

Chronic care model in primary care: can it improve health-related quality of life?

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Purpose: Chronic diseases such as hypertension, diabetes mellitus, and hyperlipidemia are public health concerns. However, little is known about how these affect patient-level health measures. The aim of the study was to examine the impact of a chronic care model (CCM) on the participant's health-related quality of life (QoL).

Patients and methods: Participants received either usual care or CCM by a team of health care professionals including pharmacists, nurses, dietitians, and general practitioners. The participants in the intervention group received medication counseling, adherence, and dietary advice from the health care team. The QoL was measured using the EQ-5D (EuroQoL-five dimension, health-related quality of life questionnaire) and comparison was made between usual care and intervention groups at the beginning and end of the study at 6 months.

Results: Mean (standard deviation) EQ-5D index scores improved significantly in the intervention group (0.92 ± 0.10 vs 0.95 ± 0.08 ; $P \leq 0.01$), but not in the usual care group (0.94 ± 0.09 vs 0.95 ± 0.09 ; $P = 0.084$). Similarly, more participants in the intervention group reported improvements in their QoL compared with the usual care group, especially in the pain/discomfort and anxiety/depression dimensions.

Conclusion: The implementation of the CCM resulted in significant improvement in QoL. An interdisciplinary team CCM approach should be encouraged, to ultimately result in behavior changes and improve the QoL of the patients.

Keywords: diabetes mellitus, hypertension, hyperlipidemia, quality of life, EQ-5D

Introduction

Diabetes mellitus, cardiovascular, and chronic kidney diseases are the major causes of mortality, and the prevalence of these diseases is increasing worldwide.¹ Despite established national and international clinical guidelines as well as effective pharmacotherapy,²⁻⁴ the management of these major diseases remains suboptimal. This situation is a major concern for Malaysia, where these diseases have reached epidemic proportions.⁵ The data from the recently concluded National Health and Morbidity survey showed that the prevalence of hypertension had increased from 32.2% in 2006 to 32.7% in 2011 for those aged 18 years and above. Similarly, the prevalence of diabetes has also increased by 31% in 5 years, from 11.6% in 2006 to 15.2% in 2011 and hyperlipidemia from 20.6% in 2006 to 35.1% in 2011 in those aged 18 years and above.^{5,6}

Therefore, creative solutions are required to address the increasing health care demand of noncommunicable disease in the country. There is growing evidence worldwide suggesting the integration of health care that provides patient-centered care,

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such as the chronic care model (CCM) is a feasible solution to this problem.^{7,8} The CCM is an evidence-based framework that advocates evidence-based health care system changes especially in primary care setting needed to improve the patient outcomes.^{9,10} In the current study, five of the six key components of CCM were used namely: patient empowerment and self-management support; delivery system design; decision support; clinical information systems, and finally community resources.

We recently conducted a study examining the use of this model in single as well as multiple chronic diseases. The primary prevention program, known as the Community Based Multiple Risk Factors Intervention Strategy (CORFIS) was a prospective, open label, multi-center, cluster-randomized study encompassing the services of general practitioners (GPs), pharmacists, nurses as well as dietitians, working together with 784 participants to improve their health outcomes by providing health education, medication counseling, treatment adherence as well as diet plan. Due to the popularity of CCM as a conceptual tool for quality improvement and health care reorganization, there is a need to determine if such interdisciplinary team approach produces better health status outcome. The objective of this study was to assess the impact of the CCM program on patient health-related quality of life (QoL).

Patients and methods

Study design and setting

This study was part of a larger community-based, controlled study, which has been described earlier.^{11,12} Briefly, GPs from the Klang valley were invited to participate in recruiting the patients for this study.¹³ Participating GP clinics were subsequently allocated to either intervention or control in a 2:1 ratio. Any participants aged 18 years and above, diagnosed with either one or more of the following diseases: hypertension, diabetes mellitus, or hyperlipidemia, and treated with pharmacotherapy for one or more of these conditions were eligible for inclusion in the study. All the participants provided written informed consent. Ethical approval was obtained from the Medical Research Ethics Committee, Ministry of Health, Malaysia (NMRR-07-688-960). Trial registration: ClinicalTrials.gov, NCT00490672.

