EFFECTS OF NURSE-LED HYPERTENSION MANAGEMENT MODEL IN MAINLAND CHINA: A RANDOMISED CONTROLLED TRIAL

ZHU XUEJIAO

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The Hong Kong Polytechnic University

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Effects of Nurse-led Hypertension Management Model in Mainland China: A Randomised Controlled Trial

ZHU Xuejiao

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CERTIFICATE OF ORIGINALITY

I hereby declare that this thesis entitled, "Effects of nurse-led hypertension management model in mainland China: A randomised controlled trial" is my own work and that, to the best of my knowledge and belief, it reproduces no material previously published or written, nor material that has been accepted for the award of any other degree or diploma, except where due acknowledgement has been made in the text.

ZHU Xuejiao **(Name of student)**

ABSTRACT

Background Hypertension is a major risk factor for stroke, ischemic heart disease, and other diseases. Its high prevalence rates coupled with low control rates not only threaten patients' health but also increase the financial burden on both the individual and the entire healthcare system. Finding a cost-effective way to manage hypertension has been an international concern. In a conventional treatment-oriented practice model, doctors play the primary role in hypertension management. However, doctors are more likely to focus on pharmacological treatments and put relatively little emphasis on non-pharmaceutical and sustained strategies for blood pressure (BP) control. Their strategies rarely involve patient self-care behaviours and the provision of structured follow-ups to monitor the effects of treatment or intervention. Compared with this medical-oriented usual care, nurse-led care is relatively low-cost and more likely to use non-pharmacological strategies that promote healthy behaviour. There is a paucity of literature, however, reporting the effects of community-based nurse-led care for hypertensive patients, especially in countries with poor resources, such as mainland China. This study fills this research gap.

Aim To develop a nurse-led hypertension management model and evaluate its effects in the community health setting in mainland China.

Methods A randomised controlled trial (RCT) was conducted in a community health centre in Guangzhou, China. A total of 134 eligible participants was recruited and randomly assigned to two groups (67 in the study group and 67 in the control group). The inclusion criteria for study participation were: (a) with a diagnosis of hypertension, (b) ≥ 18 years old, (c) with uncontrolled BP (BP reading ≥ 140 /

90 mmHg), and (d) living within the health service network of the community health centre. The exclusion criteria were: (a) with secondary hypertension, (b) taking medicine that could increase BP, (c) unable to communicate, (d) unable to be contacted by phone, (e) with diagnosis of terminal illness, (f) with co-morbidity in contradiction with the intervention programme, (g) pregnancy, breastfeeding or planning pregnancy.

The control group received usual care that included a clinic physical examination with the establishment of a health record, health education pamphlets and arrangements for routine clinic follow-ups. The study group received usual care and a 12-week intervention programme guided by the nurse-led hypertension management model. In the programme, trained community nurses led a team to deliver the following hypertension management services: a home visit followed by six follow-up telephone calls at two-weekly intervals, and referrals, if appropriate.

Outcome measures were: BP reductions (primary outcome), BP control rate, self-care behaviour, self-efficacy, quality of life, utilisation of healthcare services and patient satisfaction.

Data were collected at three time points: recruitment (T0), immediately after the intervention programme (T1), four weeks after the end of the intervention (T2). Research assistants blinded to the allocation of participants handled data collection. Ultimately, a total of 119 (89%) participants completed data collection. Missing data was replaced by carrying forward the last data with intention-to-treat.

Results Baseline demographic and clinical characteristics were equivalent between the control and study groups. A significant interaction between group and time was detected in systolic blood pressure (SBP) ($p < .05$) and diastolic blood

pressure (DBP) ($p < .05$). Both groups had a significant reduction over time in SBP ($p < .01$) and DBP ($p < .01$). When the reductions of BP from T0 to T1 were compared between groups, a statistically significant difference between groups was observed both in SBP (Control -5.10 mmHg versus Study -14.37 mmHg, $p < .01$) and DBP (Control -2.69 mmHg versus Study -7.43 mmHg, $p < .01$). However, there was no statistically significant difference between groups from T0 to T2 in SBP (Control -9.22 mmHg versus Study -14.72 mmHg, , $p > .05$) or DBP (Control -5.14 mmHg versus Study -7.43 mmHg, $p > .05$), even though the study group maintained a lower trend of BP reduction. In terms of self-care behaviours, the study group had a statistically significant improvement over time both in pharmacological self-care behaviour ($p < .01$) and non-pharmacological self-care behaviour, which included home BP monitoring ($p < .01$), salt restriction ($p < .01$) and regular physical activity ($p < .01$). The control group had a statistically significant improvement over time in two non-pharmacological self-care behaviours: salt restriction ($p < .01$) and regular physical activity ($p < .01$). A statistically significant difference between groups was observed in home BP monitoring at T1 ($p < .01$) and T2 ($p < .01$). As for salt restriction and regular physical activity, a statistically significant difference between groups at T1 was detected. For self-efficacy, there was no significant interaction between group and time, and the difference between groups and within group was also not significant. For quality of life, the study group significantly improved over time in the domains of Role-physical ($p < .01$), Bodily Pain ($p < .01$), General Health ($p < .05$), Social Functioning ($p < .01$), Role-emotional ($p < .05$) and Mental Health ($p < .01$). The control group, like the study group, had significant improvement over time in the domains of Role-physical ($p < .01$), Role-emotional ($p < .05$) and Mental Health ($p < .05$). No between-group and interaction effect was found. For the

utilisation of healthcare services at the community health centre, no statistically significant difference was found between the two groups. The study group was more satisfied with hypertensive care than the control group at T1 (Study 28.0 versus Control 7.0, $p < .01$).

Discussion This was a pioneering effort to develop a nurse-led model for managing hypertensive patients at the community level by adopting the Chronic Care Model and incorporating the Four-C model of comprehensiveness, collaboration, coordination, and continuity. This nurse-led hypertension management model involved re-organisation of the existing hypertension care delivery system, patients' self-management support, team members' decision support and establishment of a more comprehensive documentation system for patients' clinical records. The nurses in the team were equipped with the competencies required to manage hypertensive patients.

The results of this RCT confirmed that a structured and standardised 12-week nurse-led home-based care programme produced better effects on BP reduction than usual clinic-based care. The results of the study showed that, when compared with usual care, nurse-led care did not only reduce BP but also enhanced patient self-care behaviours and improved patient satisfaction. These trained healthcare providers, supported by an evidence-based designed programme, contributed to the positive outcomes. The competency training followed a structured curriculum designed to prepare the team of nurses and a physician for hypertension management. The curriculum can be helpful in standardising the preparation of care providers.

Conclusion This study presents a nurse-led model that translated evidence into practical protocols for hypertension management. By using this model and testing its

effects, this study confirmed the significant contributions of nurses to improving patient outcomes and demonstrated that nurse-led hypertension management has great potential in the community healthcare setting.

PRESENTATIONS AND PUBLICATIONS

CONFERENCE PRESENTATIONS

Zhu, X. J. & Wong, F. K. Y. (2012). Effects of a nurse-led hypertension management programme on patient adherence in the community setting: A randomised controlled trial. *Proceedings of the 15th East Asian Forum of Nursing Scholars (EAFONS), Singapore.* 22 - 24 February 2012. 21

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ABBREVIATIONS

ANNOVA	Analysis of Variance
BMI	Body Mass Index
BP	Blood Pressure
CBPM	Clinic Blood Pressure Monitoring
CDC	Centres for Disease Control and Prevention
CDSES	Short-Form Chronic Disease Self-Efficacy Scale
CHC	Community Health Centre
CVD	Cardiovascular Disease
DAIY	Disability-adjusted Life Year
DBP	Diastolic Blood Pressure
EHR	Electronic Health Record
ESH	European Society of Hypertension
ESC	European Society of Cardiology
GH	General Health
GMH	Guideline for the Management of Hypertension
GP	General Practitioner
HBP	High Blood Pressure
HBPM	Home Blood Pressure Monitoring
HIC	High Income Country
ICC	Intra-class Correlation Coefficient
ITT	Intention-to-Treat
LIC	Low Income Country
LMIC	Lower Middle Income Country

MH	Mental Health
MI	Motivational Interview
MIC	Middle Income Country
mmHg	Millimetre of Mercury
NCD	Non-communicable Disease
NHFPC	National Health and Family Planning Commission
NHM	Nurse-Led Hypertension Management
PF	Physical-Functioning
PRC	People's Republic of China
QoL	Quality of Life
RCT	Randomised Controlled Trial
RE	Role-Emotional
RP	Role-Physical
SBP	Systolic Blood Pressure
SD	Standard Deviation
SF	Social Functioning
SF-36	Short-Form Health Survey
UMIC	Upper Middle Income Country
VT	Vitality
WC	Waist Circumference
WHO	World Health Organisation

CHAPTER 1

INTRODUCTION

Hypertension, with its high prevalence rate and low control rate, is a threat to human health and economic prosperity. To effectively manage a large number of hypertensive patients is a global challenge. Helping patients control their blood pressure (BP) is the primary aim of hypertension management. Traditional hypertension management that only focuses on pharmacological treatment is not sufficient. More efficient approaches for hypertension management need to be tested and established. This chapter presents the general background, as well as the aim, objectives and research hypotheses of the study. The significance of the study is discussed at the end of this chapter.

1.1 Background

1.1.1 Hypertension and blood pressure control

Hypertension or high blood pressure (HBP) is a very common chronic condition. It is defined as a systolic blood pressure (SBP) of ≥ 140 mmHg and / or a diastolic blood pressure (DBP) of ≥ 90 mmHg respectively (James et al., 2014; Liu & Writing Group of 2010 Chinese Guidelines for the Management of Hypertension [GMH], 2011; Mancia et al., 2014). It is estimated that the worldwide prevalence rate of hypertension is 22% (World Health Organisation [WHO], 2015). The prevalence rate of hypertension is generally higher in low-income countries (LICs) and middle-income countries (MICs) than in high-income countries (HICs). WHO in 2015 estimated that the prevalence rate of hypertension was 27.6% in LICs, 25.2% in

lower middle income countries (LMICs), 20.3% in upper middle income countries (UMICs) and 18.5% in HICs. It is worth noting that BP control, which is defined as an average SBP < 140 mmHg and an average DBP < 90 mmHg among hypertensive patients (James et al., 2014; Liu & Writing Group of 2010 Chinese GMH, 2011; Mancia et al., 2014), is suboptimal. An international investigation showed that only 13% of patients have their BP controlled, and even among those who were being treated, only 33% had their BP controlled (Chow et al., 2013). The number of people with uncontrolled hypertension has been increasing in recent decades, but the situation varies in different countries and regions (Danaei et al., 2011). In some HICs, such as Canada, the rates for treatment and control of hypertension have distinctly improved in recent decades (Danaei et al., 2011; Joffres et al., 2013; McAlister et al., 2011); meanwhile, in some MICs, such as China, the prevalence rate of hypertension increased by 10% from 2002 to 2010 (Gao et al., 2013; Wang et al., 2014) while the BP control rate remains at a relatively low level, rising from 6.1% in 2002 (Li et al., 2005) to about 10% in more recent years (Gao et al., 2013; Liang, Chen, Liu, He, & Li, 2014; Wang et al., 2014). Overall, compared with UMICs and HICs, LICs and LMICs have higher BP prevalence rates but lower BP control rates.

Elevated BP is an independent risk factor for cardiovascular diseases (CVDs) and a key risk factor for many other chronic diseases, such as diabetes. Elevated BP accounts for 54% of strokes and 47% of ischemic heart disease (Lawes, Hoom, Rodgers, & for the International Society of Hypertension [ISH], 2008), the top two leading causes of death worldwide (WHO, 2012). It also increases the risk of concurrent impairments in mobility, cognition, and mood (Hajjar et al., 2011). Because of these chronic diseases and complications, hypertension has a substantial impact on the population regarding health, quality of life (QoL) and financial burden.

Currently, hypertension is the leading risk factor for the global burden of disease, especially in Asia, North Africa, the Middle East, and Central Europe (Lim et al., 2012). Globally, approximately 14% of all deaths in 2001 were attributed to hypertension (Lawes et al., 2008), with the rate rising to 15% in 2009 (Go et al., 2013). In 2001, hypertension contributed to 6% of deaths and disability-adjusted life years (DALYs), sum of years lived with disability and years of life lost (Lawes et al., 2008); by 2010, it had risen to 7% (Lim et al., 2012). Inadequate BP control consumed 10% of health expenditures globally and up to 25% of healthcare spending in some areas (Gaziano, Bitton, Anand & Weinstein, 2009). Middle and low-income regions have six times the burden of disease as high-income regions but access to less than 10% of the global treatment resources (Macmahon et al., 2008). Since HBP is preventable and modifiable, how to effectively control raised BP has been an international issue and challenge, especially for MICs and LICs.

1.1.2 Hypertension management

The factors influencing optimal BP control are multi-level and include healthcare system-related, patient-related, and healthcare providers-related factors (Borzecki, Oliveria & Berlowitz, 2005; Ogedegbe, 2008). To improve BP control, interventions targeting multi-level factors should be implemented. Hypertension management has traditionally been focused on pharmacological therapy and hypertensive patients received treatment in hospitals or clinics. The majority of hypertensive patients live in the community and struggle to achieve normal BP for the long term. WHO (2002) stresses that the management of hypertensive patients at the community level is crucial to improving BP control and reducing the negative impacts of elevated BP. Some regions in recent years have shifted the focus from hospital-based acute disease care to community-based long-term services for chronic

disease management including hypertension control. Experience from Japan has demonstrated that intervention strategies, such as regular health check-ups, activities including supporting healthy eating, and staying active at the community level, successfully improved BP control and reduced the incidences of stroke ("Community-based efforts", 2013).

Of the patient-related factors that impact optimal BP control, patient adherence is essential. Patient adherence is the extent to which a person's behaviour, including taking medicine, following a diet, and/or executing lifestyle changes, corresponds with agreed-upon recommendations from healthcare providers (WHO, 2003). For patients with HBP, pharmacological therapy and lifestyle modifications are two BP reducing interventions that are unanimously recognised and recommended (James et al., 2014; Liu & Writing Group of 2010 Chinese GMH, 2011; Mancia et al., 2014). Anti-hypertensive drugs can effectively reduce BP (James et al., 2014; Liu & Writing Group of 2010 Chinese GMH, 2011; Mancia et al., 2014) as well as reduce the complications hypertension causes (Neal, MacMahon, Chapman, & Blood Pressure Lowering Treatment Trialists' Collaboration, 2000). Although anti-hypertensive drugs can lower elevated BP in a short time, they have a high financial cost and the drugs always have side effects. For patients who have maintained a BP reading of 140-159 / 90-99 mmHg and do not have target organ damage or other risk factors for CVDs (e.g. stroke), adoption of lifestyle modifications is widely recommended before receiving pharmacological treatment (James et al., 2014; Liu & Writing Group of 2010 Chinese GMH, 2011; Mancia et al., 2014). Lifestyle modifications include a low-salt diet, regular physical activity, smoking cessation, alcohol consumption moderation, and weight reduction, all of which play a critical role in BP control. These lifestyle modifications are effective in lowering BP (James

et al., 2014; Liu & Writing Group of 2010 Chinese GMH, 2011; Mancia et al., 2014), increasing the effects of anti-hypertensive drugs, and reducing patients' long-term risk for CVDs without accompanying known harmful effects (Whitworth & WHO/ISH, 2003). For this reason, even for hypertensive patients who have been treated with anti-hypertensive drugs, adherence to a healthy lifestyle is suggested. For various reasons, however, patient adherence to the use of anti-hypertensive drugs and lifestyle modifications is far from satisfactory. Poor patient adherence results in poor BP control, increased morbidity and mortality, and increased consumption of healthcare resources. In contrast, adherent patients are three times more likely to control their BP compared with non-adherent patients (DiMatteo et al., 2002). Therefore, improving and maintaining patient adherence may be an important component of cost-effective hypertension management, especially for low-income and middle-income regions with fewer available resources. WHO (2003) suggested that adherence is a modifier of the effectiveness of the health system, and recommended that adherence examination should be incorporated into the cost-effective outcomes measurement.

