ORIGINAL ARTICLE

Community-based cardiovascular Risk Factors Intervention Strategies (CORFIS) in managing hypertension: A pragmatic non-randomised controlled trial

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SUMMARY

Background: Hypertension is the number one cardiovascular risk factor in Malaysia. This study aimed to evaluate the effectiveness of a Community-Based Cardiovascular Risk Factors Intervention Strategies (CORFIS) in the management of hypertension in primary care.

Methods: This is a pragmatic, non-randomized controlled trial. Seventy general practitioners (GPs) were selected to provide either CORFIS (44 GPs) or conventional care (26 GPs) for 6 months. A total of 486 hypertensive patients were recruited; 309 were in the intervention and 177 in the control groups. Primary outcome was the proportion of hypertensive patients who achieved target blood pressure (BP) of <140/90mmHg (for those without diabetes mellitus) and <130/80mmHg (with diabetes mellitus). Secondary outcomes include change in the mean/median BP at 6-month as compared to baseline.

Results: The proportion of hypertensive patients who achieved target BP at 6-month was significantly higher in the CORFIS arm (69.6%) as compared to the control arm (57.6%), P=0.008. Amongst those who had uncontrolled BP at baseline, the proportion who achieved target BP at 6-month was also significantly higher in the CORFIS arm (56.6%) as compared to the control arm (34.1%), p<0.001. There was no difference in the patients who had already achieved BP control at baseline. There were significant reductions in SBP in the CORFIS arm (median -9.0mmHg; -60 to 50) versus control (median -2mmHg; -50 to 48), p=0.003; as well as in DBP (CORFIS arm: median -6.0mmHg; ranged from -53 to 30 versus control arm: median 0.0mmHg; ranged from -42 to 30), p<0.001.

Conclusions: Patients who received CORFIS care demonstrated significant improvements in achieving target BP.

INTRODUCTION

Prevalence of chronic diseases is rising at an alarming rate globally. It is estimated that 46% of global disease burden is attributed to chronic diseases and this figure is expected to reach 60% by the year 2020[1]. The 2006 National Health and Morbidity Survey (NHMS) in Malaysia showed that the prevalence of hypertension is 32.2% and this makes hypertension the commonest chronic disease in Malaysia. Findings from 2006 NHMS showed that only 33% of patients diagnosed to have hypertension were aware of the diagnosis and among them, only 23% were on treatment. Among those on treatment, only 26% achieved target blood pressure (BP) control[2]. The proportion of patient achieving good control of BP was lower than that observed in the 1996 NHMS[3]. These findings, together with the high prevalence of other cardiovascular risk factors such as hyperlipidaemia, obesity and smoking, contribute to the increasing burden of cardiovascular morbidity and mortality in Malaysia[4].

Studies have shown that patients who received antihypertensive treatment at primary care clinics and private general practitioners had sub-optimal management and poor outcomes[5,6]. It has also been noted that private general practitioners in Malaysia often work in solo practice without allied health support from pharmacists and dietitians[7]. On the other hand, though public primary care clinics have access to pharmacists and dietitians, the multidisciplinary approach to patient care is not the norm due to patient load and time constraints.

Effective management of chronic diseases requires focus on the needs of the patients as opposed to the traditional primary care delivery model which provides only acute episodic care. The Chronic Care Model (CCM) developed by Wagner *et al*[8,9] which was later adapted by the World Health Organisation (WHO)[1,10], is an evidence-based framework for chronic disease management. Optimal chronic care is achieved when a well-coordinated, proactive healthcare team interacts productively with an informed and motivated patient. The CCM has greatly influenced the reorganisation of chronic disease care in many developed countries[11-13]. However, evidence is still lacking to show if such CCM is feasible or is effective in developing countries.

Therefore, this study was conducted to evaluate the effectiveness of a Community-Based Cardiovascular Risk Factors Intervention Strategies (CORFIS), which was designed based on the CCM, in managing patients with hypertension in the private primary care settings in Malaysia.