Study procedures

The participants allocated to the intervention cluster were required to attend a monthly check-up during the 6-month follow-up study period, with assessments by the pharmacist who reviewed the participants' medications and provided

counseling on adherence, medication knowledge as well as conducted medication reconciliation of existing prescription medications; dietitians who provided dietary advice including calorie calculations and the importance of regular exercise; and nurses who educated the participants on general health care issues such as the use of a glucose meter and foot care. Participants' sociodemographic data, lifestyle, medical, and medication history were collected at baseline. In addition, the health-related QoL of each participant was assessed using the EQ-5D (EuroQoL-five dimension, health-related quality of life questionnaire) at baseline and at the end of the 6-month study period.

Outcome measures

The EQ-5D instrument is a standard instrument for measuring health outcome and has been validated for use in the Malaysian population.^{14,15} This instrument provides a simple descriptive profile and a single index value for assessing health status. It comprises of five dimensions (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) with three levels of measurement each (no problems, some problems, and severe problems). It has been used in several studies to assess the QoL of patients with diabetes,^{16–18} hypertension,^{18–20} and hyperlipidemia.¹⁸ The raw values obtained from the dimension scales were subsequently converted into the Malaysian EQ-5D index tariff to obtain an overall health index score, with higher values representing better QoL. This ranges between 0 (represents death) and 1.0 (represents perfect health status).²¹ The patients also completed the EQ-5D visual analog scale (EQ-VAS), a 20 cm long VAS where the patients marked their current health status ranging from “best imaginable health state” (score of 100) to “worst imaginable health state” (score of 0).

The primary endpoint was a 0.03 point increase in the EQ-5D index and a 3.0 point increase in the EQ-VAS from baseline to 6 months, based on consensus opinion and published recommendations available.²² Secondary outcomes include changes in EQ-5D index and subscales in the various subgroups of participants as well as the EQ-VAS score.

Data analysis

All analyses were carried out with the PASW Statistics for Windows version 18 (SPSS Inc., Chicago, IL, USA). An intent-to-treat analysis was undertaken, whereby missing data were replaced using the last observation carry forward method. Continuous variables were summarized as means and standard deviations while frequencies and percentages were generated for categorical variables. Statistical comparison of

endpoints was done using a paired *t*-test. We subsequently adjusted for age, occupational status, and education status to estimate the effects of intervention on QoL using a generalized estimating equation (GEE). All analyses were conducted separately for the patients with hypertension, diabetes, and hyperlipidemia. Any *P*-value less than 0.05 was considered as statistically significant.

Results

Demographic characteristics of participants

A total of 784 participants who were diagnosed with hypertension, diabetes mellitus and/or hyperlipidemia, and treated with pharmacotherapy were enrolled into the study: 527 in the intervention arm and 257 in the usual care arm (Figure 1). However, complete data were available for only 468 participants in the intervention group and 225 participants in the usual care group, giving a response rate of 88.4%. Table 1 shows the demographic characteristics of the participants. Men constituted 59.3% (*n*=411) of the total respondents and

almost half of the participants were of Malay ethnic origin (*n*=312, 45.0%). Most of the participants had some forms of formal education. Smoking of tobacco was reported by 15.3% (*n*=106) of the participants. As there were significant differences in the baseline characteristics, comparisons between both arms were not performed.

Quality of life

QoL for intervention groups

Reported EQ-VAS QoL improved significantly by 6 points in the intervention group from 70.7 to 76.8 (*P*<0.001) and only by 1.7 points in the usual care group to 72.4 (*P*=0.314). Mean calculated EQ-5D index score also increased significantly by 0.03 points from 0.92 to 0.95 in the intervention group (*P*≤0.001). The patients in the usual care group reported an EQ-5D score of 0.94 which increased marginally to 0.95 at the end of the study (Table 2). In addition, the number of participants reporting a minimum meaningful improvement in the QoL was numerically higher in the intervention group compared with the usual care group (24.6% vs 8.0% reporting

