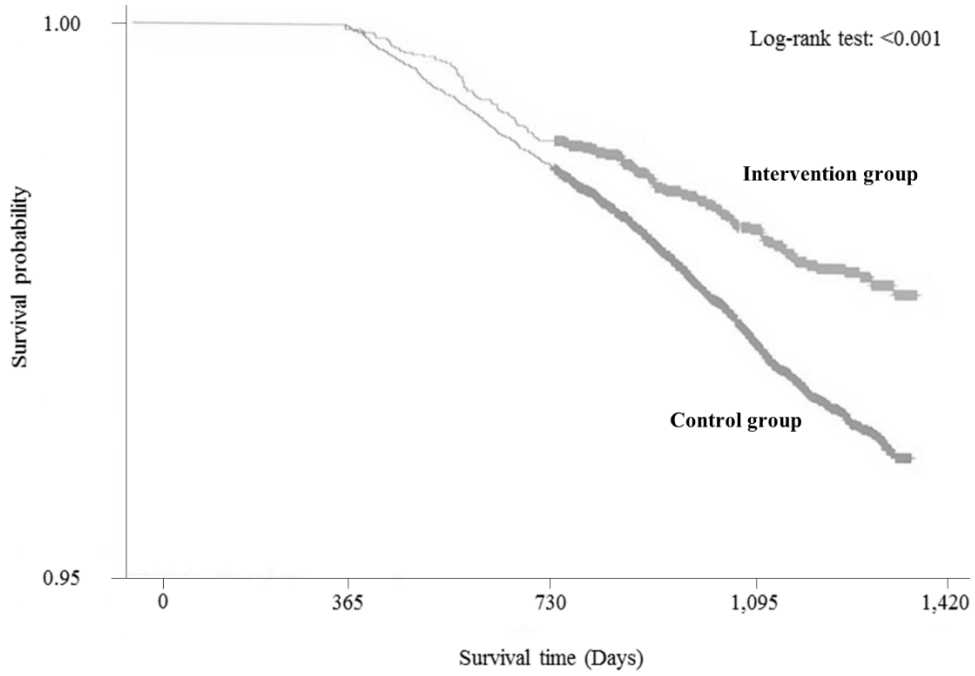

Figure 9. Kaplan-Meier survival curves

(3) Stratified Cox proportional hazard model for all-cause mortality

Table 10 shows the results of the stratified Cox proportional hazard regression for all-cause mortality. The intervention group had a lower hazard ratio (HR) for all-cause mortality than the control group (HR: 0.62, 95% CI: 0.51-0.76 vs. RR: 1.00).

Table 10. Results of stratified Cox proportional hazard regression for all-cause mortality

Variables	All-cause mortality	
	HR	95% CI
Primary care-based chronic disease management program		
Intervention	0.62	(0.51 - 0.76)
Control	1.00	
Sex		
Men	-	
Women	1.00	
Age		
30 - 49	1.00	
50 - 59	1.37	(0.88 - 2.13)
60 - 69	2.10	(1.24 - 3.55)
70 - 79	4.13	(2.24 - 7.62)
80+	6.73	(3.38 - 13.40)
Household income		
1st quintile	1.83	(1.49 - 2.25)
2nd quintile	1.22	(0.96 - 1.56)
3rd quintile	1.67	(1.36 - 2.06)
4th quintile	1.22	(1.00 - 1.50)
5th quintile	1.00	
Types of insurance		
Employee insured	1.09	(0.94 - 1.26)
Self-employed insured	1.00	
Region		
Metropolitan	1.00	
City	1.06	(0.85 - 1.33)
Rural	1.27	(1.05 - 1.54)
Region of previous program		
Yes	1.00	
No	1.19	(0.88 - 1.60)
Charlson comorbidity index	1.67	(1.12 - 2.49)
0		
1	0.78	(0.67 - 0.90)
2+	1.00	

Table 10. Results of stratified Cox proportional hazard regression for all-cause mortality (continued)

Variables	All-cause mortality	
	HR	95% CI
Hypertension		
Yes		
No	0.78	(0.67 - 0.90)
Insulin use	1.00	
Yes		
No	1.09	(0.70 - 1.71)
Disability		
Yes	1.20	(1.00 - 1.44)
No	1.00	
Diabetes complications		
Yes	0.54	(0.32 - 0.92)
No	1.00	
Hospitalization due to diabetes complications		
Yes	2.10	(1.32 - 3.36)
No	1.00	

(4) Stratified Cox proportional hazard regression for all-cause mortality according to subgroups.