The majority of hypertensive patients live in the community, which has more influencing factors related to health than in hospitals. Various barriers, such as lack of professional guidance, prevent patients from adhering to effective BP control measures. That healthcare providers might be able to help their clients remove barriers to adherence by improving how they approach their clients' problems, how they provide advice, and how they involve their clients in the treatment decision-making process is increasingly being recognised (Harmon, Lefante, & Krouse-Wood, 2006). In the traditional hospital-based acute disease care setting, doctors tend to play the leading role in controlling BP and focus on pharmacological treatment.

Non-pharmacological treatments such as lifestyle modifications or patient adherence are often overlooked. Researchers who have conducted meta-analysis studies suggest that hypertension management teams should reorganise and include nurses and / or pharmacists to enhance patient adherence (Hill, Miller, DeGeest, & American Society of Hypertension Writing Group, 2010) and BP control (Carter, Rogers, Daly, Zheng, & James, 2009; Walsh et al., 2006). Nurses, who make up a large constituency of the healthcare providers workforce, may be able to work more efficiently in hypertension management than doctors, who are often distracted from chronic care tasks by interfering with treatment and diagnosis concerns. Studies have shown that nursing interventions achieved higher patient adherence and satisfaction rates and similar effects on mortality and QoL when compared with traditional doctor-led care in the primary care setting (Horrocks, Anaerson, & Salisbury, 2002; Keleher, Parker, Abdulwadud, & Francis, 2009). Laurant et al. (2005), in a review published in the Cochrane Library, argued that there was no significant difference between the care provided by doctors from that provided by nurses regarding health outcomes for patients and cost savings. From a health economic perspective, because of the salary differential between doctors and nurses, having nurses take up some of the doctors' workload may help cost savings. Evidence from a meta-analysis (Carter et al., 2009) demonstrated that nurse-led care contributed to reducing SBP by 4.8 mmHg while other researchers (Clark Smith, Taylor, & Campbell, 2010; Glynn, Murphy, Smith, Schroeder, & Fahey, 2010) in their studies have called for further evaluation of the efficacy of nurse-led care in BP control.

1.1.3 Hypertension and hypertension management at the community level in China

China is an MIC and has the largest population in the world ("Country Classification", 2014). As is the case globally, stroke and ischemic heart disease are

the top two leading causes of death in China (WHO, 2015). Effective prevention and control of chronic diseases has been a critical issue as contemporary Chinese society has become more prosperous ("Toward a healthy and harmonious life in China", 2011). Controlling BP will reduce the incidences of CVDs. However, the hypertension control rate in China is in the 8%-11% range (Gao et al., 2013; Li, Wallhagen & Froelicher, 2010; Wang et al., 2014), which is far lower than the U.S. rate of 48% (Centres for Disease Control and Prevention [CDC], 2013). The prevalence rate for hypertension in China is rising while the BP control rate continues to be low. In recent decades, the question of how to manage hypertensive patients in China's healthcare setting has attracted more and more national and international attention. Just as in the majority of other countries, traditional hypertension management in China was hospital- or clinic-based. China explored hypertension management at the community level in the 1990s in Beijing (Wu et al., 2003). In the past two decades, the national government has expended much effort to support community level management of the country's massive number of hypertensive patients. Government policies and guidelines have supported establishment of healthcare organisations at the community level to provide healthcare services and chronic disease management as well as compensation for medical checkups and anti-hypertensive drugs for hypertensive patients at community healthcare organisations (Liu & Writing Group of 2010 Chinese GMH, 2011; National Health and Family Planning Commission of the People's Republic of China [NHFPC of the PRC], 2011, April 25; The State Council of the PRC, 2006). These existing guidelines (Liu & Writing Group of 2010 Chinese GMH, 2006; 2011) do not integrate strategies for improving patients' adherence to taking their anti-hypertensive drugs or to recommendations for lifestyle modifications. Furthermore,

due to the lack of operational protocols to implement these regulations and guidelines, the practice of hypertension management in China varies widely. A few community-based intervention studies from different regions have in recent decades tested their BP control achievements through RCTs, but the design of those studies has been poor (Lu et al., 2012). Furthermore, few studies involved healthcare providers other than doctors in hypertension management in the Chinese community health setting. It is not known whether an approach that involves nurses can be applicable to and effective in China's healthcare setting.

1.2 Aim and objectives of the study

This study aims to develop a nurse-led hypertension management (NHM) model and subject it to experimental testing in mainland China.

The objective of the study is to examine the difference between the effects of an NHM model and usual care in primary and secondary outcomes. The primary outcome of the study is BP reduction immediately after intervention, and the secondary outcomes are BP control rate, self-care behaviours, self-efficacy, QoL, utilisation of healthcare services and patient satisfaction. The specific research hypotheses are listed below.

1.3 Research hypotheses of the study

The null hypotheses for the study are as follows:

a. There is no significant difference in BP reduction between patients receiving care guided by the NHM model and those receiving the usual hypertension care;

b. There is no significant difference in the BP control rate between patients receiving care guided by the NHM model and those receiving the usual hypertension care;

c. There is no significant difference in self-care behaviours between patients receiving care guided by the NHM model and those receiving the usual hypertension care;

d. There is no significant difference in patient self-efficacy between patients receiving care guided by the NHM model and those receiving the usual hypertension care;

e. There is no significant difference in QoL between patients receiving care guided by the NHM and those receiving the usual hypertension care;

f. There is no significant difference in utilisation of healthcare services between patients receiving care guided by the NHM and those receiving the usual hypertension care.

g. There is no significant difference in patient satisfaction between patients receiving care guided by the NHM model and those receiving the usual hypertension care.

1.4 Significance of the study

Hypertension management is still a big challenge even though more and more anti-hypertensive drugs have been developed. This study makes an early attempt to develop an NHM model by translating international scientific evidence into a series of protocols tailored to the community health setting in China. While having nurses undertake roles in the community health setting is not new, the traditional nurses'

role in practice has been confined to being assistants to physicians in clinics. In the NHM model, the nurses' role is extended from one that is less active to taking on more independent tasks, such as teaching, guidance and counselling, as well as case management and surveillance in managing patient conditions.

In practice, an increasing number of interventions are carried out by nurses, but there is a lack of systematic gathering of data that measure what outcomes they achieve for patients. In this study, in which the NHM model was subjected to an RCT in a community health setting, the contribution of nurses to enhancing patient outcomes was demonstrated in multiple domains by strong scientific evidence. The study proved that hypertensive patients at the community level benefitted from interventions guided by the NHM model in clinical and functional outcomes as well as in satisfaction. As a result of implementing this model, patients' BP readings were significantly reduced, which is closely related to reducing the risk for complications; patients' self-care behaviours were enhanced, which is conducive to patients taking an active role in chronic disease management and thereby reducing the risk of CVDs and consumption of healthcare resources; and patients' satisfaction with community healthcare was increased, which may strengthen the role of the community healthcare organisation in disease management.

The study proved that the NHM model is feasible and practicable in guiding hypertension management in a resource-poor healthcare setting. The NHM model that evolved in the course of this study can be helpful to other countries or regions with a similar healthcare setting to cope with the increasing burden of hypertension that communities are experiencing.

In addition, the positive outcomes in the study were produced by healthcare providers who had been trained so that they were equipped with the necessary competencies. In conducting this study, a training curriculum was developed to prepare the team of a doctor and four nurses, and this curriculum can help standardise the preparation of nurses and doctors in hypertension management.

CHAPTER 2

LITERATURE REVIEW

2.1 Introduction

Hypertension has created a heavy health and financial burden globally. This chapter starts a review of the epidemiology of hypertension. Increasing prevalence but persistently low control rates has become a problem worldwide, especially for MICs and LICs. Many factors at different levels are related to BP control. Patient adherence is an essential and modifiable factor of poor BP control. Thus, the status of barriers to hypertensive patient adherence is also reviewed. An approach has yet to be identified that organises and delivers care to optimally help hypertensive patients overcome the obstacles to BP control. Therefore, literature regarding strategies for hypertension management, including how to improve patient adherence, how to optimise the healthcare system, and the key agents of BP control intervention, is also studied. Nurses have gradually demonstrated their strengths in hypertension management, but the organisation of intervention strategies in a nurse-led hypertensive programme is not clearly demonstrated and whether the nurse-led intervention can improve BP outcome still needs further convincing evidence. Therefore, nurse intervention targeting improvement of patient outcome is also examined. The results of these reviews of the relevant literature provide evidence for the establishment of an NHM model. At the end of the chapter, the healthcare settings for hypertension management in China are introduced to provide insights to

the need for the development of an NHM model tailored to Chinese hypertensive patients.

2.2 Epidemiology of hypertension

WHO (2015) estimated that the prevalence rate worldwide of hypertension in adults (> 18y) was 22.3% in 2014, slightly lower than that in 2010, when it was 22.7%. The data from WHO (2015) (Table 2.1) showed that the prevalence rate in LICs and LMICs had increased slightly, from 26.7% in 2010 to 27.6% in 2014, and 25.0% in 2010 to 25.2% in 2014, respectively. Meanwhile, a slight decrease was recorded in UMICs (21.0% in 2010 to 20.3% in 2014) and HICs (19.7% in 2010 to 18.5% in 2014). In the WHO region classification, the prevalence rate in Southeast Asia increased slightly while other regions decreased or stayed the same. In an earlier study published in *The Lancet*, Danaei et al. (2011) found that the trend of global BP readings registered a tiny decline from 1998 to 2008, but the situation in different regions varied; BP readings remained stable or even decreased slightly in HICs countries while increasing in some LICs and MICs; SBP is currently highest in LIC and MIC countries.

An alarming trend is that hypertension is generally under-diagnosed, under-treated and under-controlled worldwide. The number of people with uncontrolled hypertension increased from 605 million to 978 million from 1980 to 2008 (WHO, 2015). Although the treatment and control of hypertension has distinctly improved in some HICs countries, such as Canada (Danaei et al., 2011; Joffres et al., 2013; McAlister et al., 2011), the low control rate is still a serious challenge for other countries, such as China. Danaei et al. (2011) advocate the targeting of effective population-based and personal interventions in LICs and MICs.

Table 2.1 The prevalence of hypertension in different regions (age 18+ years)

	2010 (%)	2014 (%)
Global	22.7	22.3
World Bank Income Group		
Low-income	26.7	27.6
Lower-middle-income	25.0*	25.2
Upper-middle-income	21.0	20.3*
High-income	19.7	18.5
WHO region		
Africa	23.3	23.3
Americas	20.1	19.5
Southeast Asia	22.4	22.6
Europe	29.6	28.1
Eastern Mediterranean	22.5	22.4
Western Pacific	20.5*	20.1*

Data resource: Global Health Observatory Data Repository. Blood Pressure. 2015
* China's location

China is an MIC and has the largest population in the world ("Country Classification" 2014). CVDs including stroke and ischemic heart disease, the top two leading cause of death in the MICs and HICs (WHO, 2012), accounted for 45% of total deaths in China (WHO, 2015). As a high-risk factor for CVDs, hypertension has been the leading risk factor for death and years of life lost in China. WHO estimated in 2010 that the prevalence rate was about 20% among adults (＞18y), and estimated a similar rate in 2014 (WHO, 2015). That is comparable to the average rate of the corresponding World Bank Income Group and WHO region. A recent nationwide survey showed that from 2009 to 2010 the prevalence rate in China had reached 30% (Wang et al., 2014), which was similar to the rates in the United States (Nwankwo, Yoon, Burt, & Gu, 2013; Yoon, Burt, Louis, &, Carroll, 2012) and England (Fan et al., 2014) (Table 2.2). Compared to the steady prevalence rate in developed countries in recent decades, the prevalence rate of hypertension in China

from 2002 to 2010 increased by about 10% (Gao et al., 2013; Li et al., 2005; Wang et al., 2014). Furthermore, the prevalence rate of hypertension is increasing with age. In China, a total of 57% of the elderly had hypertension in 2007-2008 (Gao et al., 2013); by 2010, the figure was as high as 69% (Li et al., 2012). With China's rapidly ageing population, the prevalence rate of hypertension will tend to increase steadily.

By contrast, the awareness rate, treatment rate and control rate of hypertension in China are all especially low. As shown in Table 2.2, the awareness rate in China was 43%-45%, slightly lower than the international rate of 47% and far lower than the 71%-83% in developed countries such as Canada and the United States. Furthermore, only 20%-36% of Chinese hypertensive patients receive treatment, which is also far lower than the international rate of 41% and the 58%-79% in developed countries. What's worse is that only 8%-10% of hypertensive patients in China had controlled their BP. Even though a survey found that some regions had achieved a control rate among adults of 18% (Wang et al., 2013), that is still far from satisfactory when compared with that of other countries where the control rate ranges from 37% to 65%.

As shown in Table 2.2, the data reported from different Chinese cities reveals that hypertension prevention and control is a serious problem. The prevalence of awareness, treatment, and control of hypertension was 43%, 36%, and 12%, respectively, in Beijing (Cai, Liu, Zhang, Li, & Wang, 2012), 43%, 38%, and 15%, respectively, in Guangdong province (Ma et al., 2012), and 46%, 36% and 10%, respectively, in Henan province (Fan et al., 2014). One survey conducted in Liaoning province in 2009-2010 showed that only 28% of patients received treatment and only 4% of hypertensive patients had controlled their BP (Meng et al., 2012). The

possible reason for the relatively low treatment and control rates in Liaoning is that this province is located in Northeast China, which has a higher prevalence rate of hypertension than other regions (Bai, Tang, Li, Gu, & Xue, 2012).

How to effectively manage hypertensive patients in China, which exemplifies the gap between massive numbers of hypertensive patients with uncontrolled BP and limited resources, is not only a national issue but also a global issue.