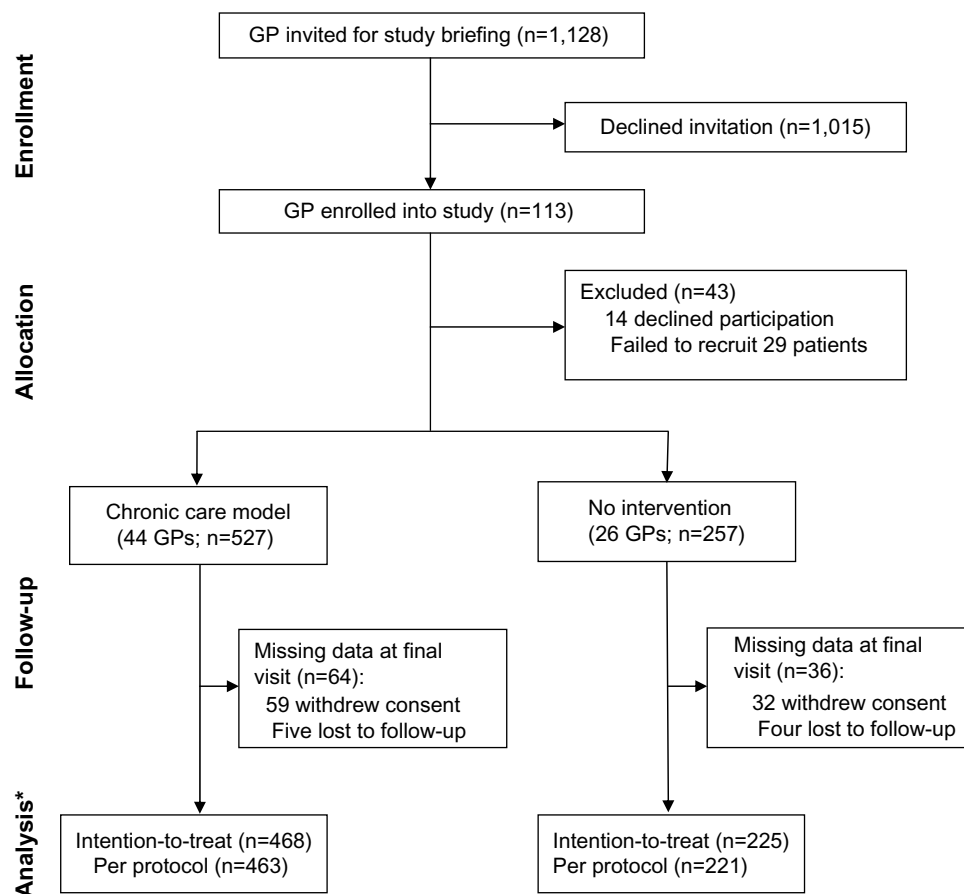


Figure 1 Flowchart of participants in the study.

Note: *Participants who successfully completed 6 months follow-up were included in the analysis.

Abbreviation: GP, general practitioner.

Table 1 Baseline demographics and clinical characteristics of participants in the study

Variable	Intervention group (n=468)	Usual care group (n=225)	P-value
Mean age (SD), years	47.4 (9.4)	50.1 (10.2)	0.001**
Sex, n (%)			0.163*
Male	286 (61.1)	125 (55.6)	
Female	182 (38.9)	100 (44.4)	
Race, n (%)			<0.001*
Malay	208 (44.4)	104 (46.2)	
Chinese	119 (25.4)	82 (36.4)	
Indian	125 (26.7)	38 (16.9)	
Others	16 (3.5)	1 (0.5)	
Employment status, n (%)			<0.001*
Employed	368 (78.6)	162 (72.0)	
Jobless	11 (2.4)	1 (0.4)	
Housewife	46 (9.8)	49 (21.8)	
Retired	43 (9.2)	13 (5.8)	
Education, n (%)			<0.001*
Primary	25 (5.3)	42 (18.7)	
Secondary	208 (44.4)	116 (51.6)	
Graduate and above	176 (37.6)	52 (23.1)	
Illiterate	59 (12.6)	15 (6.7)	
Disease status,*** n (%)			
Hypertension	306 (65.4)	173 (76.9)	0.002*
Hyperlipidemia	268 (57.3)	104 (46.2)	0.006*
Diabetes	292 (62.4)	130 (57.8)	0.244*
Tobacco use, n (%)			0.08*
Past	44 (9.4)	13 (5.8)	
Current	78 (16.7)	28 (12.4)	
Never	346 (73.9)	184 (81.8)	