MATERIALS AND METHODS
This was a pragmatic, non-randomized multi-centre controlled trial. Blinding was not possible due to the nature and complexity of the intervention. This study was approved by the Medical Research Ethics Committee of the Ministry of Health Malaysia (MOH) and was conducted in accordance with the Declaration of Helsinki and Good Clinical Practice (GCP) requirements. All participants gave their written informed consent. This study was registered with clinical trial.gov and reporting was done in accordance to the CONSORT Statement 2010 [14, 15].

Study sites
Seventy General Practitioners (GPs) who were registered in the National Medical Health Directory from the state of Selangor and Kuala Lumpur were invited to participate. They were allocated to either the intervention or control group in a 2 to 1 ratio.

Study population
The GPs recruited patients who attended their clinics between January to June 2008 according to the inclusion and exclusion criteria. The inclusion criteria were patients aged $\geq$ 18 years, were diagnosed with hypertension with or without diabetes mellitus or hyperlipidaemia, and were currently on at least one medication for one or more of these conditions. Women who were pregnant or were breast feeding, patients who had history of unstable angina, acute myocardial infarction, heart failure, clinically significant valvular heart disease, stroke or who had serum creatinine of more than 150umol/L in the preceding 6 months, and who had coronary revascularisation procedure were excluded.

Study intervention
The study intervention, referred to as the CORFIS programme, was developed in accordance with the Medical Research Council (MRC) guidance on developing and evaluating complex interventions to improve health outcomes [16]. The underlying framework in developing the complex intervention for CORFIS was based on 5 out of the 6 interrelated elements of the CCM [8,9] as described below:

1. *Delivery system re-design* – Allied health care team consisting of a pharmacist, dietitian and nurse educator was constituted purposefully to support individual GPs. They provided patient education and counselling as well as taught patients on self-monitoring. Tele-monitoring services, provided by trained nurse advisors helped to reinforce self-care, monitor treatment adherence and provide necessary care support. The team undertook regular assessment tailored to the needs of individual patients, which formed the basis of a mutually agreed care plan including regular follow-up visits to the GPs and other members of the team.

2. *Decision support* - Each team member delivered care according to an agreed management and drug treatment protocol which was developed based on local clinical practice guidelines (CPGs) for hypertension [17], published by the MOH. Medical nutrition therapy was advocated for patients by dietitians according to a clinical protocol based on evidence-based practice guidelines for hypertension. Selected clinical specialist advisors consisting of general physicians, endocrinologists, cardiologists, ophthalmologists and nephrologists provided remote disease organ screening review (retinopathy, cardiac diseases and nephropathy) as well as feedback to participating GPs on therapeutic decision making or treatment modification for individual patients via the online clinical information system.

3. *Clinical Information System* - A custom designed, secure web-based application was set-up to capture patients' data as well as to organise and coordinate care among all the healthcare providers. This included electronic laboratory result transmission and project management. The system also provided reminders to prompt both the providers and patients on specific actions to be taken such as clinical visit appointment, blood sampling and home monitoring. Patients were able to access their personal medical records, educational materials, local support link and recording of self-monitored BP (SMBP), self-monitored random blood glucose (SMBG) and pedometer readings through a secure web-based portal at www.corfis.gov.my

4. *Patient empowerment and self-management support* – Individualised patient-centred care was enforced throughout the study. The trained allied health professionals counselled the patient monthly at their assigned GP clinics. Continuity of care for patient by the same care-provider was emphasised to establish positive rapport between the patients and the healthcare team members. Home monitoring devices such as digital automatic BP monitors *(OMRON IA2)*, home blood glucose monitors *(ABBOTT Optium Exeed)* and pedometers *(OMRON HJ-113)* were loaned to the patients for the duration of the study.

5. *Community Resources* - Patients were provided with information on local patient associations and support groups with the aim of fostering mutual support and motivation of self-care. Focus group sessions were conducted to facilitate discussion.