Table 2.2 The rates of awareness, treatment and control of hypertension internationally and in China

Country or city (Author and publication year)	Sample and sample size	Awareness rate	Treatment rate	Control rate (in treated patients)	Control rate
International survey, 2003-2009 (Chow et al., 2013)	628 communities in 17 countries, 35-70y, 142042	47%	41%	33%	13%
HICs	3 countries, 10349	49%	47%		19%
UMICs	7 countries, 36463	53%	48%		16%
LMICs (China located)	3 countries, 58476	44%	37%		10%
LICs	4 countries, 31685	41%	32%		13%
USA, 2009-2010 (Yoon et al., 2012)	≥18y	82%	76%		53%
USA, 2011-2012 (Nwankwo et al., 2013)	≥18y	83%	76%		52%
Canada, 2009 (McAlister et al., 2011)	20-74y, 3487	83%	79%		65%
England, 2011 (Fan et al., 2014)	≥16y, 4540	71%	58%	63%	37%
Germany, 2008-2011 (Neuhauser, Adler, Rosario, Diederichs, & Ellert, 2014)	18-79y, 7095	82%	72%		51%
National China, 2007-2008 (Gao et al., 2013)	≥20y, 47325	45%	36%		11%
National China, 2009-2010 (Wang et al., 2014)	13 provinces, ≥18y, 50171	43%	34%	27%	9%
National China, 2009 (Liang, Liu, Du, & Qiu, 2014)	9 provinces, ≥18y		20%		8%
Beijing, China, 2008 (Cai, Liu, Zhang, Li, & Wang, 2012)	18-79y, 5760	43%	36%		12%
Zhejiang, China, 2010 (Wang et al., 2013)	≥18y, 17437	54%	46%		18%
Liaoning, China, 2009-2010 (Meng et al., 2012)	33 communities, 18-74y, 25196	43%	28%	13%	4%
Guangdong, China, 2002 (Ma et al., 2012)	≥20y, 13889	43%	38%		15%
Henan, China, 2012 (Fan, et al., 2014)	159 countries, 15-74y, 18942	46%	36%	29%	10%

2.3 Factors related to blood pressure control

Poor BP control is a pervasive problem despite pharmacological therapy impacts reducing hypertension-related morbidity and mortality. Hill et al. (2010) found that two major factors are related to inadequate BP control. One is the lack of effective action on the part of the healthcare provider on uncontrolled BP. The other is inadequate patient adherence to treatment recommendations. Borzecki et al. (2005) and Ogedegbe (2008) pointed out that apart from healthcare provider-related factors and patient-related factors, factors related to the medical environment also impact BP control. In the view of Ogedegbe et al., medical environment-related factors include access to care, patient-provider interaction, and characteristics of the practice setting; provider-related factors include knowledge, attitudes regarding appropriate BP control, as well as the measures taken to control BP; patient-related factors include socio-demographic characteristics, health beliefs, clinical factors and patient adherence. The factors related to the medical environment both influence and are influenced by patient-related factors and provider-related factors (Borzecki et al., 2005).

Of all these factors that stand in the way of adequate BP control, patient adherence is key (WHO, 2003; Hill et al., 2010). Although some patients who fully adhere to taking their medications and following the recommendations of healthcare professionals still fail to have their BP well under control (e.g. patients with secondary hypertension or having sympathomimetic, nonsteroidal anti-inflammatory medicines), patient adherence and BP control are nonetheless closely related. Patient adherence is considered to be an independent factor for BP control. On the one hand, patients with high adherence are more likely to control their BP, with adherent

patients reportedly three times more likely to control their BP than non-adherent patients (DiMatteo et al., 2002). On the other hand, non-adherence directly impacts results and is related to the wasting of resources. Even when well-known effective interventions are employed, lack of patient adherence can render them ineffective.

2.3.1 Status of patient adherence

2.3.1.1 Status of patient adherence to anti-hypertensive drugs treatment

Patient adherence to pharmacological treatment is generally unsatisfactory. More than 50% of hypertensive patients do not take all of their prescribed medications (WHO, 2003). Mazzaqlia et al. (2009) investigated 18,806 Italians and reported that six months after being diagnosed, only 8% of the newly diagnosed hypertensive patients continued to take their medications at least 80% of the time. They also found that more than 50% of patients took the recommended anti-hypertensive drugs fewer than 40% of the time. Liu, Quan, Chen, Qian, and Khan (2014) conducted a three-year follow-up on more than 148,000 hypertensive patients in different ethnic populations in Canada. They found that Chinese people were less likely to adhere to their prescriptions of antihypertensive drugs than Caucasians, with the adherence rate being 56% and 66%, respectively. Liu et al. pointed out that the reason for low adherence rates may be related to the fact that the Chinese people had lower awareness of the consequences of high BP. Canada's patient adherence rate to pharmacological treatment is relatively high compared with other countries. Gee et al. (2012) followed 6,017 hypertensive patients in the Canadian Community Health Survey from 2008 to 2009. They found that only 5% stopped taking anti-hypertensive medications after one year. Close to 90% of patients reported taking medications as prescribed, while only less than 10% reported occasionally missing a

dose. Gee et al. believed the encouraging results were due to an evidence-based knowledge translation programme for national hypertensive patients and healthcare professionals that had been in place in Canada since 2000. In addition, Canada has developed a well-funded healthcare system that provides medications to seniors and low-income patients free of charge (Gee et al., 2012). Patient adherence is poor in China, although the reported adherence rate among hypertensive patients varies. Wei et al. (2013) investigated 200 participants who had a high risk of CVDs and were receiving pharmacological treatment. Only 38% of the patients in the study reported that they never missed taking their medication. Meng et al. (2012) reported that only 28% of patients from communities in Liaoning province took anti-hypertensive drugs regularly. Hu, Li, & Arao (2013) investigated 318 hypertensive patients in Beijing and found that 61% of them adhered to their anti-hypertensive drug regimen. The study by Cai et al. (2012) also showed that a total of 55% of elderly hypertensive patients in Beijing received regular therapy at the community level.

The various adherence rates may result from different ways of measuring patient medication adherence. Many measurements, including patient self-report, pill counts, and electronic medication monitoring, have been used to monitor patients' adherence to taking their anti-hypertensive drugs. Patient self-report, including surveys and medical chart reviews, is viewed as a feasible and affordable method and is popular in practice. However, patient self-report has a bias in recall and social desirability of response. Pill counts is an objective method but it has deficiencies such as high staff burden, single-point estimation and uncertainty of timing of adherence or non-adherence. Electronic medication monitoring can objectively record a patient taking medication in the appropriate doses and at the right time, but

the high cost restricts its application. Furthermore, although pill counts and electronic medication monitoring are objective methods, they still are open to bias if patients waste pills or share pills with others. Another factor that should be noted is the methodology of the measurement, which includes timing adherence (Schroeder, Fahey, Hollinghurst, & Peter, 2005) and correct doses (Gee et al., 2012). Some studies did not specify the methodology (Cai et al., 2012; Hu et al., 2013; Meng et al., 2012).

2.3.1.2 Status of patient adherence to non-pharmacological treatment

Despite the well-known benefits of a lifestyle that includes a healthy diet, regular physical activity, moderation of alcohol consumption, smoking cessation, and maintaining a healthy weight, only a small proportion of adults follow these healthy behaviours. King, Mainous, Carnemolla and Everett (2009) compared two early large-scale national surveys, one in 1988-1994 and the other in 2001-2006, on the adherence rate among American adults (40-74 y) to a healthy diet, regular exercise, moderate alcohol consumption, non-smoking and maintaining a healthy weight. King et al. found that only the rates of moderate alcohol consumption improved, and non-smoking remained unchanged. All the other adherence rates declined over the past decades. The adherence rate of all five healthy habits decreased from 15% to 8%. For the population with hypertension, the rate of adherence was as low as 5% in the 2001-2006 survey (King et al., 2009). Miller, Sales, Kopjar, Fihn, & Bryson (2005) analysed the rate of healthy behaviours based on an investigation of 38,851 adults ($>$ 18 y) from 13 states. The data showed that only 5% of participants were fully adherent to all three behaviours (not smoking, physical activity, and healthy diet) while 18% of participants did not follow any of

the suggestions. Among patients with heart diseases, the fully adherent rate was only 7% but the non-adherence rate was 16%. Although the studies by King et al. (2009) and Miller et al. (2005) did not directly investigate hypertensive patients, the adherence to lifestyle change among hypertensive patients is also worrying. Hypertensive patients may adhere to at least one suggestion of healthy behaviours, including exercise, BP measurement, healthy diet, quitting smoking and taking recommended medications, but only a few achieved full adherence. A study investigating 150 hypertensive patients who had been tracked by a clinic for at least one year reported that only 13% of hypertensive patients adhered to all of the above recommendations (Uzun et al., 2009).

Regarding a single health behaviour, the patient adherence rate is varied. The adherence rate of hypertensive patients to physical activity was 25% in Canada (Campbell, McAlister, Quan, & Hypertension Outcomes Research Task Force, 2013) and 31% in Turkey (Uzun et al., 2009). In terms of diet, a total of 65% of Turks were observing salt intake restrictions (Uzun et al., 2009). The situation of smoking cessation appears to be better than other healthy behaviours. A total of 80% of hypertensive patients were non-smoking in Turkey (Uzun et al., 2009). In China, only a few studies have been done on hypertensive patient adherence to healthy behaviours.

In an investigation involving 318 hypertensive patients who had been diagnosed with hypertension for at least one year in a rural community in Beijing, Hu et al. (2013) reported that nearly 80% of the hypertensive patients were non-smokers and did not consume alcohol. Fifty-two percent of the patients reported being engaged in physical activities for four or more days each week, and 44% measured their BP

biweekly, on average. Li, Hu, Dong, Xie, & Zhou (2015) conducted a survey of rural participants (n = 3795) who were aware of hypertension. In 2011, 69% of the participants did not smoke and 63% reported no alcohol consumption, 42% reported measuring BP regularly, but only 10% reported taking action to control body weight. The wide range of the reported rates may relate to different definitions and measurements of behaviour adherence. Despite the difficulty in comparing the adherence rates of different studies, the data all point to the necessity of enhancing healthy behaviours among hypertensive patients.

To date, there is no standardised measurement to accurately determine whether a patient is following the advice of medical professionals. The measurements that have been typically used in practice are (a) comparing the advice of the medical professional with the patient's self-reported behaviours, such as what kind of food the patient ate and what kind of exercise the patient engaged in; or (b) objective measures, such as testing 24-hour urinary sodium excretion to assess adherence to a low sodium diet. Although measurements based on patient self-report are susceptible to biases such as memory problems as well as social desirability, they can be improved upon and validated by using multiple measures of adherence and controlling statistically for bias or by using constructs, such as using body weight to test patient adherence to dietary suggestions. Compared with other measures, measurements based on self-report are acceptable, affordable and simple, so in practice they are commonly employed.

2.3.2 Barriers to patient adherence

Patient adherence is a problem that is not only driven by the patients themselves but also influenced by various and intricate factors. Understanding the different

barriers to adherence will be useful in organising the targeted interventions to improve adherence outcomes as well as clinical outcomes. WHO (2003) classified the barriers of patient adherence to drug treatment in five categories: patient-related factors, social and economic factors, condition-related factors, health system and healthcare team-related factors, and therapy-related factors. Hypertension-related literature is reviewed and summarised in Table 2.3.

Table 2.3 Barriers to patient adherence to pharmacological treatment

Category	Barrier	Reference
Social and economic factors	Age	Vawter, Tong, Gemilyan, & Yoon, 2008
	Lower income	Vawter et al., 2008
	Less education or illiteracy	AlGhurair, Hughes, Simpson, & Guirguis, 2012; Vawter et al., 2008; WHO, 2003
	Absence of insurance	Vawter et al., 2008
	Unemployment	WHO, 2003
Patient-related factors	Unaware of hypertension	Scheltens et al., 2010
	Perception of hypertension and treatment is not in concordance with practitioners' view	Borzecki et al.,2005; Horne, Clatworthy, Polmear, & Weinman, 2001; Vawter et al., 2008
Condition-related factors	Lack of symptoms	AlGhurair et al., 2012; Vawter et al., 2008; WHO, 2003
Therapy-related factors	Complexity of medical regimen	AlGhurair et al., 2012; Hill et al., 2010; Li et al., 2010; WHO, 2003
	Side effects of medicine	Hsu, Mao, & Wey, 2010; Vawter et al., 2008; WHO, 2003
Healthcare team / health system-related factors	Poor instructions	WHO, 2003
	Lack of knowledge	
	Inadequate time	
	Lack of incentives and feedback on performance	
	Limited medication supply	

Patient adherence problems to non-pharmacological recommendations share many similar barriers to those to pharmacological treatment, but behaviour is often influenced by many other factors, including circumstances (WHO, 2003). Only a few studies have been done on barriers to hypertensive patients' adherence to healthy behaviours (Mansyur, Pavlik, Hyman, Taylor, & Goodrick, 2013). Mansyur et al.

investigated a total of 185 low-income African-Americans with hypertension and found that the main barriers to smoking cessation were stress, habit, and addiction; to regular physical activity were acute medical conditions, weather and being ‘‘too busy’’; and to salt restriction were taste, convenience, and cost.

As different patients may encounter various barriers, it is necessary to evaluate individual obstacles to help patients overcome barriers to adherence before intervention is applied. Since patients often face more than one barrier, the barriers should be systematically explored. Some of the obstacles to adherence are impossible to modify at the individual level, and healthcare providers may need to modify the contextual environment or provide more support to help the patient overcome barriers to BP control.

2.4 Strategies for hypertension management

A lot of interventions have been conducted at different levels to enhance the effects of hypertension management. In the early stages, interventions focus on patient education, based on the assumption that greater knowledge can improve patient adherence. However, with the increasing awareness that patient adherence is a kind of behaviour and is also influenced by other factors, some research studies turned to targeting other factors that are external to the patient, such as the healthcare system and the role of healthcare providers. Some interventions were launched to reform the traditional healthcare system so as to support diagnosis, evaluation and treatment, particularly in the use of pharmacologic agents. Some interventions used guidelines from professional societies and voluntary health organisations to enhance hypertension diagnosis, treatment, and control. In recent decades, research studies have examined these interventions conducted on a national and international scale.

BP outcomes, such as BP readings, reduction of BP readings, and BP control rate, are well recognised in evaluating the effects of the management of hypertensive patients. The strategies for hypertension management and BP outcomes are reviewed in the following paragraphs.

2.4.1 Enhancing patient adherence

WHO (2003) suggested that adherence is a modifier of the effectiveness of the health system. Many researchers were aware of the complexities of patient adherence and conducted different interventions to help the patient overcome different barriers. Schroeder, Fahey, & Ebrahim's meta-analysis (2004) examined the effects of 58 different interventions on patient medication adherence. They found that, while 19 (37%) interventions improved adherence, only 30% showed improved clinical outcomes. These included BP reduction (a net reduction of SBP from 0 to 19.5 mmHg and DBP from 0 to 12.7 mmHg) and BP control rate (a net increase from 0 to 18%). Schroeder et al. classified the effective interventions into: (a) patient-related factors, such as counselling, health education and motivation, support and reminder of patient; (b) therapy-related factors, such as simplification of dose regimens; (c) healthcare system and healthcare providers related factors, such as the involvement of nurses and pharmacists, financial incentive, a reminder; and (d) combination of interventions. Schroeder et al. concluded that simplification of dose regimens was a powerful strategy to improve patient outcome with a relative increase in adherence rate by 12%, but more evidence is still needed on the effectiveness of this intervention on BP control because 38% of the studies did not report a BP outcome. They also suggested that patient education alone seemed largely unsuccessful, but complex interventions (e.g. patient motivation, a patient-centred approach,

involvement of other professionals such as trained nurses) appeared to improve the patient adherence rate by 5% to 41%. Schroeder et al. pointed out that further evidence from well-designed experimental trials is needed, since 74% of the studies did not report the randomisation process, 79% failed to report the power calculation and 69% did not report the blinded treatment allocation. Furthermore, none of the studies met all the above quality criteria.