Notes: *P-values based upon χ^2 test; **P-values based upon t-test; ***percentage exceeds 100% as some patients had >1 disease state.

Table 2 Distribution of participants reporting moderate or severe problems in different dimensions and the EQ-5D index scores

	Baseline	End of study	P-value
Intervention group (n=468)			
Mobility, n (%)	32 (6.8)	25 (5.3)	0.412*
Self-care, n (%)	3 (0.6)	0 (0)	0.249*
Usual activity, n (%)	21 (4.5)	17 (3.6)	0.514*
Pain/discomfort, n (%)	147 (31.4)	81 (17.3)	<0.001*
Anxiety/depression, n (%)	112 (23.9)	70 (15.0)	0.001*
EQ-5D index score, mean (SD)	0.92 (0.10)	0.95 (0.08)	<0.001**
EQ VAS, mean (SD)	70.74 (16.53)	76.81 (15.28)	<0.001**
Usual care group (n=225)			
Mobility, n (%)	10 (4.4)	8 (3.6)	0.641*
Self-care, n (%)	0 (0)	0 (0)	
Usual activity, n (%)	5 (2.2)	4 (1.8)	0.752*
Pain/discomfort, n (%)	43 (19.1)	41 (18.2)	0.810*
Anxiety/depression, n (%)	46 (20.4)	40 (17.8)	0.548*
EQ-5D index score, mean (SD)**	0.94 (0.09)	0.95 (0.09)	0.084*
EQ VAS, mean (SD)	70.72 (25.42)	72.35 (24.81)	0.314**

Notes: Data are utility value 0–1 (mean [SD]), VAS scores 0–100 (mean [SD]), and number and percentage of patients reporting problems within the five dimensions. *P-value based on χ^2 test; **P-value based on paired t-test.

Abbreviations: EQ-5D, EuroQoL-five dimension, health-related quality of life questionnaire; EQ-VAS, EQ-5D visual analog scale.

Table 3 Patients with a minimum clinically significant change in outcome from baseline to 6 months

	Intervention group	Usual care group
Whole cohort		
EQ-5D index score	n [†] =468	n [†] =225
Improving by > MIC, n* (%)	115 (24.6)	18 (8.0)
Worsening by > MIC, n* (%)	33 (7.1)	9 (4.0)
EQ-VAS score	n [†] =460	n [†] =223
Improving by > MIC, n* (%)	208 (45.2)	46 (20.6)
Worsening by > MIC, n* (%)	67 (14.6)	27 (12.1)
Hypertension		
EQ-5D index score	n [†] =306	n [†] =173
Improving by > MIC, n* (%)	76 (24.8)	15 (8.7)
Worsening by > MIC, n* (%)	22 (7.2)	7 (4.0)
EQ-VAS score	n [†] =302	n [†] =172
Improving by > MIC, n* (%)	141 (46.7)	38 (22.1)
Worsening by > MIC, n* (%)	43 (14.2)	19 (11.0)
Diabetes mellitus		
EQ-5D index score	n [†] =306	n [†] =173
Improving by > MIC, n* (%)	67 (25.0)	6 (5.8)
Worsening by > MIC, n* (%)	20 (7.5)	4 (3.8)
EQ-VAS score	n [†] =262	n [†] =104
Improving by > MIC, n* (%)	125 (47.7)	24 (23.1)
Worsening by > MIC, n* (%)	36 (13.7)	11 (10.6)
Hyperlipidemia		
EQ-5D index score	n [†] =233	n [†] =106
Improving by > MIC, n* (%)	55 (23.6)	7 (6.6)
Worsening by > MIC, n* (%)	17 (7.3)	6 (5.7)
EQ-VAS score	n [†] =230	n [†] =104
Improving by > MIC, n* (%)	105 (45.7)	20 (19.2)
Worsening by > MIC, n* (%)	33 (14.3)	17 (16.3)