Table 11 shows the results of stratified Cox proportional hazard regression for all-cause mortality according to subgroups. Participants in the intervention group who were women (HR: 0.49, 95% CI: 0.35-0.70), aged 30-49 years (HR: 0.17, 95% CI: 0.04-0.84), 60-69 years (HR: 0.66, 95% CI: 0.41-1.06), 70-79 years (HR: 0.49, 95% CI: 0.34-0.71), had 1st (HR: 0.17, 95% CI: 0.05-0.60), 4th (HR: 0.35, 95% CI: 0.16-0.74), and 5th (HR: 0.68, 95% CI: 0.43-1.07) quintiles of household income, and living in a rural region (HR: 0.57, 95% CI: 0.43-0.77) had stronger effects of the reduction for all-cause mortality than those in the control group.

Table 11. Results of stratified Cox proportional hazard regression for all-cause mortality according to subgroup

Variables	All-cause mortality		
	Intervention		Control
	HR	95% CI	HR
Sex			
Men	0.73	(0.57 - 0.93)	1.00
Women	0.49	(0.35 - 0.70)	1.00
Age			
30 - 49	0.17	(0.04 - 0.84)	1.00
50 - 59	0.80	(0.52 - 1.23)	1.00
60 - 69	0.66	(0.41 - 1.06)	1.00
70 - 79	0.49	(0.34 - 0.71)	1.00
80+	0.89	(0.52 - 1.50)	1.00
Household income			
1st quintile	0.17	(0.05 - 0.60)	1.00
2nd quintile	1.20	(0.30 - 4.80)	1.00
3rd quintile	1.10	(0.46 - 2.66)	1.00
4th quintile	0.35	(0.16 - 0.74)	1.00
5th quintile	0.68	(0.43 - 1.07)	1.00
Region			
Metropolitan	0.79	(0.37 - 1.67)	1.00
City	1.12	(0.63 - 2.00)	1.00
Rural	0.57	(0.43 - 0.77)	1.00
Region of previous program	0.73	(0.57 - 0.93)	
Yes	0.49	(0.35 - 0.70)	1.00
No			1.00

4. Diabetes complications outcomes

Table 12 shows the results of outcomes related to diabetes complications. PCDMP had an effect of reduction of diabetes complication-specific hospitalization (RR: 0.82, 95% CI: 0.76-0.88) and mortality (cause-specific hazard ratio (CSH):0.63, 95% CI: 0.42-0.93). However, there was no significant association for length of stay (RR: 0.92, 95% CI: 0.83-1.02) and emergency department visits (RR: 0.94, 95% CI: 0.87-1.01).

Table 12. Results of outcomes related to diabetes complications

Diabetes complications cause-specific outcomes	Primary care-based chronic disease management program		
	Intervention		Control
	RR/CSH	95% CI	RR/HR
Hospitalization	0.82	(0.76 - 0.88)	1.00
Length of stay	0.92	(0.83 - 1.02)	1.00
Emergency department visits	0.94	(0.87 - 1.01)	1.00
Diabetes complications-specific mortality	0.63	(0.42 - 0.93)	1.00

V. Discussion

1. Discussion of the study method

This study aimed to investigate the effect of PCDMP on health care utilization outcomes and mortality among patients with newly diagnosed type 2 diabetes mellitus using time-dependent propensity score matching, multiple linear regression, NB Poisson regression, stratified Cox proportional hazard model, and Cox proportional cause-specific hazard model.

We used nation-wide data from the NHIS-NSC database, collected nationally between 2002 and 2015; the data represented approximately 2% of the Korean population in 2002. In addition, the data used in the current study included those in the medical treatment records including diagnosis codes and the exact dates of treatment or diagnosis.

For matching between the intervention group and the control group, we conducted propensity score matching using time-dependent covariates. In some longitudinal studies that focus on high-risk groups over time, patients are exposed to treatment at different times, and eventually, the majority of participants are treated [30]. A structural modeling approach that uses time-varying covariates in the regression model to control for confounding and identify the causal effect of a time-

varying treatment has been developed. However, relatively less effort has channeled toward the application of propensity score methods in longitudinal observational studies [30]. Bu Lu proposes a faster and simpler algorithm for risk set matching by using the hazard component as the time-dependent propensity score [30]. This matching algorithm is fast and easy to implement with large data sets and can be constructed to model the treatment assignment [30].