Conduct of study
The intervention was delivered over a period of 6 months. Visits by the allied health team occurred within 30 days after the initial recruitment and baseline investigations [such as HbA1c, fasting blood sugar (FBS), serum lipid profile, serum creatinine, blood chemistry and urinalysis] and then at monthly interval thereafter for 6 months. Thus, all patients in the intervention arm were required to attend at least 3 visits including the 6-month follow-up. Those who did not comply with this schedule were considered as lost to follow-up. There was no limit to the number of GP visits a patient was allowed to make in either arm during the course of the study.

Table I: Baseline characteristics of hypertensive patients allocated to the intervention and control arms.

Characteristics		Intervention N = 309	Control N = 177	P value
Age, years; Mean (SD)		49 (9)	52 (10)	0.0044
Gender; n (%)	Male	197 (64)	97 (55)	
	Female	112 (36)	80 (45)	
Ethnic Group; n (%)	Malay	136 (44)	84 (47)	0.0061
	Chinese	98 (32)	70 (40)	
	Indian	66 (21)	22 (12)	
	Other	9 (3)	1 (1)	
Education Attainment; n (%)	Primary	18 (6)	36 (20)	<0.0011
	Secondary	145 (47)	94 (53)	
	Tertiary	111 (36)	38 (22)	
	Nil / Missing	35 (11)	9 (5)	
Occupation; n (%)	Legislator senior officials	21 (7)	10 (6)	<0.0011
	Technicians, associate professionals	33 (11)	16 (9)	
	Service worker, shops & market sales workers	26 (9)	16 (9)	
	Craft & Related Trades Workers	7 (2)	3 (2)	
	Elementary occupations	12 (4)	6 (3)	
	Professionals	50 (16)	14 (8)	
	Clerical workers	38 (12)	16 (9)	
	Skilled agricultural, fishery workers	1 (0)	0 (0)	
	Plant & machine operators assemblers	4 (1)	13 (7)	
	Others / Missing	117 (38)	83 (47)	
Cardiovascular Comorbidities; n (%)	HPT only	77 (25)	57 (32)	
	HPT + DM	52 (17)	29 (16)	
	HPT + HLP	85 (28)	47 (27)	
	HPT + DM + HLP	95 (30)	44 (25)	
Tobacco use; n (%)	Never use	214 (69)	142 (80)	0.0051
	Former (quit >30 days)	32 (10)	10 (6)	
	Current use (any tobacco use within last 30 days)	44 (14)	23 (13)	
	Unknown / Missing	19 (7)	2(1)	
Family history; n (%)	Hypertension	208 (67)	118 (67)	
	Diabetes Mellitus	149 (48)	81 (46)	
	Hyperlipidaemia	74 (24)	20 (11)	
*Cumulative CVD risk factors; n (%)	0–1 risk factor for CVD	52 (17)	39 (22)	
	≥ 2 risk factors for CVD	110 (36)	64 (36)	
	Presence of coronary artery disease or diabetes	147 (47)	74 (42)	
Sitting Systolic Blood Pressure (SBP); mmHg	Mean (SD)	135 (16)	136 (18)	
	Median (min, max)	134 (92,196)	130 (110,210)	
Sitting Diastolic Blood Pressure (DBP); mmHg	Mean (SD)	84 (10)	85 (11)	
	Median (min, max)	85 (58,118)	82 (58,130)	
Standing Systolic Blood Pressure (SBP); mmHg	Mean (SD)	136 (16)	137 (18)	
	Median (min, max)	134 (98,195)	134 (106,220)	
Standing Diastolic Blood Pressure (DBP); mmHg	Mean (SD)	88 (10)	88 (11)	
	Median (min, max)	90 (37,123)	88 (65,130)	
BMI; kg/m^2	Mean (SD)	29 (6)	29 (5)	
	Median (min, max)	28 (15,65)	28 (19,54)	
Waist circumference (WC); cm	Mean (SD)	95 (12)	94 (11)	
	Median (min, max)	95 (35,140)	93 (68,126)	
Total Cholesterol; mmol/L	Mean (SD)	5.2 (1.0)	5.4 (1.1)	
	Median (min, max)	5.2 (2.4,8.6)	5.4 (3.0,8.9)	
HDL; mmol/L	Mean (SD)	1.2 (0.3)	1.2 (0.3)	
	Median (min, max)	1.2 (0.7,2.3)	1.2 (0.8,2.0)	
LDL; mmol/L	Mean (SD)	3.2 (0.9)	3.3 (1.0)	
	Median (min, max)	3.2 (0.7,6.5)	3.3 (1.3,6.5)	
Triglyceride; mmol/L	Mean (SD)	1.8 (1.1)	1.9 (1.1)	
	Median (min, max)	1.5 (0.4,9.5)	1.6 (0.4,7.4)	
Total Cholesterol/HDL Ratio	Mean (SD)	4.3 (1.0)	4.5 (1.2)	
	Median (min, max)	4.2 (1.9,7.5)	4.4 (2.1,8.5)	
Fasting Blood Glucose; mmol/L	Mean (SD)	6.4 (2.5)	6.6 (3.1)	
	Median (min, max)	5.6 (3.7,21.4)	5.5 (3.1,23.7)	
HbA1C; %	Mean (SD)	6.9 (1.8)	6.9 (1.7)	
	Median (min, max)	6.3 (4.1,13.6)	6.2 (4.7,13.0)	