Notes: MIC, minimally important change defined as 0.03 points in the EQ-5D index score and 3 points in the EQ-VAS score. *These numbers represent the number of patients who attended final visit 6-month postintervention, and percentages are based on these numbers. The number of patients with data for each endpoint (n[†]) is presented before each endpoint.

Abbreviations: EQ-5D, EuroQoL-five dimension, health-related quality of life questionnaire; EQ-VAS, EQ-5D visual analog scale.

a 0.03 point improvement in the EQ-5D index score; Table 3). After adjusting for baseline differences, the intervention was associated with an improvement in EQ-VAS score but not EQ-5D scores (Table 4).

QoL for various disease states

The intervention was associated with an improvement in QoL and EQ-VAS score in all the three disease states studied (Table 5). A modest improvement in EQ-VAS score was observed in the usual care group but this did not reach statistical significance. During the study, QoL increased significantly in the intervention group irrespective of disease state, resulting in >80% of the patients reporting no problem for all the five dimensions studied. The biggest improvement was noted in the pain/discomfort dimension where there

Table 4 Results of the GEE regression analyses

Parameter	EQ-5D index score		EQ-VAS score	
	Estimate (SE)	P-value	Estimate (SE)	P-value
Intercept	0.96 (0.04)	<0.01	65.74 (7.0)	<0.01
Allocation				
CORFIS	−0.01 (0.01)	0.11	1.44 (1.7)	0.42
Usual care (reference)				
Education status				
Primary	0.01 (0.02)	0.64	−7.46 (4.1)	0.07
Secondary	0.01 (0.01)	0.48	−0.09 (2.4)	0.97
Tertiary	0.02 (0.01)	0.21	−1.19 (2.6)	0.64
Illiterate (reference)				
Race				
Malay	0.03 (0.02)	0.22	4.41 (4.0)	0.27
Chinese	0.02 (0.02)	0.50	3.76 (4.1)	0.36
Indian	−0.01 (0.02)	0.82	4.79 (4.2)	0.25
Others (reference)				
Occupational status				
Employed	0.00 (0.01)	0.99	−1.75 (3.3)	0.60
Housewife	−0.01 (0.02)	0.51	−3.39 (3.5)	0.34
Jobless	−0.02 (0.03)	0.48	−3.33 (5.1)	0.51
Retired (reference)				
Age (years)	−0.00 (0.00)	0.12	0.09 (0.1)	0.25

Abbreviations: CORFIS, Community Based Multiple Risk Factors Intervention Strategy; EQ-5D, EuroQoL-five dimension, health-related quality of life questionnaire; EQ-VAS, EQ-5D visual analog scale; GEE, generalized estimating equation; SE, standard error.

was a statistical improvement in all the three disease groups studied, followed by anxiety/depression dimension which was significantly improved in the patients with diabetes in the intervention group. No differences were noted in the usual care group at the end of the study (Table 4). The GEE analysis revealed that age and race were strongly associated with better EQ-VAS score and QoL, respectively, in the patients with hyperlipidemia ($P<0.05$). However, there were no associations between age, education, employment status, and race in the patients with hypertension and diabetes.