The results of this study should be interpreted carefully owing to the following limitations. First, for decades, the use of administrative data has been considered a potential limitation due to its possible inaccuracy. For instance, ICD-10 codes in the cohort data may not always represent patients' real disease status because the primary purpose of their use is to facilitate patients' health insurance claims. However, a previous study demonstrated a 70% correspondence between NHIS-NSC claims codes and medical record codes. Second, because the study was conducted using administrative data, we could not control the potential confounders that could affect mortality, including health-related behaviors such as smoking, drinking, and physical activity; household composition and marital status; and the presence of caregivers. Third, we did not include uninsured patients with diabetes because this used insurance claim data. Fourth, we did not control for the severity of type 2 diabetes mellitus. However, we considered the duration of type 2 diabetes mellitus and the use of insulin to partially control for the severity of diabetes. Fifth, only patients with type 2 diabetes who visited medical institutions were included as captured by the claim data. Therefore, patients who exhibited symptoms of diabetes complications but did not visit medical institutions were not included in the sample.

Lastly, this study defined patients with newly diagnosed diabetes and new-onset diabetes complications based on a set wash-out period. However, this relied on an assumption because records preceding 2002 do not exist in an electronic format. Therefore, we could not rule out the potential contamination of the inclusion criteria of the study population.

2. Discussion of the results

This study investigated the effect of PCDMP on COC, healthcare utilization outcomes, and health outcomes among patients with newly diagnosed type 2 diabetes mellitus. PCDMP was associated with an increase in COC and MPR, as well as a reduction in all-cause mortality and hospitalization, length of stay, and outpatient visits after controlling for covariates. Moreover, PCDMP was associated with a reduction in diabetes complication-specific hospitalization and mortality.

Additionally, PCDMP led to increase in COC and medication adherence among patients in the intervention group. These findings suggest that PCDMP induced patients to change their healthcare utilization behaviors leading to continuous treatments in preferred clinics and by healthcare providers with greater accountability for patients' outcomes. The improvement of COC can enhance drug compliance and persistence as demonstrated in previous studies [36]. A high usual provider continuity index is likely to increase the likelihood of medication adherence [37-39]. In addition, patients with higher COC have better drug compliance scores than patients with lower COC. Moreover, an increase in the number of outpatient visits could facilitate the delivery of proper medical services and augment medication adherence among patients with type 2 diabetes [40-43]. These results also imply that use of the same healthcare provider improves COC, which leads to better adherence and persistence [36].

Furthermore, the copayment reduction policy could also contribute to enhanced medication adherence and COC [44-49]. Our findings are consistent with the

results of a systematic review study, which showed that drug adherence could be improved through policy-level changes that lower the cost of care [36]. Moreover, a study evaluating the effectiveness of discounts on out-of-pocket costs of prescription drugs found that high out-of-pocket costs affect the frequency and persistence of drug prescriptions [50-52].

Previous studies that investigated the effect of a disease management program, found a substantial reduction in all-cause mortality. In other long-term evaluations of management and self-management programs for diabetic patients, a decrease in mortality and cardiovascular events have been observed [53, 54]. There are some possible explanations for these findings. First, patients enrolled in disease management programs have a lower degree of morbidity and are highly motivated to adhere to treatment regimens and better glucose control compared to individuals who do not enroll in such programs [55, 56]. Second, patients enrolled in disease management programs receive treatment of higher quality compared to regular care patients; thus, they have fewer exacerbations and complications and can manage the disease better [57]. Therefore, the survival benefit of the program participants would be related to the high-quality care offered in such a setting. Regarding hospitalization, when individual educational components of the diabetes care management program were examined, diabetes education sessions were more beneficial than certified diabetes educator visits in reducing the incidence of hospitalization [58]. Patients with controlled blood glucose levels and an opportunity to attend a diabetes education session have the most significant reduction in hospitalization risk [59-61]. As exemplified in this study, attendance of diabetes

educational sessions in primary care settings coupled with blood glucose control is associated with hospitalization risk reduction.

VI. Conclusion

In this study, we found that PCDMP has positive and desirable effects on all-cause and diabetes complications-specific healthcare utilization outcomes and mortality. The PCDMP was associated with an increase in COC and MPR and a reduction in all-cause mortality and hospitalization and length of stay after controlling for covariates. Moreover, participation in the program was associated with a reduction in diabetes complication-specific mortality, hospitalization, and length of stay outcomes. Although we observed a positive effect of the PCDMP, the effect was short term, warranting the need for further studies to investigate whether the short-term effects could be sustained over a longer duration of the program.