Haynes, Ackloo, Sahota, McDonald, & Yao (2008) reviewed 83 interventions in 70 RCTs associated with long-term adherence to prescribed medications. Only 36 interventions showed positive effects on improving adherence and only 25 interventions resulted in at least one treatment outcome. They found that almost all of the effective interventions for bringing about patient adherence to long-term therapies were complex. Six in twelve studies showed effects on patient adherence to hypertension therapy and a BP outcome (BP reading or BP control rate). Haynes et al classified hypertension-related interventions into two categories. One was interventions targeting the healthcare system and healthcare providers related factors, such as more instructions for patients, communication by telephone follow-up or mail, convenience care (e.g. home visit), home blood pressure monitoring (HBPM), provision of patient-tailored care, and augmented pharmacy services. The other was interventions targeting patient-related factors, such as counselling about possible side-effects, and sending reminders to patients. Haynes et al. revealed that more than 60% of the studies did not report the concealment of allocation that might have a bias on the grouping.

Hill et al. (2010) reviewed various interventions for improving patient adherence in the United States. Hill et al. ’s review of the literature suggested that

strategies to improve patient adherence should focus on clinical outcomes, such as simplifying the treatment regimen and supporting patients' BP self-monitoring; empowering the patient, such as evaluation of adherence barriers and use of behaviour change interventions; team-based approaches, such as using a collaborative model and self-management support; reforming healthcare policy, such as adopting adherence as a critical healthcare issue and structuring and supporting behavioural intervention in communities. In their summary, Hill et al. pointed out a glaring oversight in the current patient adherence studies: few studies focused on improving the skills of healthcare providers in communicating with and counselling patients to help them improve and maintain adherence behaviour despite evidence showing that the quality of the patient-provider relationship, including the way of communicating with patients and winning their trust, is directly related to proper adherence behaviour in patients with chronic conditions. Another oversight is the dearth of information on how to optimise practice and office arrangements and organisation or how to improve overall care processes to achieve optimal BP control.

Based on a review of the literature, we also found that most adherence studies only recruited patients being treated with anti-hypertensive drugs and focused on medication adherence; only a few studies have been done on patient adherence to non-pharmacological interventions. In addition, the majority of intervention studies that included patient adherence did not include clinical outcomes, such as a BP outcome (Borzecki et al., 2005; Hill et al., 2010; Schroeder et al., 2004). Further evidence of both the adherence and clinical outcomes from the above interventions are needed.

2.4.2 Optimising the healthcare system

Traditionally, hypertensive patients received treatment and care in hospitals and clinics, but their limited healthcare resources are insufficient to meet the huge demands posed by chronic diseases. Community-based hypertension management, through effective use of minimal resources to meet maximal demands, will increase patients' access to healthcare. WHO also stresses that the management of hypertensive patients at the community level is crucial to the improvement of BP control (2002). Some countries, such as Japan, have in recent years changed the focus of their chronic disease management from hospital-based acute disease care to community-based long-term services. Japan launched a series of community-based intervention programmes in 1961 in which nurses and doctors in the community provide regular health check-ups and health guidance free of charge for community residents who are over 40 years old and have a high risk of stroke. Through home visits or phone calls, health workers and volunteers in the programme informed and reminded the elderly to go for health check-ups. By collaborating with school teachers and restaurant owners to establish healthy cooking schools, children and their parents changed their dietary behaviour. These community-based interventions resulted in an 85% stroke reduction in Japan ("Community-based efforts" 2013 March).

China started in the 1960s to screen for risk factors for CVDs by using an interventional protocol at the Capital Iron and Steel Company in Beijing. In the 1970s, worksite-based interventions for CVDs were launched (Wu et al., 2003). The intervention strategies were: (a) Face-to-face health education in factory clinics and regular distribution of health-related information through television and on

blackboards; (b) Lifestyle modification, such as training the factory canteen staff to choose healthy foods and cook healthy meals; (c) Screening, follow-up, and management; (d) Provision of training for the factories' healthcare providers. Through sustained management from 1974 to 1998, SBP decreased in the intervention group by 1 mmHg for males and 4 mmHg for female participants, while in the comparison group, males registered a 2-11 mmHg increase and females a 6-8 mmHg increase. DBP remained unchanged in the intervention group but increased 2-6 mmHg for males and 3-6 mmHg for females in the comparison group. Other risk factors for CVD, such as body mass index (BMI) and serum cholesterol level also were relatively lower in the intervention group than in the comparison group. The lesson learnt from this programme is that worksite-based interventions are feasible and effective, but it is unknown whether this model is suitable in the community outside of a worksite, where patients face more barriers, such as lack of skills in the preparation of healthy foods.

In Canada, the Cardiovascular Health Awareness Program (CHAP), a community-based programme that targeted BP reduction, was initiated in 2000 in the province of Ontario (Kaczorowski et al., 2008). The healthcare providers in the programme included physicians, pharmacists, nurses, and volunteers. The programme involved BP monitoring, assessment of risk for CVDs, providing tailored information on modifiable risk factors for participants, and training the elderly in the community to work as health educators. It resulted in reducing SBP by 19 mmHg and DBP by 9 mmHg (Ye et al., 2013). The programme also showed benefits for improving patient medication adherence and lifestyle modification, and resulted in a reduction in the risk of CVD morbidity (Jones et al., 2008; Kaczorowski

et al., 2011; Ye et al., 2013). The programme now is implemented in large urban communities in Canada (see CHAP website http://chapprogram.ca/). To conclude, the successful community-based intervention programmes mentioned above always used team-based multi-strategy interventions and involved lifestyle modifications.

Traditionally, healthcare providers treated or followed-up with patients through face-to-face interaction in hospitals and clinics. Factors such as long waiting time and difficulty getting an appointment in these practice settings may block patient access to healthcare. Recently, healthcare providers have used telecommunications technology, such as phone and video, to diagnose, treat, and follow-up with patients outside of hospitals and clinics. Mistiaen and Poot (2008) conducted a meta-analysis involving 33 tele-intervention trials, in which healthcare providers exchanged information with patients, provided health education, identified complications and managed symptoms, gave reassurances and provided quality service. As a result, they concluded that telephone follow-up was effective in some trials, but the evidence varied. Though it has yet to be shown if tele-follow-up is better than face-to-face visits in patient's clinical outcomes, the researchers recognise that the convenience of the telecommunication approach can increase patient satisfaction (Currell, Urquhart, Wainwright, & Lewis, 2000; Wong, Chow, Chan & Tam, 2013).

2.4.3 Key agents of hypertension management

Interdisciplinary team-based care is an important component of hypertension management (Hill et al., 2010). In conventional healthcare settings, doctors play a leading role on the team while the role of other professionals goes unnoticed. The doctors diagnose disease, prescribe and adjust pharmacological therapies for hypertensive patients. However, because of their limited numbers, doctors fall far

short of the need to manage the massively increasing number of hypertensive patients. The demands on their time mean doctors are unable to perform an assessment of patient barriers to BP control or to conduct non-pharmacological interventions. Researchers have turned to exploring the traditional roles of other healthcare providers for ways to aid in the management of hypertension, such as the non-dispensing role of pharmacists (Cater et al., 2009; Nkansah et al., 2010), or bringing in volunteers to supplement healthcare professionals (Kaczorowski et al., 2008), or even training hypertensive patients themselves as intervention performers (Fu et al., 2000, Fu et al., 2003).

2.4.3.1 Pharmacists' role in hypertension management

Most interventions by pharmacists are performed in outpatient medical clinics and community pharmacies but seldom at a patient's home. The pharmacists' role is in pharmacological treatment, such as pharmaceutical therapy optimisation and identification of drug-drug interactions, but some non-pharmacological roles for pharmacists have emerged, such as patient education, adherence assessment, monitoring of disease control and adverse drug reactions, and support of physicians (e.g. provision of recommendations for therapy modifications to physicians or resolution of medication-related problems) (Cater et al., 2009; Nkansah et al., 2010). In the meta-analysis done by Carter et al., researchers analysed the contributions of pharmacists to reducing BP and found that treatment recommendations provided by pharmacists were significantly associated with an improvement in BP. Community pharmacists and pharmacists in primary clinics were associated with a reduction of SBP by 8 mmHg and 9 mmHg, respectively. In the studies with large effect size, pharmacists' recommendations in treatment contributed to a 9-mmHg SBP reduction.

Nkansah et al. reviewed 43 studies that looked at the role of pharmacists in patient outcomes. In eight studies targeting hypertension, Nkansah et al. found that pharmacists helped to reduce SBP by 4-12 mmHg. In a further meta-analysis, Nkansah et al. found that pharmacists contributed to reducing SBP by 6 mmHg and DBP by 3 mmHg. They also reported that the pharmacists played a role in enhancing patient QoL.

2.4.3.2 Volunteers' role in hypertension management

Researchers have also attempted to explore more available community resources, such as volunteers, to complement the limited numbers of healthcare providers. In a programme conducted in Canada (Kaczorowski et al., 2008), volunteers who had received training from a community nurse, assessed the participants' CVD risk factors and assisted elderly residents of the community in measuring their BP. The volunteers forwarded the results of CVD monitoring and assessment to the patients' physicians and pharmacists and also referred patients to nurses or pharmacists for further assessment. The results showed a remarkable reduction in BP readings (SBP 19 mmHg and DBP 9 mmHg) in the elderly patients as well as reinforcement of adherence behaviours (Ye et al., 2013). However, this volunteers collaboration approach requires a substantial existing volunteer base and good organisation. In those community settings that lack an organised cadre of volunteers, it may be hard to implement this kind of approach on a large scale (Fu et al., 2006).

Some programmes trained hypertensive patients to work as volunteers to conduct group-based interventions for patients in the community. Using the Chronic Disease Self-Management Programme (CDSMP) (Lorig, Sobel, Ritter, Laurent, &

Hobbs, 2001), Fu et al. (2003) trained non-medical personnel who had been diagnosed with hypertension to acquire the skills to deal with this health condition, and to acquire knowledge about medications, communication and nutrition. As a result, Fu et al. found that the programme was successful in improving the self-care behaviours of hypertensive patients and resulted in a significant reduction of BP of patients in Shanghai. This programme has now been implemented in Zhejiang province and other areas in China. However, this kind of approach can only be an adjunct to interventions led by healthcare professionals because volunteers cannot provide professional input, such as assessments or counselling of the patients.

Huang, Chen, Zhou & Wang (2014) trained family members of hypertensive patients in China to supervise the patient's behaviours, such as medicine intake, seeking healthcare and BP monitoring. With the support of family members, patient adherence rates increased by 42% and BP readings were significantly reduced after six months. Since the study by Huang et al. lacked a control group to exclude the effects of confounding factors, this innovative way of hypertension management needs to be confirmed by further evidence.

2.4.3.3 Nurses' role in hypertension management

Nurses always play a silent but irreplaceable role in practice. In contrast to their traditionally dependent role, nurses in chronic disease management tend to play more of an assistant's role to physicians. Nurses possess unique skills in patient management and non-medication counselling techniques that other professionals usually do not have (Carter et al., 2010). A recent meta-analysis study (Carter et al., 2010) showed that nurse-led interventions resulted in reducing SBP by 5 mmHg. Some studies have compared the effects of nurse-led and the doctor-led care on

patient outcome in primary healthcare settings (Keleher et al., 2009; Laurant et al., 2005). For instance, Keleher et al.'s meta-analysis, which included nine studies that compared nurse-led care with doctor-led care on outcome measures for mortality, QoL, adherence, knowledge and satisfaction in care. They found similar effects between nurse-led care and doctor-led care on mortality and QoL while patient adherence and satisfaction were better under nurse-led care than under doctor-led care. Laurant et al. in a meta-analysis study published in the Cochrane Library, analysed a total of 16 of 25 selected studies that compared the effects of nurse-led and doctor-led care of chronic diseases in the primary care setting. They examined indicators including physical function, patient satisfaction, scheduled return visits, prescription-ordered hospital admissions, hospital referrals, and attendance at accidents and in emergency rooms. Laurant et al. concluded that nurse-led care and doctor-led care had no appreciably different effect on patient outcomes, care processing, and resource utilisation or related costs. Nurse-led interventions have now been proposed as a promising approach for hypertension management (Carter et al., 2009; Clark et al., 2010; Walsh et al., 2006). However, researchers in these studies have called for further evaluation of nurse-led care in the efficacy of BP control because many studies had methodological limitations and the follow-up period was generally short (Carter et al., 2009; Clark et al., 2010; Glynn et al., 2010).

2.5 Nurse-led interventions in hypertension management

WHO (2015) estimated that there are about 20 million nurses worldwide. Translating clinical evidence to practical nursing care, these millions of nurses could be an effective force in hypertension management and improving patient outcomes. Searching the Cochrane Library, a well-recognised evidence database, using

hypertension or BP and nurse as keywords in the title and abstracts fields produced three pieces of literature on nurses engaged in intervention for hypertensive patients. Two were meta-analysis studies on the potency of nurse-led interventions on BP control (Clark et al., 2010; Glynn et al., 2010). The other one was an examination of the cost-effectiveness of nurse-led behavioural intervention (Datta et al., 2010). Glynn et al. examined 72 RCTs, six of whom worked in nurse-led care, and evaluated the effects of the intervention on improvement of BP management in the community. They analysed the effects on BP outcome of six intervention strategies: self-monitoring, educational intervention of patients, educational interventions for the health professionals, nurse-led or pharmacist-led care, organisational interventions, and reminder systems. They concluded that nurse-led care resulted in a 0-13 mmHg reduction of SBP and a 0-8 mmHg reduction of DBP for hypertensive patients. They recommended that further evaluation should be conducted because of the relatively small sample size and the heterogeneous results. After analysing 33 articles on nursing intervention, Clark et al. pointed out that treatment algorithms, nurse prescribing, telephone monitoring and community monitoring all showed effects on BP reduction, with nurse prescribing resulting in the greatest reductions in BP (SBP - 9 mmHg and DBP - 4 mmHg). Since nurses are allowed to prescribe only in a minority of countries (Bhanbhro, Drennan, Grant, & Harris, 2011), it is not known whether other roles assumed by nurses can impact BP outcomes. Datta et al. conducted an analysis of cost, including inpatient cost, outpatient cost, total cost and cost-effectiveness, based on a nurse-led telephone-based behaviour intervention programme. They reported that nurse-led behavioural intervention was a low-cost approach, and using this approach is unlikely to increase healthcare utilisation and

costs. The findings of the above meta-analysis studies, however, suggest that nurse-led care still needs more substantial evidence to prove its effectiveness in BP outcomes and cost-effectiveness (Clark et al., 2010; Datta et al., 2010; Glynn et al., 2010). It should be noted that the selection criteria in these meta-analysis studies would have excluded some studies, especially the qualitative studies. These meta-analyses, however, serve the purpose of providing objective evidence informing readers about the overall effectiveness of nurse-led interventions. In these meta-analysis studies, the authors used different classifications of the interventions, which resulted in difficulty in extracting the effect components. These studies focused on BP outcome, especially BP reduction, and omitted other indicators of patient outcomes, such as adherence outcome and QoL. Furthermore, what approach is effective in how nurse-led care is delivered to the hypertensive patients is unclear, because the studies do not elaborate on it. Therefore, literature on the effects on patient outcome of nurse interventions in hypertension management needs to be reviewed.