Table 5 EQ-5D scores in hypertensive, diabetic, and hyperlipidemic patients

Disease	Hypertension		Diabetes		Hyperlipidemia	
	Intervention group	Usual care group	Intervention group	Usual care group	Intervention group	Usual care group
EQ-5D index score	n=306	n=173	n=268	n=104	n=292	n=130
Baseline	0.93 (0.10)	0.94 (0.09)	0.92 (0.10)	0.94 (0.09)	0.93 (0.10)	0.95 (0.09)
End of study	0.95 (0.09)	0.95 (0.09)	0.95 (0.10)	0.94 (0.09)	0.96 (0.09)	0.95 (0.09)
P-value*	<0.001	0.082	<0.001	0.608	<0.001	0.513
EQ VAS score	n=302	n=131	n=262	n=81	n=288	n=96
Baseline	71.9 (16.5)	70.3 (25.8)	69.5 (17.2)	66.7 (27.2)	70.0 (16.5)	72.3 (25.8)
End of study	77.6 (14.8)	72.2 (25.8)	75.8 (15.9)	69.5 (26.6)	76.6 (15.1)	75.1 (22.7)
P-value*	<0.001	0.508	<0.001	0.488	<0.001	0.392

Notes: *P-value based on paired t-test for within-group differences. EQ-5D scores were computed using the Malaysian index. Higher EQ-5D and EQ-VAS scores represent better quality of life.

Abbreviations: EQ-5D, EuroQoL-five dimension, health-related quality of life questionnaire; EQ VAS, EQ-5D visual analog scale.

Discussion

Metabolic diseases have been shown to negatively impact a person's QoL.²³ In this multi-center study, the involvement of other health care professionals in addition to usual GP care was found to significantly improve the QoL of participants as well as their health status after 6-month participation. These improvements could be attributed to several factors namely: improved patient compliance, modification of diet and life-style, psychological support as well as patient empowerment. This combined strategy is simple, culturally acceptable and easily scaled up, and does not require any access to specialist services which may be scarce in a developing country. The data from this study concur and further support those from various other similar studies,^{17,24} suggesting that these benefits can be realized in clinical practice, which is reflected by an improvement in QoL from a patient's perspective.

To our knowledge, this is the first community-based controlled trial of its kind in the South East Asian region, where the burden of cardiovascular and chronic kidney diseases is high.²⁵ The study involved a large patient number in a community-based setting, with close follow-up for 6 months. We used the EQ-5D questionnaire, which has been widely used in various studies and validated in the Malaysian population.^{14,15,20,26} Thirdly, we initiated a study which focused on empowering the patient to manage their own conditions such as providing dietary counseling, training on insulin injection, and self-monitoring of blood glucose to achieve their individual metabolic targets. This is highly novel in Malaysia and was not available at the point of time the study was conducted.

This study has some potential limitations which need to be addressed. Firstly, it included various types of the patients with a wide range of drug regimens. It is possible that the improvement in the patient's condition or even adherence may have

led to this improvement in the QoL. However, as the results of this study reflect actual medical condition, we believe the results will provide useful information and insights into the patient's concerns and hopes. Secondly, the study was relatively short and hence underpowered to determine its effects on cardiovascular outcomes such as mortality. Nevertheless, the data from other studies suggest that a sustained systolic blood pressure reduction of 5% would reduce the absolute risk of cardiovascular death by 20% over the next 2 decades. Similarly, the UK Prospective Diabetes Study study has shown that a 1% reduction in HbA_{1c} will reduce microvascular and macrovascular complications over the next 10 years.²⁷ Lastly, the allocation of GP clinics to the usual care or intervention group could not be performed at random due to logistic reasons and also the willingness of GP clinics to participate in the study. To encourage participation, a 2:1 ratio of intervention to usual care randomization was adopted. This probably resulted in differences in the baseline characteristics between the two cohorts of participants, which may contribute to the differences in the results.

Conclusion

Implementation of the CCM into GP practice was significantly related to improved QoL of the participants, highlighting the importance of a multi-disciplinary team approach to provide collaborative care to the patients with chronic conditions. An adaptation of the CCM model may serve as a template for future health care system remodeling, to help improve access to quality and effective health care services especially in primary care.

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Author contributions

FMYA conceived, directed, and designed the CORFIS study. SWHL conducted statistical analyses. SSC designed the

CORFIS study and assisted in statistical analyses. BE and TP participated in the study design. LCK coordinated the CORFIS study. All authors contributed toward data analysis, drafting and critically revising the paper, gave final approval of the version to be published, and agree to be accountable for all aspects of the work.

Disclosure

The authors report no conflicts of interest in this work.

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