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Korean abstract

의원급 만성질환관리 프로그램이 제 2 당뇨병 환자의 의료이용과 사망에 미치는 영향

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서론: 인구의 고령화, 의료기술의 발달, 생활방식 등의 변화로 만성질환은 전 세계적으로 급증하고 있으며, 이로 인한 합병증 발생과 의료비 지출의 부담 또한 증가하고 있다. 만성질환의 관리를 최적화하고 환자의 결과를 개선하기 위해서는 일차의료의 역할이 중요하다. 일차의료 기반 만성질환관리 프로그램은 당뇨병 환자의 의료이용행태에 대한 변화와 개선을 위해 도입되었으나, 당뇨 관련 건강 결과 개선에 직접적인 효과를 본 연구는 부족한 실정이다. 본 연구는 일차의료 기반 만성질환관리제가 새로 진단된 제 2 형 당뇨병을 가진 환자의 의료이용행태와 건강 결과 및 사망에 미치는 영향을 파악하고자 하였다.

연구방법: 시간 의존 공변량 사용한 성향점수 매칭법(Propensity score matching with time-dependent covariates)을 사용하여 일차의료 기반

만성질환관리 프로그램에 참여한 중재군과 참여하지 않은 대조군을 1:5 비율로 매칭하였으며, 매칭 변수로는 연령, 성별, charlson 동반질환지수, 인슐린 사용여부, 당뇨 합병증 발생, 당뇨 합병증으로 인한 입원을 사용하였다. 총 31,368 명의 연구대상자를 최종 선정하였으며, 다중 선형회귀분석(Multiple regression), 음이항 포아송 회귀 분석(Negative binomial Poisson regression), 층화콕스비례위험모델(Stratified Cox proportional hazard model), 경쟁위험(Competing risk)을 적용한 층화콕스비례위험모델(Stratified Cox proportional hazard model)을 사용하여 의약품 복약순응도, 치료 지속성, 외래 방문 횟수, 입원 횟수, 재원 일수, 응급실 방문횟수, 모든 사망 및 당뇨합병증으로 인한 의료이용 및 사망을 분석하였다.

연구결과: 연구대상자 31,368 명 중 16.67%(5,228 명)는 중재군에, 83.33%(26,140 명)는 대조군에 배정되었다. 중재군의 로그 치환 치료지속성은 대조군보다 15% 높았으며(Exp(β): 1.15, 95% CI: 1.14−1.16), 중재군의 로그 치환 의약품 복약순응도 또한 대조군보다 12% 높았다(Exp(β): 1.12, 95% CI: 1.12−1.13). 중재군의 외래방문 횟수는 대조군에 비해 64% 높았으나(RR: 1.64, 95% CI: 1.58−1.71), 입원 횟수와 재원 일수는 대조군보다 각각 16% (RR: 0.84, 95% CI: 0.79−0.90), 21% (RR: 0.79, 95% CI: 0.72−0.87) 낮았다. 하지만, 응급실 방문횟수는 두 군 간 통계적으로 유의미한 차이는 없었다. 모든 사망자는 3.18%(999 명)이며, 중재군은 모든 사망에 대한 위험비가 대조군에 비해 38% 낮았다(HR: 0.62, 95% CI: 0.51−0.77). 마지막으로, 중재군의 당뇨병 합병증 관련 입원횟수 및 사망위험비는 대조군에 비해 각각 18% (RR: 0.82, 95% CI: 0.76−0.88), 37% (HR: 0.63, 95% CI: 0.42−0.93) 낮았으나, 재원 일수와 응급실 방문횟수에 대해서는 통계적으로 유의미한 차이는 없었다.

결론: 본 연구에서는 의원급 만성질환 관리프로그램이 모든 원인 및 당뇨 합병증 관련 의료이용 결과와 사망에 긍적적인 영향을 미치는 것을 확인하였다. 의원급 만성질환 관리프로그램은 치료지속성과 복약순응도를

증가시키고, 외래 방문 횟수, 입원 횟수, 재원 일수, 모든 원인 사망위험 감소에 영향을 주는 것을 확인 할 수 있었다. 또한 이 프로그램에 참여하는 대상자들에게서 당뇨 합병증으로 인한 입원 횟수와 사망위험을 감소시키는 효과를 확인할 수 있었다. 환자에게는 진찰료 본인부담 경감과 더불어 건강지원서비스 제공 등의 혜택을 제공하고, 참여의원에는 평가를 통한 인센티브를 제공하여 환자 관리의 질을 향상했기 때문에 만성질환관리 프로그램이 환자의 의료이용 행태와 건강상태에 긍정적인 효과를 미쳤을 가능성이 있다. 하지만 프로그램 도입 이후 3 년이라는 단기 효과만을 확인할 수 있었기 때문에 의원급 만성질환관리 프로그램의 장기 효과를 평가하는 후속 연구가 필요하다.