Abbreviation: SD = standard deviation; HPT = hypertension; DM = diabetes mellitus; HLP = hyperlipidaemia; CV = cardiovascular; CAD = coronary artery diseases; BMI = body mass index; TC = total cholesterol; HDL = high density lipoprotein; LDL = low density lipoprotein; HbA1C = glycosylated haemoglobin.
* Risk factors are defined as dyslipidaemia, hypertension, diabetes, smoking, family history of premature cardiovascular disease and obesity
1 denotes Pearson chi-square test
4 denotes Independent t-test

Table II: Primary outcome: proportion of hypertensive patients who achieved target blood pressure at 6-month follow-up

Variables	Intervention; n=309 n (%)	Control; n=177 n (%)	Crude OR (95% CI)	p-value
Hypertensive patients with				
• Uncontrolled BP at baseline	159 (51.5)	88 (49.7)	0.93 (0.64 – 1.35)	0.784[1]
• Controlled BP at baseline*	150 (48.5)	89 (50.3)		
Total hypertensive patients who achieved target BP at 6-month	215 (69.6)	102 (57.6)	1.68 (1.15 – 2.47)	0.008[2]
Hypertensive patients with uncontrolled BP at baseline who achieved target BP at 6-month	90 (56.6)	30 (34.1)	2.52 (1.47 – 4.33)	<0.001[2]
Hypertensive patients with controlled BP at baseline maintain target BP at 6-month	125 (83.3)	72 (80.9)	1.18 (0.59 – 2.33)	0.663[2]

[1] denotes Fisher's exact test
[2] denotes Pearson chi-square test
* Blood pressure control is defined as BP of <140/90mmHg (for those without diabetes mellitus) and <130/80mmHg (for those with diabetes mellitus).

Table III: Secondary outcome: change in the mean blood pressure at 6-month as compared to baseline

Variables	Intervention; n=309	Control; n=177	p-value
SBP at baseline; Median (IQR)	134 (92 to 196)	130 (110 to 210)	0.702[3]
DBP at baseline; Median (IQR)	85 (58 to 118)	82 (58 to 130)	0.906[3]
SBP at 6-month; Median (IQR)	128 (87 to 181)	130 (98 to 193)	<0.001[3]
DBP at 6-month; Median (IQR)	80 (52 to 111)	83 (51 to 120)	<0.001[3]
Change in SBP at 6-month from baseline; Median (IQR)	-9 (-60 to 50)	-2 (-50 to 48)	0.0033
Change in DBP at 6-month from baseline; Median (IQR)	-6 (-53 to 30)	0 (-42 to 30)	<0.0013

[3] denotes Mann Whitney U test

Outcome Measures
The primary outcome was defined as the proportion of patients who achieved target BP after 6 months. Target BP for patients without diabetes mellitus (DM) was ≤140/90 mmHg and with DM was ≤130/80 mmHg [18].