Studies that met the following criteria were examined to identify effective intervention strategies for establishing a nurse-led model for hypertension management in the community:

a. Studies targeting adult hypertensive patients with uncontrolled BP.
b. Studies that report the effects of the interventions being studied on any of the following patient outcomes: BP readings, BP reduction, or BP control rate and / or adherence to anti-hypertensive drugs or self-care behaviours or lifestyle modifications. BP outcome is a well-recognised indicator for evaluating the effects of hypertension

management. Adherence outcome is chosen because patient adherence is the key modifier of the effectiveness of hypertension management.

c. Studies using the RCT design or meta-analysis that represents the gold standard for determining efficacy and effectiveness.
d. Studies that were conducted in the community setting or primary care healthcare setting because community-based intervention has been suggested as a cost-effective way to manage hypertension.
e. Intervention delivered by professional nurses including practice nurses, nurse practitioners, clinical nurse specialists, advanced practice nurses.

Eventually, 14 RCTs were identified, as shown in Table 2.4. The research locations of the studies were the United States (n = 7), the United Kingdom (n = 2), Italy (n = 1), Norway (n = 1), Jordan (n = 1), the Netherlands (n = 1), and Hong Kong China (n = 1).

Table 2.4 International literature on nurse-led intervention on patient adherence and blood pressure

	Author, year	Country, C/S sample size (attrition rate) characteristic of participants	RCT kind Intervention (Duration of intervention)	Model	Performer and performer size vs. sample size	TGC	TP	CM	Sur	BP			RF	Self	Ad	Qol	K	Cost	Drug	SU	St
										Reduction	Readings	Control									
1	Alhalaiqa et al., 2012	Jordan, 68/68 (7%), recruited in an outpatient department, uncontrolled BP & non-adherence	RCT single blinded C: clinician-led (nurse and medical staff) monthly clinics (HBPM & medical review & laboratory investigations) S: MI 20 min *7 times conducted in clinics or at home & C (7week)	Adherence therapy	Experienced nurse, 1 vs.68	C	X	X	X	√ (+)	X	X	X	Belief (+)	M (+)	X	√ (+)	X	√ (-)	X	X
2	Artinian et al., 2007	USA, 193/194 (13%), recruited after free screening at the community, uncontrolled BP	Stratified RCT C: arrangement of the regular visit of primary care providers & pamphlet S: 2 home visits for HBPM training and counselling, tele-counselling based on BP readings weekly within first 3 months & monthly * 2 times & bimonthly once & C (12m)	X	Trained registered nurses ? vs. 194	TCG	X	X	√	SBP (+)	√ (-)	√ (-)	X	X	X	X	X	X	X	X	X

	Author, year	Country, C/S sample size (attrition rate) characteristic of participants	RCT kind Intervention (Duration of intervention)	Model	Performer and performer size vs. sample size	TGC	TP	CM	Sur	BP			RF	Self	Ad	Qol	K	Cost	Drug	SU	St
										reduction	Readings	Control									
3	Baig et al., 2010	USA, 50/50 (15%), recruited in churches, uncontrolled BP	RCT C: Telephone referral by health workers S: Clinic visit & monthly mailings & weekly calls & referral (4m)	X	Registered nurse, ? vs. 50	TC	X	√	√	√	C (+)	X	X	X	B &M (-)	X	√ (-)	X	X	X	X
4	Beune et al., 2014	Netherlands, 71/75(5%), recruited in the primary healthcare centres, uncontrolled BP	Cluster RCT C: usual care provided by physician S: 3 times * 30-minute culturally-sensitive counselling at 2 weeks, 8 weeks, 20 weeks & written educational material & referral if applicable & C (6m)	Culturally-sensitive framework	Trained practice nurse 1 vs. 75	TC	X	√	X	√ (-)	DBP (+)	X	√ (-)	X	B (+)	X	X	X	X	X	X
5	Bosworth et al., 2005	USA, 259/259 (5%), recruited in clinics, 57% with uncontrolled BP and all patients with anti-hypertension treatment	RCT C: usual care but without details S: nurse-led phone calls bimonthly to conduct standardised and tailored health education (6m)	Health Decision Model	Nurse practitioners with research background, 2 vs. 259	T	X	X	X	X	X	X	X	√ (+)	√ (+)	X	√ (-)	X	X	X	X

	Author, year	Country, C/S sample size (attrition rate) characteristic of participants	RCT kind Intervention (Duration of intervention)	Model	Performer and performer size vs. sample size	TGC	TP	CM	Sur	BP			RF	Self	Ad	Qol	K	Cost	Drug	SU	St
										reduction	Readings	Control									
6	Bosworth, Olsen, Duldley et al., 2009	USA, C 143/S1 151/S2 144/S3 150 (20%), recruited in clinics, 57% with uncontrolled BP and all patients with anti-hypertension treatment	Cluster RCT C: reminder S1: nurse-led phone calls bimonthly using behavioural intervention S2: decision support for providers S3: S1 & S2 (24m)	Health Decision Model	Nurse practitioner, 2 vs. 294	T	X	X	X	√ (-)	X	√ (+) *[1]	X	X	X	X	X	X	X	X	X
7	Chiu et al., 2010	HK China 32/32 (2%), recruited in a clinic, newly diagnosed & uncontrolled BP	RCT C: 45min nurse clinic consultation S: Biweekly phone*2 & C (8week)	X	Practice nurses, 1 vs. 32	TCG	X	√	√	√ (+)	√ (+)	√ (+)	X	X	M (+) B (+)	X	X	X	X	X	√ (+)
8	Cicolini et al., 2014	Italy, 101/102 (3%), recruited in a primary centre, uncontrolled BP	RCT C: 3 times * one-hour nurse-led educational programmes S: email alerts weekly * 24 and phone calls & C (6m)	X	Trained nurse care manager, ? vs. 102	E-teaching	X	X	√	√ (+)	√ (+)	X	√ (+)	X	B (+)	X	X	X	X	X	X

[1] Second analysis conducted between patient received behavioural intervention and non-behavioural intervention

	Author, year	Country, C/S sample size (attrition rate) characteristic of participants	RCT kind Intervention (Duration of intervention)	Model	Performer and performer size vs. sample size	TGC	TP	CM	Sur	BP			RF	Self	Ad	Qol	K	Cost	Drug	SU	St
										reduction	Readings	Control									
9	Denver et al., 2003	UK, 60/60 (4%), recruited in a nurse-led clinic, uncontrolled BP & received treatment for high BP & combined with DM	RCT C: a reminder letter for GP of patients S: face to face visits in the nurse-led clinic monthly * 3times & every 6 week * 2 times & C (6m)	X	Nurse specialist, 1 vs. 60	TC	√	X	√	SBP (+)	SBP (+)	X	√ (-)	X	X	X	X	X	X	X	X
10	Gabbay et al., 2013	USA, 313/232 (57%), recruited in clinics, including uncontrolled BP	RCT C: physical examinations & laboratory tests every 3 months S: 7 times * 1-hour MI in clinics, regarding the review, reminder (24m)	X	Trained nurse case managers, 3 vs. 232	C	X	√	√	X	SBP (+)	X									
11	Hebert et al., 2012	USA, C 176/S1 120/S2 120 (28%), recruited in clinics, uncontrolled BP	RCT C: pamphlet & regular visits by clinicians S1: HBPM * pamphlet S2: S1 & A face to face counselling & a home visit monitor & regular phone follow-up (9m)	X	Registered nurse, 1 vs. 120	C	X	√	√	√ (+)	√ (-)	√ (-)	√ (-)	X	√ (-)	X	X	X	√ (+)	X	X

	Author, year	Country, C/S sample size (attrition rate) characteristic of participants	RCT kind Intervention (Duration of intervention)	Model	Performer and performer size vs. sample size	TGC	TP	CM	Sur	BP			RF	Self	Ad	Qol	K	Cost	Drug	SU	St
										reduction	Readings	Control									
12	Pezzin et al., 2010	USA, C 292/ S1 267/S2 286 (25%), recruited at a home care organisation, newly diagnosed & uncontrolled BP	Cluster RCT C: assessment, medication review, a plan of care, patient education, monitoring, tailored hand on care S1: 2 alert emails to nurse & HBPM with a monitor and log & information S2: a home visit & biweekly phone counselling & S1 & C (12week)	X	Trained nurses &health educator, 92 vs. 221	TCG	√	X	√	- +*2	- +*	- +*	X	X	X	X	X	√ (↑)	X	X	X
13	Schroeder et al., 2005	UK, 117/128 (17%), recruited in clinics, uncontrolled BP	RCT C: BP check & electronic monitor *3 times S: a 20min adherence support consultation & a 10min session at 2 month & C (6m)	Self-regulatory model of illness behaviour	Trained nurses 21 vs. 128	C	X	X	X	X	√ (-)	X	X	X	M (-)	X	X	√ (-)	X	X	X

2 Second analysis conducted on stage 2 patients

	Author, year	Country, C/S sample size (attrition rate) characteristic of participants	RCT kind Intervention (Duration of intervention)	Model	Performer and performer size vs. sample size	TGC	TP	CM	Sur	BP			RF	Self	Ad	Qol	K	Cost	Drug	SU	St
										reduction	Readings	Control									
14	Tonstad et al., 2007	Norway, 20/31 (10%), uncontrolled BP	Open RCT C: brief advice S: face to face 60min meeting * 1 & 30min monthly meeting *5 (6m)	Behavioural self-management & TTM	Nurse, 1 vs. 31	T	√	X	X	X	√ (-)	X	↑ (+)	X	X	X	X	X	X	X	X

RCT: Randomised controlled trial, HBPM: Home blood pressure monitoring, C: Control group, S: Study group, MI: Motivational interview, TGC: Teaching, guidance and counselling, including self-management, motivational interview, TP: Treatment and procedure, including medicine and team collaboration, CM: Case management including referral, Sur: Surveillance, including follow-up and BPM, BP: Blood pressure, Control: Control rate, RF: Risk factor or other objective indicators, Self: Self-confidence or self-efficacy of belief, Ad: Adherence, QoL: Quality of life, K: Knowledge, D: Drug number, SU: Service utilisation, St: Patient satisfaction，M: Medicine adherence，B: Behavioural suggestion adherence

In terms of outcomes considered in these studies, apart from BP outcome and patient adherence, risk factors for CVDs, self-efficacy, QoL, knowledge, and cost were also reported. The majority of these RCTs (n = 13) reported BP outcome including BP readings (n = 11), BP reduction (n = 10), or BP control (n = 5). Of the 14 studies, 71.4% (n = 10) showed positive findings in nurse-led interventions for one or more BP indicators. Eight of these studies showed a significant reduction in BP readings, and three showed an increase in the BP control rate. Nine (64.2%) studies adopted patient adherence as an outcome measure, with 56% (5/9) of these studies showing beneficial results in the intervention group. Of the seven studies that reported BP outcome through adherence to medication or a healthy lifestyle, 57% (4/7) of the studies showed improved adherence together with BP reduction, while two found a decrease in BP without any improvements in adherence outcomes. Six studies examined risk factors of CVDs and one found a significant reduction. Two studies considered self-efficacy or belief outcome and both showed significant reinforcement. Three studies reported knowledge as an outcome, but only one showed improvement. Two studies looked at the cost of intervention and one reported that intervention increased costs. Two studies examined patient satisfaction, but only one showed positive results. Only one study reported patients' QoL but did not find a significant difference compared with usual care. None of the studies found evidence of harm related to nurse-led hypertension care.

Nurses performed interventions in all 14 of these studies, but only seven studies reported that the nurses had taken part in any training programme. Most of the studies did not specify the nurses' qualifications or the training programme. A total of six studies reported a model used to guide the intervention programme and five studies used behaviour change-related models. The duration of intervention ranged

from 7 weeks to 24 months. In most studies (9 / 14), the intervention period was 3 to 6 months. The intervention approaches reported in the studies varied, with seven studies using phone calls as an intervention, four using home visits, four using face-to-face consultation in the clinic, and one using email. The most common intervention strategy was counselling and health education followed by BP monitoring. Five studies reported that nurses used a referral to other professionals. Only one involved pharmacological treatment conducted by nurses. Two studies used counselling as single intervention strategies and the others used combined intervention strategies. Six studies were guided by a model or conceptual framework. The most common model used was the health behaviour-related model, and one reported using a culturally sensitive framework.

The interventions used in a nurse-led intervention programme for hypertensive patients were various and complex, but few studies used a standardised system to classify them. In the following paragraph, the Omaha System, an international standardised taxonomy, will be used to structure the results of the review on intervention related to nurse-led care. The Omaha System has been adopted in the terminology model for the International Organisation for Standardization (see the Omaha System on http://www.omahasystem.org/, 2015) The Omaha System classifies care into four categories: teaching, guidance and counselling, treatment and procedures, and case management and surveillance (Martin, 2005).

2.5.1 Teaching, guidance, and counselling

Based on the Omaha System (Martin, 2005, p. 373) teaching, guidance, and counselling in the context of hypertension management mainly refers to providing health education, encouraging BP monitoring, and motivating hypertensive patients to make decisions and solve problems.

Health education is a very common intervention strategy used by healthcare providers in hypertension management. In practice, nurses are more likely than physicians to conduct health education on diet and nutrition (Baig, Mangione, Sorrell-Thompson & Miranda, 2010). WHO (2003) stresses that health education is a fundamental component of broader interventions for improving patient adherence. Health education can help patients obtain the disease-related knowledge necessary to stick with appropriate health behaviours. In a large-scale cross-sectional study that recruited 8,779 hypertensive patients, Scheltens et al. (2010) found that patients who were aware of hypertension, compared to those who were not, had higher adherence to recommendations regarding lifestyle modifications. They also found that patients with controlled BP adhered to more lifestyle modification items than those with uncontrolled BP. It is worth noting that two meta-analysis studies in the Cochrane Library demonstrated that education alone has little effect on patient adherence and BP control (Glynn et al. 2010; Schroeder et al. 2004). Schroeder et al. analysed six studies of patient education and also concluded that education alone is unsuccessful in improving patient adherence and BP control. Glynn et al.'s study, which reviewed 20 RCTs involving patient education as part of the intervention, pointed out that if health education is not executed in conjunction with other interventions, such as HBPM, an appointment reminder system, and nurse-led or pharmacist-led intervention, it is unlikely to lower BP directly.

The differing results of the effects of health education may be related to the fact that the interpretation of health education was different across the studies. In Schroeder et al.'s meta-analysis (2004), the educational programme included the use of slides, audiotape, booklet, written educational material, group education, lecture, discussion, and knowledge test. In Glynn et al.'s study (2010), the content of health

education was unclear. Lagger, Patakya, and Golay (2010) reviewed 360 articles on health education and found that only 4% of the studies detailed the contents of education and allowed the reproduction of the interventions, while nearly 73% of the studies failed to describe the content of education. WHO (see WHO website http://www.who.int/topics/health_education/en/) defines health education as *any combination of learning experiences designed to help individuals and communities improve their health, by increasing their knowledge or influencing their attitudes*. Many health education studies focused on knowledge improvement by providing written materials, lectures, and personal counselling. However, knowledge is rarely enough to change behaviour, such as the lifestyle behaviours that are essential for BP control. Schroeder et al. suggested using combined interventions and using the motivational interview (MI) approach in health education to improve patient adherence. Lagger et al. suggested that behaviour changes should be incorporated into health education to enhance BP control.