Secondary outcomes were changes in the mean/median BP at the end of the study as compared to baseline.

Sample Size Calculation
Sample size was calculated based on the proportion of patients with hypertension who had good control, that is BP<140/90 mmHg, based on the NHMS 2006 results, which was 27% [4]. The outcome target for this study was set at 1.5 times higher than 27%. By using a two group χ^2 test of equal proportion, type I error of 0.05 and 80% power of detection, 290 patients were required for the intervention group and 145 patients for the control group (2:1 ratio). Adding a 15% drop out rate, the total sample size should be 500.

Statistical Analysis
All data were analysed using the Statistical Package for Social Sciences (SPSS Inc., Chicago, IL, USA), version 16. Continuous variables were described using summary statistics such as mean, median, standard deviation, maximum and minimum values. Categorical (nominal/ordinal) variables were described using frequencies and percentages. Chi square test was used to assess effectiveness of the intervention using the difference in the proportion of patients who achieved BP target. Multivariate logistic regression analysis was used to measure the effect of confounders. A p-value of less than 0.05 was considered as statistically significant.

The intention to treat analysis was conducted. Participants with missing data at 6-month follow-up had their data imputed by method of Last Observation Carried Forward (LOCF).

RESULTS
Seventy GPs participated in the study. Forty four GPs were allocated to the intervention group and 26 GPs to the control group. The participating GPs recruited 486 patients with hypertension, 309 were in the intervention group and 177 were in the control arm. However, 275 in the intervention and 149 in the control group completed the study. (Figure 1)

Table I shows the baseline characteristics of the study participants. Age, ethnicity, education attainment, occupation and smoking status were significantly different between the two groups.

Table II shows the primary outcome at 6-month follow-up. The proportion of participants with hypertension who achieved target BP was significantly higher in the intervention group (69.6%) as compared to the control group (57.6%) (p<0.008). Amongst those who had uncontrolled BP at baseline, the proportion who achieved target BP at 6-month was also significantly higher in the intervention group (56.6%) as compared to the control group (34.1%) (p<0.001). There was no significant difference in the achievement of target BP at 6-month among patients who had already achieved BP control at baseline.

Table III shows the overall change in median systolic and diastolic BP (SBP and DBP) after 6 months. There were significant reductions in SBP in the intervention group.
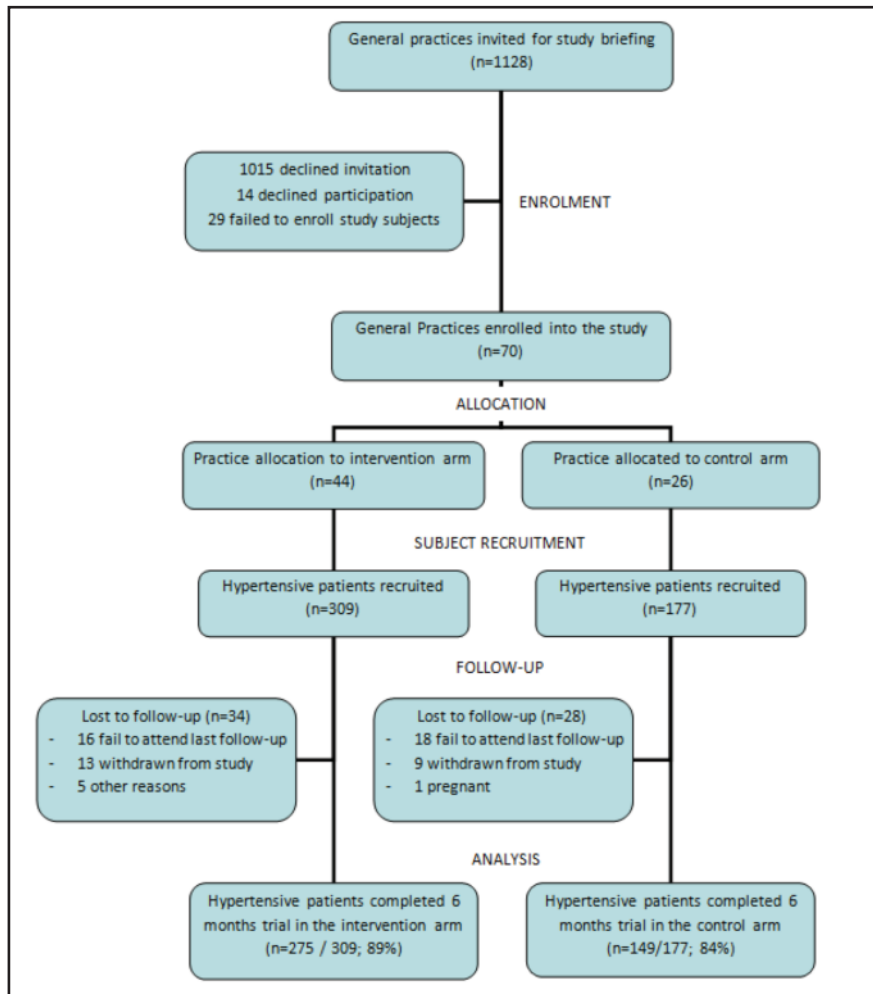
Fig. 1 : CORFIS Trial Profile: Enrolment of GP practices and recruitment of hypertensive patients.

There was no difference in the mean number of antihypertensive agents prescribed in both groups. However, there were differences in the types of antihypertensive agents prescribed by the GPs in the intervention group compared to the control group. In the intervention group, angiotensin receptor blockers (ARBs) was the most popular choice (43%), followed by angiotensin converting enzyme inhibitors (ACEIs), diuretics and calcium channel antagonists (CCAs). In the control arm, 59% of antihypertensive agents prescribed were thiazide diuretics, followed by ACEIs, beta-blockers, ARBs and CCAs. GPs in both groups did not change their drug prescribing pattern during the 6 months of the study period but the volume of prescriptions increased in both groups.

A multivariate logistic regression analysis was conducted to analyse the potential confounding factors identified at baseline between the intervention and control groups. These include age of participants, ethnicity, education attainment, occupation and smoking status. Apart from participants who were smokers, none of the factors identified had an effect on achieving the target BP. Based on the analysis, hypertensive patients who were active smokers would benefit less from the

CORFIS intervention(OR=0.39, 95% CI 0.19-0.82, p=0.012). No adverse events were reported throughout the study.

DISCUSSION
The CCM represents an evidence-based conceptual framework for improved patient care and clinical outcomes as shown by several systematic reviews [19-21]. This study provided evidence that chronic disease management strategy based on the CCM is effective in improving BP control. The proportion of participants who achieved BP target in the CORFIS group was significantly higher compared to the control group. This is particularly so among participants who had uncontrolled BP at baseline. Significant reductions in both SBP and DBP were also observed in the CORFIS group compared to the control group. The improvement in clinical outcomes seen in the CORFIS group were not affected by confounding factors such as age, ethnicity, education attainment and occupation of the participants. These improvements were more likely to be attributed to the CORFIS intervention. However, hypertensive patients who were active smokers would benefit less from the CORFIS intervention.

Evidence to support the elements of the CCM used to design the CORFIS programme is robust. Multidisciplinary primary care team plays a pivotal role in improving the clinical outcomes, given the complexity of managing chronic conditions [22-24]. Studies using nurse-led or pharmacist-led multidisciplinary interventions revealed significant improvement in the process of care and BP control [25-27]. The multidisciplinary team members in the CORFIS arm were trained in patient-centred communication and counselling skills to empower the patients to self-manage. There is enough evidence to show that patient-centred counselling, behavioural interventions and self-management support improved BP control compared to usual care, beyond the benefits afforded by medications alone [28-30].