Bosworth et al. (2005) used bi-monthly phone calls to implement a nurse-led, standardised and personalised behavioural education programme for hypertensive patients. At the six-month follow-up, they found that patients' confidence had improved in the study group. As for the patients who were non-adherent at recruitment, more patients in the study group than in the control group adhered to medicine therapy. At the 24-month follow-up, patients receiving intervention showed a higher BP control rate than those receiving usual care. In another study, Bosworth, Olsen, Grubber et al. (2009) examined the differences in the effects of the following: usual care, bi-monthly behavioural education by phone only, HBPM three times weekly only, and nurse-led behavioural education combined with HBPM. They found that behavioural intervention alone did not improve BP control, although

HBPM did show a slight improvement of BP control at 24 months. However, the combined intervention approach resulted in a clinically significant improvement in BP control of 11% compared with usual care. The reduction of SBP and DBP were 4 mmHg and 2 mmHg, respectively, more than the reduction achieved under usual care. Cicolini et al. (2014) found that when email alerts and telephone follow-ups were combined with an educational programme, patients' adherence rate and BP control increased more than with the mere provision of an educational programme.

BP monitoring is a critical method for hypertension diagnosis and surveillance of the effects of treatment or intervention because patients will not know their BP unless their BP is measured. Traditionally, healthcare providers measure patients' BP when patients visit the clinic. Clinic blood pressure monitoring (CBPM) or office BP monitoring has always been used as the cornerstone for diagnosis and treatment. CBPM, however, may cause "white coat effect" which means that some patients' BP will increase in response to the medical environment. Therefore, CBPM may not represent these patients' real BP readings. By contrast, HBPM can display patients' actual and dynamic changes of BP in familiar surroundings. HBPM is a convenient and inexpensive method for the management of hypertension. It is recommended by a number of guidelines, such as the European Society of Hypertension, the European Society of Cardiology (ESH / ESC) (Mancia et al., 2013), the American Heart Association, the American Society of Hypertension, Preventive Cardiovascular Nurse Association (AHA / ASH / PCNA) (Pickering, Miller et al., 2008), and the Chinese Hypertension League (Liu & Writing group of 2010 Chinese GMH, 2011). Recently, ESH/ESC (Mancia et al., 2013) insisted that the validity of HBPM is comparable to CBPM in the prediction of prognosis. ESH / ESC (Mancia et al., 2013) suggested that HBPM is suitable for patient self-care, especially in primary care. In

the United States, the HBPM guidelines suggest that the results of HBPM can be used as a basis for clinical diagnosis and as a reference for adjusting pharmacological treatment (Pickering, White, & American Society of Hypertension Writing Group, 2008). The guidelines also clearly reminded healthcare providers to help patients choose a reliable device and teach them how to take accurate measurements through HBPM (Mancia, 2014; Pickering, White et al., 2008; Wang et al., 2011), because some patients did not like taking their BP at home because the lacked the skills or did not have the financial resources to purchase their own BP monitoring device (Hu et al., 2013). In practice, increasing evidence has shown that HBPM may enhance patient adherence and help BP control. Hill et al. (2010) pointed out that patients who use HBPM are more likely to adhere to medicine therapy. Glynn et al. (2010) summarised in a meta-analysis study that self-monitoring is related to a net reduction in SBP of 2.5 mmHg and DBP of 1.8 mmHg. However, HBPM alone or HBPM combined with hypertension information may not improve BP control (Bosworth, Olsen, Dudley et al., 2009, Pezzin et al., 2010). In another meta-analysis, Agarwal, Bill, Hecht and Light (2011) also demonstrated that HBPM alone has little impact on BP control if no action is taken based on the results of HBPM monitoring. When HBPM is combined with other interventions, such as anti-hypertensive drugs (Agarwal et al., 2011), nurse management (Bosworth, Olsen, Grubber et al., 2011; Hebert et al., 2012; Pezzin et al., 2010), patient behavioural intervention (Bosworth, Olsen, Dudley et al., 2009), patient counselling (AbuDagga, Resnick, & Alwan, 2010), or telephone follow-up (Mancia et al., 2013), it contributes to better BP control and reduction.

Counselling is a common intervention approach used by nurses in practice. Datta et al. (2010) stated that nurses often spend more time in counselling than

doctors. Baig et al. (2010) compared nurses' counselling with physicians' and reported that nurses tended to provide similar counselling in the use of medication as physicians, but nurses employ more non-pharmacological advice such as diet and physical activity for patients. Tonstad, Alm, and Sandvik's study (2007), using six sessions of nurse-led counselling meetings regarding lifestyle modification, did not show positive results in improvement of BP control. In a study reported in the Cochrane Library (Schroeder et al., 2004), practice nurses aimed to help patients solve non-adherence problems by using two face-to-face counselling sessions. However, no positive outcome in patient adherence to medications or in BP control was found in the six-month of follow-up. Schroeder et al. pointed out that some MI strategies and complex interventions appear promising for the improvement of patient adherence and BP control, but more evidence based on well-designed RCTs is needed. WHO (2003) also recommended training healthcare providers in counselling skills, such as using a non-judgmental manner, to motivate patients' self-care. The MI (Miller & Rollnich, 2002) involves techniques including using a non-judgmental, non-confrontational and non-adversarial manner. By involving patients in the decision-making in their care, MI often can motivate patients to manage their health conditions. Studies support using MI (Miller & Rollnich, 2002) in counselling because it is more likely to guide healthcare providers to see results in improving patients' adherence and BP reduction (Alhalaiqa et al., 2012; Ma, Zhou, Zhou & Huang, 2014). Ma et al. conducted a study to test the effects of MI on BP control in the Chinese community setting. In Ma et al.'s study, trained clinical nurses provided eight 30-minute MI counselling sessions in 24 weeks to 60 patients with essential hypertension, resulting in improvements in patients' BP control, patient adherence to both medication and lifestyle behaviours, and patients' QoL. Alhalaiqa et al. offered

seven weekly one-on-one consultations to a total of 68 hypertensive patients. This intervention changed patients' belief in the efficacy of medication and led to a significant improvement in adherence behaviour as well as BP control. Nevertheless, Mansyur et al. (2013) stressed that MI may increase patient self-efficacy in a short time but if used without the strategies to change behaviour, patient outcome may be not improved.

2.5.2 Treatment and procedure

The Omaha System defines treatments and procedures as *technical activities such as wound care, specimen collection, resistive exercises, and medication prescriptions that are designed to prevent, decrease, or alleviate signs and symptoms of the individual/family/community* (Martin, 2005, p. 373). In the context of hypertension management, treatment and procedure mainly refers to prescriptions of anti-hypertensive drugs and aerobic exercise. The effects of anti-hypertension drugs are well recognised, but traditionally, the nurse's role in pharmacological treatment was dependent on the doctor. That is now changing, and the nurse's role in pharmacological treatment is expanding. Bhanbhro et al. (2011) reported that 22 countries have legislation for nurse prescribing. By examining 17 studies on nurse prescribing in primary care, they concluded that nurse prescribing at the community level was efficient, and that patients found this acceptable and helpful as a way to access healthcare services. Clark et al. (2010) in a meta-analysis pointed out that the use of treatment algorithms and nurse prescribing had high effects among nurse-led hypertension interventions, especially for nurse prescribing in the American healthcare system. Denver et al. (2003) used health education and intensifying anti-hypertensive treatment for hypertensive patients combined with diabetes in a nurse-led clinic in the United Kingdom. The study demonstrated that nurse-led care could

reduce SBP and enhance BP control more than usual care. Though Bhanbhro et al. stated that more evidence of the effects of nurse prescribing on clinical outcome was needed, the role of nurses in improving patient outcome should not be overlooked. In the majority of countries or regions, nurses are not allowed to prescribe medicines; nonetheless, they still can play a central role in facilitating pharmacological treatment, such as getting patients to visit their GPs or pharmacists (O'Neil, Cunningham, Wittala, & Bartley, 2014). Furthermore, nurses often encourage patients to stay active and to engage in physical activities for health promotion and BP control, but their recommendations are usually informal and not in the form of a written prescription. In a study conducted in Canada, although nursing practitioners gave exercise prescriptions to 59% of patients, the nursing practitioners themselves reported only a fair level of confidence in the prescription. More than 60% needed a curriculum in health education to improve their competency (Lamarche & Vallance, 2013). A study (Kallings, Leijon, Hellenius, & Stahle, 2008) proved that exercise prescriptions are helpful for getting patients to adopt a more physically active lifestyle and for improving their QoL. Although most prescriptions were written by doctors (74%), in this study, 12% of the prescriptions were written by nurses, proving that nurses' prescriptions for exercise are feasible and effective in practice.

2.5.3 Case management

Case management is a collaborative process that involves activities such as coordination and referral to facilitate service delivery and guide hypertensive patients toward the use of appropriate resources (Martin, 2005, p. 373). As mentioned above, team-based intervention is a core of hypertension management (Hill et al., 2010; Walsh et al., 2006). Nurses need to refer patients, as appropriate, to other professionals of the team for additional support, such as medication

adjustments or laboratory orders. It should be mentioned that if the nurse refers patients to other professionals and does not continue to follow up and check on the patients' health condition, the effect of nurse-led referral would not be superior to non-medical personnel referral in adherence outcome and BP reduction (Baig et al., 2010). Combined with MI in intervention, nurses initiating a referral and following up on patients' health condition showed effects on SBP readings (Gabbay et al., 2013). Traditionally, the treatment of hypertension was provided by physicians. O'Neil et al. (2014) pointed out that clinical pharmacy specialists may be an alternative to physicians as a supporting prescriber to nurses. The data they reviewed and analysed showed that pharmacy specialists and physicians have similar effects on improving BP reduction and BP control rate in practice.

2.5.4 Surveillance

The Omaha System defines surveillance as activities including detection, measurement, critical analysis, and monitoring intended to identify the hypertensive patients' status in relation to hypertension (Martin, 2005, p. 373). By following patients' health conditions, healthcare providers can dynamically monitor patients' health changes and assist patients to handle health problems properly. As a result, patient adherence will be improved, and BP will be controlled (Glynn et al., 2010; Hill et al., 2010). Clinical follow-up and community-based follow-up are common methods for monitoring changes in patients' health conditions. In recent decades, telephone follow-up has emerged and become more popular due to its convenience and cost effectiveness (Currell et al., 2000). In a meta-analysis of tele-intervention conducted by hospital-based health professionals, Mistiaen and Poot (2008) pointed out that tele-follow-up has not to date been shown to be effective in improving patient satisfaction or the physical health of the patient. The telephone follow-ups

varied in a number of aspects including who made the call, and the duration, frequency, and structure of the calls. How to effectively conduct tele-follow-up still needs to be further explored. Glynn et al. found that telephone follow-up alone was likely to be ineffective, but when the regular reminder was used together with intense anti-hypertensive drug therapy, it reduced BP readings and hypertension-related mortality. Cicolini et al.'s study (2014) used emails to alert patients to follow the professional recommendations and telephoned the patients to help them overcome barriers to doing so. Such intervention strategies significantly improved patient adherence and BP reduction and control rate. In other programmes, trained nurses combined telephone follow-up with other intervention strategies, such as self-monitoring BP and face-to-face counselling, to reinforce patient adherence (Chiu & Wong, 2010) as well as BP control (Chiu & Wong, 2010; Pezzin et al., 2010; Rudd et al., 2004).

In summary, hypertensive patients with uncontrolled BP are more likely to be effectively managed by nurse-led combination interventions. Nurse competency is a key factor related to effective results, but most of the current studies of successful interventions do not describe the details of the nurses' qualifications or what kind of training was provided for them before the intervention was conducted. Clark et al. (2010) pointed out that the effects of nurse-led interventions on BP control resulted from prescriptions written by nurse practitioners. Only a few nurses are allowed to write prescriptions, therefore, when adopting a nurse-led intervention strategy in practice, the competency of the nurses should be considered.

Furthermore, it is worth mentioning that the processes and results of interventions will be influenced by structural factors, such as the features of the

healthcare setting. In the following section, we review the healthcare system in China.

2.6 Healthcare system in China

China faces a heavy burden caused by hypertension just like most countries worldwide, but the healthcare system in China has particular features. Since the healthcare delivery systems in Taiwan, Hong Kong, and Macao are all different from that in China, in the following paragraphs, the description of the healthcare system is of the one in mainland China only.

Rapid demographic and epidemiological changes in the past few decades, including striking declines in fertility and child mortality and increases in life expectancy, have brought big challenges for China. Historically, the healthcare system in China was principally concerned with acute problems, such as certain infectious diseases. However, the rapid rise of non-communicable diseases (NCDs) means they now are a contributing factor in about 80% of deaths in China, and of the deaths from NCDs, 45% are due to stroke and ischemic heart disease (National Centre for Chronic and Noncommunicable Disease Control and Prevention, 2012). Reduction of high-risk factors for CVDs such as hypertension has been a focus of public health policy. However, the traditional healthcare system and public health measures in biomedical science are not suitable for the management of chronic diseases in China.

As early as 1969, in a factory in Beijing, clinical researchers started to screen hypertensive patients and found the rate of hypertension to be about 12%, or more than twice the national prevalence rate. In 1972, a hypertension management programme was started in the factory. In this programme, patients got varying

degrees of care depending on their level of risk for CVDs. Ultimately, the programme rapidly reduced the comorbidity of stroke. The effects of this programme have been acknowledged by WHO. However, in an acute disease healthcare setting, a shortage of healthcare organisations to carry out the model limits its implementation

In 1999, NHFPC of the PRC and nine other departments issued a joint statement (1999) that stressed the importance of healthcare services at the community level and required the establishment of community health centres (CHC) to provide primary care. In 2006, a joint statement issued by China's State Commission Office of Public Sector Reform, the ministries of health, finance and civil affairs (2006, August 18) reaffirmed the CHCs' function as the main health organisations at the community level responsible for identifying and managing hypertensive patients. The statement encouraged small-scale general hospitals to convert to CHCs to take up the work of disease prevention and control. The statement also put forward requirements for setting up a CHC, including the requirement of standardised management of hypertension (NHFPC of the PRC, 2009, October 10; 2011, April 25) and published hypertension guidelines (Liu & Writing group of 2010 Chinese GMH, 2011) to support hypertension management at the community level.

By 2011, a total of 7861 CHCs had been established and 83.6% of them are government-run (NHFPC of the PRC, 2014). In terms of hypertension management, the government reimburses the CHCs for the public health services (including prevention and control of hypertension) they provide to residents under the service network free of charge. The amount of compensation has increased by 67%, from RMB 15 per resident in 2009 to RMB 25 in 2011 (NHFPC of the PRC, 2011, April

25), and the government had set a target for it to exceed RMB 40 per person in 2015. At the same time, medical insurance policy was reformed to encourage management of hypertensive patients in the community. Under the reformed insurance policies, patients are required to pay 80% of the bill for hospital services, but hypertensive patients seeking treatment at CHCs are required to pay only 70% or less of the bill, including the cost of medications and exams (NHFPC of the PRC, 2011, April 25).

Though the government has increased support to CHCs, the funding is still insufficient. Zhang, Zhou, and Fang (2008) reported that the average government investment accounts for less than 8% of the total revenue of community health centres. Therefore, community health organisations rely heavily on profits from drug prescriptions and medical income to keep their books balanced. In for-profit CHCs, medical treatments occupy the majority of the daily work of health providers, who therefore have limited time to spend on hypertension management. With the increasing support from the government to community health organisations, medical treatment-oriented service will hopefully gradually shift and be more focused on the prevention and control of chronic diseases.

2.6.1 Hypertension management in China

As a result of the gradual development of the framework and organisation of hypertension management at the community level, many hypertensive patients are benefitting from health services provided in the community and some researchers have reported the achievement in international journals. X. J. Chen et al. (2014) trained 14 doctors at a CHC in Yulin, Sichuan province, to provide hypertension management guided by the national policy and regulations. From 2004 to 2007, these trained doctors provided more than 3,000 hypertensive patients with annual medical checkups and quarterly face-to-face follow-up, wrote prescriptions, if

necessary, provided health education, took BP measurements, and conducted symptoms assessment. At the end of nine years of this programme, they found that patients' BP was significantly reduced (SBP reduced by 14 mmHg and DBP reduced by 8 mmHg), and the BP control rate was dramatically increased, by about 50%. X. H. Liang et al. (2014) in Chongqing, also in Sichuan province, examined the effects of GP-led team-based hypertension management for 6,681 hypertensive patients at the community level. The team consisted of GPs, nurses, clinical pathologists and public health doctors. Their hypertension management included a physical examination and at least four follow-up visits in an outpatient department or in patients' homes as required by the national policy and regulations (NHFPC of the PRC, 2009, October 10). As a result, managed patients reduced their SBP and DBP by 4 mmHg and 3 mmHg, respectively. Since there was no control group (X. J. Chen et al., 2014; X. H. Liang et al., 2014), the evidence of the effects of these measures stipulated by the national law on BP outcome would warrant confirmation through experimental trials. Since the BP control rate in China has remained low, researchers have also attempted to explore effective ways to supplement basic hypertensive care. Gao et al. (2015) established a Chinese hypertension group visit model and tested it in an RCT with 1,024 participants from Shanghai. The intervention in this model included structured health education and consultations provided by the physician-led group consisting of a GP, a social worker, and a nurse together with 18-20 volunteer patients. Compared with usual care, these group visits showed more effects on patient adherence to anti-hypertension drugs and life modifications, reduction of DBP, as well as self-efficacy. The average reduction of DBP resulting from this model was 1.1 mmHg more than under usual care. The model also enhanced patient medication adherence rates, physical activities, and diet by 14.7%, 9.7%, and 10.1%,

respectively, which was significantly higher than that in the control group of 2.0%, 1.6%, and 8.0%, respectively.

The majority of the reports on hypertension intervention studies conducted in the community in China were written in Chinese. Most of them have issues in the quality of the methodology. In a meta-analysis study of the effectiveness of interventions for hypertension care in Chinese communities, Lu et al. (2012) pointed out that these RCT studies were generally of low-quality. Only three of the 91 studies analysed used adequate randomisation sequence generation to examine the effects in question. In a further review of the 87 trials in the meta-analysis report (see Appendix 1 Studies involved community-based interventions on hypertensive patients in China), we found that the majority of the studies did not describe the intervention (e.g. frequency, duration, providers) in detail. Only 30% (n = 26) briefly mentioned who provided the intervention and few studies detailed the qualifications of the providers. Among them, 14 studies were of GPs in the community, 11 studies involved nurses, and one study looked at volunteers. As for outcome measures, BP reading and BP control rate were reported in most of the studies (44 / 87 versus 45 / 87); some studies reported the status of self-care behaviours, including adherence to anti-hypertensive drugs (25 / 87), and non-pharmacological treatments (40 / 87), such as diet, physical activities; a few studies reported patient knowledge (24 / 87); a small number of studies involved utilisation of healthcare services (7 / 87) and BP monitoring (8 / 87); and three studies measured patient self-efficacy.

2.6.2 General practitioners in hypertension management in China

In the existing Chinese CHCs, GPs are in charge of the management of hypertension. The GP's function is similar to family physicians and primary care physicians in other countries. However, the educational background of these GPs is

comparatively lower than physicians working in hospitals. The 2013 China Health Statistical Yearbook (NHFPC of the PRC, 2014) reported that 59% of GPs did not have a bachelor's degree. Only 41% had received a bachelor's degree or postgraduate training, compared with 70% of doctors in hospitals who had received similar training. The competency of these GPs in hypertension management is worrying. Chen et al. (2013) investigated 147 GPs' knowledge and training needs in Shanghai CHCs. When tested on their knowledge of the hypertension management guidelines, the accuracy rate of their knowledge of hypertension management was only 49.2%. Ren (2004) conducted a survey among 400 GPs in Beijing and found that only 29% had been trained on how to use the guidelines, and when tested on their knowledge of the guidelines, only 56.3% passed. Ren reported that more than 55.5% of GPs had access to the guidelines, but only 29% had received training on how to use the guidelines, such as pharmacological treatment and assessment of risk factors for CVDs. Only 56.3% of GPs could answer correctly when tested on their knowledge of the guidelines. Chen et al. found that the reasons for the difficulties GPs had in providing health education were that they lacked time, knowledge, and techniques to use in health education that would produce behaviour change, particularly among patients with poor adherence. These reasons are similar to a WHO report (2003) that lack of knowledge, inadequate time, lack of incentives and lack of feedback on performance may be important barriers to healthcare providers adhering to protocols or guidelines.

2.6.3 Nurses in hypertension management in China

Although nurses in China play an important role in hypertension management, few RCT studies (Ma et al., 2014) examined nurses' contribution. Ma et al. trained 12 clinical nurses to conduct regular MI with a total of 60 hypertension patients who

were receiving anti-hypertensive drug treatment. After the six-month intervention, results showed that the intervention enhanced patient adherence and improved BP reduction as well as QoL. Because this study had a high nurse-to-patient ratio, the feasibility of using this as a way to manage massive numbers of hypertensive patients needs to be considered. It would be reasonable to adopt the experience of successful nurse-led intervention programmes, but the nurses' competency, one of the most important components of the nursing dose (Manojlovich & Sidani, 2008), should also be considered. Since most successful intervention programmes are implemented by advanced practice registered nurses or experienced nurses in the HICs, the feasibility of NHM in mainland China is unknown.

The majority of nurses working in the community in mainland China graduated from professional schools (equivalent to the level of senior high school), although as the educational level of China's nurses has improved in recent years, fewer nurses fall into this category. Data for 2013 (NHFPC of the PRC, 2014) showed that less than 7% of nurses in the community had a bachelor's degree or above, which is lower than the 14% of nurses with the same level of education who are working in hospitals. When compared with nurses who produced a positive outcome in hypertension management in other healthcare settings, such as in the United States, the competency of community nurses in mainland China needs to be enhanced (Guo et al., 2006). Appropriate training is likely to help nurses become competent in care and disease management. In 2011, the National Centre for Chronic and Noncommunicable Disease Control and Prevention (2012) published the National Nursing Action Plan for the years 2012-2015, which supported increasing the number of community nurses and improving the competence of nurses in chronic disease management. Some training programmes were launched in recent years by

health departments in collaboration with nursing related associations. S. L. Wang et al. (2008) provided an effect-based training programme for Chinese community nurses. They found that nurses who completed the programme improved their essential skills in assessing, planning, implementing and evaluating patients with chronic disease, and they were competent in the delivery of chronic disease management. So far, we have not found literature on the effects of attempts to improve the competency of community nurses engaged in hypertension management. There is an absence of evidence showing that community nurses in mainland China can lead hypertension management to improve patient outcome.

2.7 Summary

Patients face various barriers to BP control and many attempts at different levels have been made to improve patient outcome, but BP control is still suboptimal. Managing hypertensive patients at the community level and through team-based management is an effective strategy. GPs usually play the leading role in hypertension management, but limited manpower means they are insufficient to manage the massive numbers of hypertensive patients. Large numbers of nurses may be a substitute source of manpower and the results from previous studies support the effects of nurse-led care in improving patient outcomes, although the evidence is inconsistent and its effects on other indicators should be tested. Hypertension is a global issue, especially for the MICs and LIMs where BP control is a more serious problem. The local healthcare settings and the competency of community nurses will influence the effects of nurse-led interventions. Currently, there is a paucity of evidence showing that the nurses in the MICs and LIMs can successfully improve patient outcomes. It is necessary to launch a well-designed study to provide evidence from these countries.

CHAPTER 3

METHODOLOGY

3.1 Introduction

To establish a feasible and effective NHM model, a feasibility study was done before starting the main study. This chapter begins with a discussion of the feasibility study and lessons learned, followed by a description of the design of the RCT. The main principles of the RCT, including the use of randomisation, placebos, and blinded techniques, are described. The research setting is introduced as well as the method used for detection and recruitment of participants. This chapter presents how the NHM model was developed and what guided the design of the intervention. Each component of the NHM intervention is introduced. Then the method for calculating sample size is described, followed by a description of the outcome measurement and the data collection method. Ethical issues considered in the study are also addressed. At the end of the chapter, a description of the data analysis plan, including how to manage the missing data and analyse the collected data, is presented.

3.2 Feasibility study

The purpose of the feasibility study was to test the applicability of the intervention protocols in the NHM programme to provide insights into how to establish an effective NHM model in the community healthcare setting in China. The full details of this feasibility study can be found in a published article (see Appendix 2 A published article: Development and evaluation of a nurse-led hypertension management model in a community: a pilot randomised controlled trial).

3.2.1 Methods

The feasibility study was conducted in a standard CHC in Hangzhou, Zhejiang province, China. The study recruited participants who were: (a) diagnosed with hypertension, (b) ≥ 35 years old, and (c) living within the health service network of the CHC. The study excluded participants who were: (a) unable to communicate, (b) unable to be contacted by phone, (c) terminally ill, (d) known to have co-morbidities in contradiction to the intervention programme (e.g., exercise) or (e) pregnancy.

It was a two-arm, single-blinded study. The data collectors were blinded to the randomisation process and the grouping results. A computer-generated randomisation table was created to determine participants' assignment before they were recruited.

The intervention period was eight weeks. After patient assignment, the control group received the usual care provided by the CHC healthcare providers based on national requirements (NHFPC of the PRC, 2009, October 10). In addition to this usual care, the intervention group received an NHM intervention programme that was designed on the basis of the Four-C framework developed by Wong, Mok, Chan, and Tsang (2005). The four Cs refers to comprehensiveness, collaboration, coordination, and continuity. These features were present in the assessment, intervention, and organisation as well as documentation of the study. The details of the Four-C features were the same as those of the main study, which is described in section 3.7.2.2 of this methodology chapter. The intervention programme included a home visit and two to four telephone calls. A home visit was conducted by nurses working in the CHC (community nurse). Two monthly telephone follow-up calls were made to those whose BP at recruitment was below 140 / 90 mmHg, while those whose BP at recruitment was equal to or higher than 140 / 90 mmHg got four

follow-up telephone calls at two-week intervals. The phone calls were made by the community nurses assisted by volunteer nursing students. The community nurses and nursing students were invited to attend a training programme before study commencement.

Socio-demographic data, clinical information and outcome measurements were collected by the data collectors at recruitment. Outcome data were also collected at week 8, immediately after the intervention. Outcome data were BP readings, self-care adherence, self-efficacy, QoL and patient satisfaction. BP readings were measured by the data collectors using a calibrated mercury sphygmomanometer. In face-to-face interviews, the data collectors also collected other outcome data based on questionnaires, which included the Self-Care Behaviour Scale, the Short-form Chronic Disease Self-Efficacy Scale (CDSES) (Chinese Version), the Short-Form Health Survey (SF-36) (Chinese version), and the Patient Satisfaction Scale.

3.2.2 Findings

Of the 73 participants recruited, 15 were lost to follow-up or dropped out of the programme, resulting in an attrition rate of 20.5%. Based on the comparable socio-demographic and health characteristics of the two groups, the results were as described below.

An examination of the reliability of the questionnaires found that the intra-class correlation coefficient (ICC) was 0.92 on the Self-Care Behaviour Scale for test-retest reliability. The Cronbach's coefficient alpha α was 0.82 on the CDSES, 0.92 on the Patient Satisfaction Scale, and ranged from 0.71-0.94 in eight domains of the SF-36. The results indicated that these questionnaires used for the outcome measures of the study were reliable.

In terms of the effects on the outcomes, the intervention group exhibited better effects of self-care behaviour than the control group in salt restriction, HBPM, and pharmacological treatment as well as patient satisfaction. In the remaining outcomes, there was no statistically significant difference between the two groups: BP readings, self-efficacy, most domains of QoL, and self-care behaviours (smoking cessation, salt restriction, and regular physical activity).

3.2.3 Lessons learned

This feasibility study confirmed that the intervention protocols in the NHM were feasible, and the instruments were reliable. The intervention programme guided by the Four-C model resulted in greater patient self-care behaviours and satisfaction at the end of eight weeks than did usual care, but the study did not provide adequate evidence to support its effects on improvement of BP, self-efficacy and QoL.

The probable reasons for the intervention group's inability to obtain statistically significant results in reducing BP are: Firstly, eight weeks might not be long enough for the effects of the intervention programme to show up, even though in an earlier study (Chiu & Wong, 2010), an eight-week nursing intervention programme showed its effectiveness in reducing patient BP. That successful study targeted those who were newly diagnosed or in the early stage of hypertension, but the majority of patients in the CHC had a long history of hypertension and suffered from other chronic diseases. Therefore, it is possible that more time is needed for effects to show in participants with complex health conditions. Pezzin et al.'s (2010) study using a home visit and biweekly follow-up phone calls reduced BP for patients with uncontrolled BP and improved the BP control rate in 12 weeks. In the main study, the period of community-based intervention was therefore extended to 12 weeks. Secondly, the lack of BP reduction effect might have been because baseline BP

levels were relatively low and the majority of patients had their BP controlled. A previous study with a large sample size (Pezzin et al., 2010) showed that a significant reduction in BP was more likely to happen amongst patients with a higher BP reading. It was decided that the main study would just focus on patients with uncontrolled BP.