An organized clinical information system of registration, recall and regular review appeared to be the most effective in improving BP control [31]. In the CORFIS study, a custom designed web-based application was used to organise patients' data and coordinate care among all the healthcare providers. As for decision support, integration of locally relevant evidence-based CPGs into the fabric of patient care is fundamental to putting evidence into practice in managing chronic diseases [32]. Vigorous stepped care approach to antihypertensive drug treatment has been shown to improve outcomes [31]. In the CORFIS study, team members were trained to utilise a stepped care protocol developed based on the local CPGs. GPs from the intervention arm were found to be more likely to adhere to the CPGs as demonstrated by the higher usage of ACEIs and ARBs as primary treatment choice compared to beta-blockers and thiazide diuretics in the control group. Recent evidence suggested that adherence to evidence-based prescribing guidelines for hypertension resulted in substantial savings in prescription costs [33]. Joint participation and enhancing information exchange between primary care and secondary care physicians in a planned delivery of care has been shown to improve management of chronic diseases and lead to better outcomes [34]. In the CORFIS arm, the GPs were supported by a group of clinical specialist advisors in managing difficult cases. Evidence has also shown that building collaborative network with the community resources helped to address complex health issues in chronic disease care [35]. The CORFIS study incorporated the community collaboration by conducting focus support group sessions to foster mutual support and motivation for self-care.

Limitations of the Study
The CORFIS study has provided valuable insights on the limitations and constraints of conducting a pragmatic controlled trial in primary care in Malaysia. This includes the infeasibility of randomising the GP clinics due to geographical distance and shortage of allied health support team. Blinding was also not possible as in most of the other complex intervention trials. The short duration of this study posed an important question on whether the significant improvement in BP outcomes was sustainable over a longer period of care.

Given the limitations and the current constraints faced by the private GPs, the results of this study are encouraging. In reality, challenges to provide high quality chronic disease care based on the CCM in the private GPs is common [36]. Substantial investments would be required by most of the GPs to implement those changes and to expend the necessary resources which are not conducive in the current payment mechanism. Without government funding, it would be too expensive for the GPs to employ allied health team to support chronic disease care. Often, comprehensive chronic disease care packages are not covered by private health insurance companies. In the absence of universal funding scheme, it is often too expensive for patients with multiple chronic conditions to bear the out-of-pocket payment to the GPs. As a result, the over-subsidised public primary care sector is overburdened to provide care to the majority of patients with chronic conditions.

The rising epidemic of chronic diseases puts the private general practice in demand to play a greater role in chronic disease management. Therefore, the results of this study should offer potential to leverage significant policy change towards a more integrated healthcare system supported by a universal funding mechanism. The recently announced proposal by the Malaysian government to set up a social health insurance scheme which will integrate the private and public primary care services under a common network of care[37], offers a potential solution for the private GPs to work in collaboration with other healthcare providers in improving the delivery system for chronic diseases.

CONCLUSION
In conclusion, this is a landmark study in Malaysia that has proven that patients who received multifaceted chronic care intervention demonstrated significant improvements in the clinical outcomes. Further research to evaluate the cost-effectiveness of this intervention and the sustainability of the improved outcomes over long term should be conducted. There is also a need to evaluate the effectiveness of this intervention in the public primary care setting where a larger proportion of patients with chronic conditions are receiving care.

AUTHORS' CONTRIBUTIONS
WHHL & ASR wrote the manuscript and were involved in the design and coordination of the CORFIS Study. WS, KKN, JH, SPD, CLT, VKML, SSC, FYMA, TK, WSSC and GPP contributed to the critical revision of the manuscript. ZM & TOL played a major role in the conception and design of the study, contributed to the critical revision of the manuscript and intellectual content; and provided expertise and oversight throughout the process. All authors read and approved the final version.

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