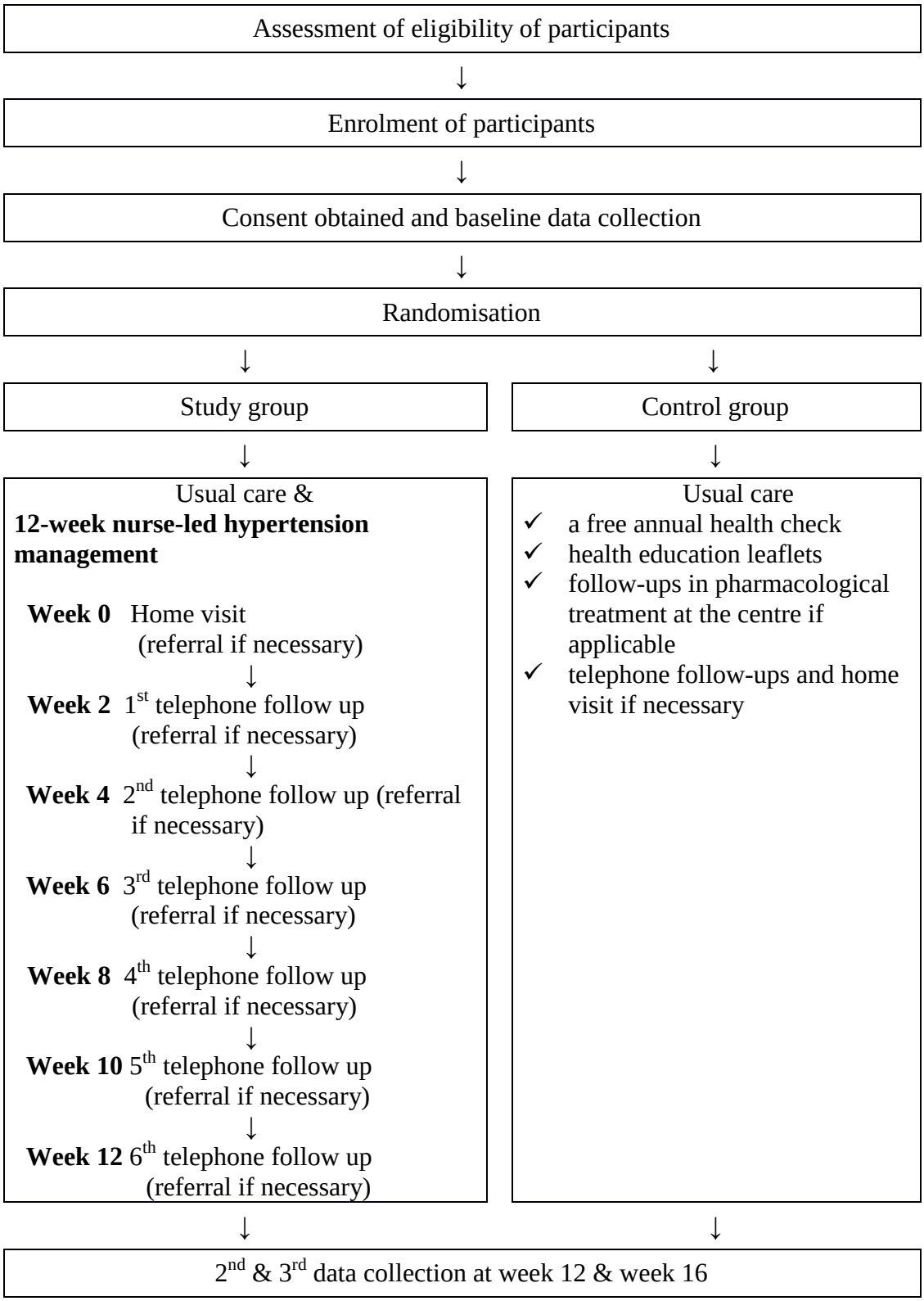
An important lesson learnt from this feasibility study was the importance of facilitation by the healthcare organisation in supporting the intervention programme Firstly, this programme was regarded as a research exercise and not a service, and thus was not incorporated into daily practice. The trained nurses had to extend their working hours to conduct the intervention programme in addition to their day-to-day clinic duties. The resulting increased workload hindered the trained nurses' motivation to perform the intervention protocols, which may have impacted the adherence rate to the intervention programme (Brooten & Youngblut, 2006). Secondly, the patients had one or more co-morbidities that often required pharmacological treatment or special nutrition and exercise guidance. In this study, the trained nurses tried to refer patients to GPs for pharmacological treatment and continuously followed the patients' health condition, but a referral system for various disciplines and professionals did not exist at the community level. Acting on referrals between nurses and GPs would be difficult in a healthcare system that has not incorporated a referral system into its routine practice. This lesson reminded the researchers that these influencing factors of healthcare system should be embraced in the design of the future study.

To summarise, this feasibility study demonstrated that NHM can be a promising way to manage hypertensive patients at the community level, but the support of the healthcare organisation needs to be strengthened for it to succeed.

3.3 Research design

The study adopted an RCT, which is viewed as the highest level of evidence (see Oxford Centre for Evidence-based Medicine website http://www.cebm.net/oxford-centre-evidence-based-medicine-levels-evidence-march-2009/), to test the hypotheses of a study. The study was a two-group parallel block random controlled trial (block of 2 & ratio 1:1) with a single-blind design. The data collectors were blinded to the randomisation process and the results of the grouping as well as the intervention used in the study. Figure 3.1 is a flowchart of the stages of the study, beginning with the assessment of eligible participants, then enrolment, followed by consent form signing and baseline assessment, then allocation at random, and finally the 12-week intervention and two follow-up assessments. The details of the processes are described in the paragraphs that follow.

Figure 3.1 Flowchart of the research design



3.4 Research setting

The study was conducted in a CHC in the Huang-Hua-Gang sub-district of Yue-Xiu District, Guangzhou, Guangdong province, China. The CHC is a standard urban healthcare organisation at the community level (State Commission Office of Public Sectors Reform, Ministry of Health, Ministry of Finance & Ministry of Civil Affairs of the PRC, 2006). Like most community healthcare organisations in China, it had previously been a small public hospital. The CHC serves a population of 80,000-100,000 residents.

Based on the hypertension prevalence rate of 23% in Guangzhou (Song & Meng, 2009), the projected number of hypertensive patients in this service area is between 18,400 and 23,000. At the commencement of this study, about 2,000 hypertensive patients had received hypertension management as required by the national policy (NHFPC of the PRC, 2009, October 10). GPs were in charge of the outpatient hypertension treatment of these patients and they had the leading role of care. A standardised process for following up hypertensive patients' outcomes and interdisciplinary team-based management did not previously exist. Similar to many medical-oriented healthcare organisations throughout China, this centre was searching for an appropriate way to effectively manage hypertensive patients. The centre's staff was comprised of 16 GPs and 33 community nurses. The number of community nurses met national staffing requirements, which specify three community nurses and three GPs for every 10,000 residents (State Commission Office of Public Sectors Reform et al., 2006, August 18) while the number of GPs fell short of the requirement. Because of this situation and to meet service needs, the director of the centre was willing to adopt and test the NHM model in practice. In collaboration with the director of the centre, who mobilised available resources for

the research study, a research team was formed. The team consisted of a GP, four community nurses, and a doctoral student researcher.

3.5 Detection and recruitment of participants

Recruitment of participants took place from August 2012 to May 2013. Four strategies were used in patient enrolment:

a. The doctoral student researcher pre-screened potential participants using the medical records for BP in the pre-existing database of the centre's health information management system. Then the researcher invited potential participants to the centre for screening based on the inclusion and exclusion criteria of the research study as described in Table 3.1.

b. The researcher also collaborated with the centre's healthcare providers who were responsible for outpatient consultation and they conducted physical examinations and health education workshops to seek out eligible participants.

c. The researcher posted recruitment posters in community organisations and at the CHC to attract potential hypertensive patients to take part in the programme.

d. The participants and the centre's healthcare providers invited other residents to receive screening, making use of the "snowball effect" resource. After potential participants were screened, eligible participants were enrolled in the study.

Table 3.1 The inclusion and exclusion criteria for the participants

Inclusion criteria	a.	Patient has a diagnosis of hypertension (confirmed with the medical record);
	b.	Patient has uncontrolled BP: SBP ≥ 140 mmHg and / or DBP ≥ 90 mmHg in the last two clinic visits and at recruitment (confirmed with the medical record);
	c.	Patient is ≥ 18 years old (confirmed with the identification card);
	d.	Patient lives within the service network of the CHC (confirmed with the health record system).
Exclusion criteria	a.	Patient has a diagnosis of secondary hypertension (confirmed with the medical record);
	b.	Patient is taking medicine that could increase BP, such as sympathomimetic, nonsteroidal anti-inflammatory (confirmed with the medical record and the GP of the team);
	c.	Unable to communicate;
	d.	Unable to be contacted by phone;
	e.	With diagnosis of terminal illness (confirmed with the GP of the team);
	f.	With co-morbidity in contradiction with the intervention programme (e.g. not fit for exercise) (confirmed with the GP of the team);
	g.	Pregnancy, breastfeeding or planning pregnancy (based on self-report).

3.6 Randomisation techniques

Before recruiting participants, a research staff not involved in the study randomly allocated a total of two-hundred sequence numbers into two groups by using the IBM SPSS Statistics for Windows, Version 20.0 (Armonk, NY: IBM Corp.). By using a block size of 2 and treatment size of 2, a total of 100 pairs of numbers were created by the software. In each pair number, one was assigned to the study group while the other would automatically fall into the control group by the software. The research staff placed each result of the grouping allocation into a sealed opaque envelope, which was assigned a sequence number from 1 to 200. The coordinators kept these sealed opaque envelopes. In the current study, a total of 134

participants were finally recruited, so a total of 134 envelopes were used. After each eligible participant agreed to participate in the study and signed the consent form, research assistants who were blinded to the study intervention and patients' grouping collected baseline data on each participant. A serial number was produced for each participant according to the order of data collection. Then, the collected data were sent to the trained head nurses who worked as coordinators. Upon receipt of each patient's documentation, the coordinators opened the corresponding envelope with the same number of the documentation to reveal the grouping result and arranged for subsequent follow-up.

3.7 Interventions

Participants in the control group received usual care while the study group received an NHM programme of 12 weeks in addition to usual care.

3.7.1 Usual care

Usual care included a free annual health check, health education leaflets published by the local health department, and follow-ups with pharmacological treatment by the GPs. The follow-ups were arranged by doctors when patients needed to get medicines refilled at the centre. The healthcare providers in the CHC also provided home visits or telephone follow-ups for patients as needed.

3.7.2 Nurse-led hypertension management model

3.7.2.1 Components of the nurse-led hypertension management model

The NHM programme was designed based on two models: the Chronic Care Model (CCM) (Wagner et al., 2001) and the Four-C Model proposed by Wong et al. (2005). The NHM model adopted four structural components from the CCM (Wagner, 1998; Wagner et al., 2001), which were self-management support, decision

support, clinical information system and delivery system design. The NHM guided community nurses acting as case managers to conduct the interventions, which had these four features: comprehensiveness, collaboration, coordination and continuity. These are the principles of the Four-C Model (Wong et al., 2005; Wong, Chow & Chan, 2010). The NHM was supposed to improve patient outcomes, including BP outcome, self-care behaviour, self-efficacy, QoL, utilisation of healthcare services and patient satisfaction. The incorporation of these characteristics will be detailed in the description below of the intervention design.

3.7.2.1.1 Delivery system design

Table 3.2 Team member roles and responsibilities

Team Member	Number	Responsibility
Trained community nurses	4	Home visit, telephone follow-up, initiate referral
General Practitioner	1	Treatment of the referred patients
Coordinators	2	Organisation and mobilisation of resources
Researcher	1	Decision support and quality control

With the facilitation of the manager of the centre, an NHM team was established. The team consisted of four trained community nurses, one GP, the researcher, and two coordinators. Each team member had his or her own responsibility as shown in Table 3.2. Four qualified trained community nurses were in charge of conducting the protocols. All four were females, with a mean age of 26 years, and their working years in community healthcare was, on average, seven years. Three of them had bachelor's degrees, and one had an associate's degree. The GP was responsible for providing pharmacological treatment for referred patients. Two head nurses did not directly conduct interventions on patients but worked as study coordinators. The head nurses were in charge of facilitating the allocation of

resources and time to allow the community nurses to do the interventions, and the researcher was responsible for supporting the community nurses' decision-making and for controlling the quality of care delivered.

The trained community nurses visited each participant once at his or her home, followed by five to six biweekly telephone follow-ups. They also referred participants to visit the GP if necessary.

3.7.2.1.1.1 Home visit

The trained community nurses visited patients in their homes within three days of patient recruitment. During the home visit, she assessed the patient's health problems and evaluated the patient's knowledge, behaviour and status of identified health problem using the Omaha System (Chinese Version) (Martin, 2005, p. 359-377; Wong, 2012) (see Appendix 3 The Omaha System). According to the results of the assessment, the trained nurse used a guidance of intervention (See Appendix 4 Intervention guideline) to conduct teaching / guidance / counselling, treatment and procedure, and case management, which are the intervention categories of the Omaha System. Although the national guidelines (Liu & Writing Group of 2010 Chinese GMH, 2011; Wang & Yao, 2009) were used in deciding the contents of the intervention guidance, the guidance of intervention used in the current study included additional information emphasising self-management skills, such as how to control salt intake, engage in regular physical activities and perform and record HBPM, as well as medication storage. The trained community nurses taught the patient the goal of self-management such as consuming salt less than 6 g per day, engaging in an aerobic physical activity for at least 20 minutes per day and at least three days per week. The trained community nurses guided the patients to choose

foods helpful for lowering BP, to choose aerobic exercises (e.g. brisk walking, stretching exercises), to identify high BP readings and to know the possible side-effects of the anti-hypertensive drugs patients were using. To enable the self-management skills, a salt-restriction spoon and a salt container with a scale, and a pill box with marked labels of the date were provided for each patient. An electronic BP monitor was lent to the patient if necessary. To emphasise the importance of behaviour change, at the end of the home visit, the trained nurse negotiated with the patient to come up with a mutually agreed-upon goal that was incorporated into a self-care behaviour contract (see Appendix 5 Health Behaviour Contract). The patient was asked to sign the self-care behaviour contract to enhance his or her awareness of self-management. During the home visit, if the trained nurse found that the patient met the referral criteria, which will be elaborated on in Section 3.7.2.1.1.3, the nurse would arrange for him / her to go see the GP on the research team at the study centre and would follow up with the patient after the referral. The home visits typically lasted about 60 minutes. The trained community nurses documented in each case record the results of the assessment, the intervention categories performed, and the mutual goals set for self-care behaviour.

3.7.2.1.1.2 Telephone follow-up

The trained community nurse made six biweekly follow-up telephone calls to each patient after the home visit. Before calling the patient, the trained nurse would review the patient's case record to identify the target of intervention. The trained nurse monitored the patient's health condition and focused on previously identified health problems. The trained nurse also evaluated changes in knowledge, behaviour, and status of identified health issues during the follow-ups. During each phone call, the trained nurse communicated with patients in a nonjudgmental, empathetic and

encouraging manner as well as giving them feedback. During each phone call, the nurse and patient reviewed the self-care behavioural contract and also discussed whether to continue using it without any changes or to modify it. Patients were recommended to attend a face-to-face follow-up at the centre if deemed necessary. During the face-to-face follow-up, if the patients met the referral criteria, the trained community nurses would initiate a referral. The same procedure was followed in each call. Each phone call lasted about 10 minutes on average. A recording of each phone conversation was saved on a data storage card, and the results of monitoring, assessment, and intervention were recorded in the case record.

3.7.2.1.1.3 Referral

When a patient reported a BP reading that was higher than his or her usual reading, the trained community nurses assessed the patient's adherence and / or any illnesses or other circumstances that might affect BP control. After the trained nurses confirmed that the HBPM was consistent with the guidance, the patient with elevated BP was advised to see the trained nurses in the CHC face to face. If the patient met the following conditions, he or she would be referred to the GP:

a. presented symptoms that may require an adjustment or change in medication;

b. needed a further health check, and

c. had SBP $\geq$ 180 mmHg or DBP $\geq$ 110 mmHg.

When the patient was referred to the GP, the trained community nurses would provide patient-related information to the GP, including the patient's BP reading, relevant self-reported information and, if necessary, medication lists, pharmacy refill

information, and any recommendations for a change in the medication. The trained nurses would continue to follow-up with every referred patient as stipulated by the intervention programme design, and the information regarding the referral was recorded in the patient's referral record (see Appendix 6 Referral Record).

3.7.2.1.2 Decision support

The nurses strengthened their decision-making skills through pre-intervention training and implementing the protocols. The details of the training programme and the intervention protocols are presented in the following paragraphs. A case manager booklet for hypertension management, which included the intervention schedule, intervention protocols, targets of interventions and information related to anti-hypertensive drugs, was compiled for the community nurses to refer to.

3.7.2.1.2.1 Training programme

The pre-intervention training programme was created based on information gleaned through literature review and consultations with an expert in hypertension management. The literature that was reviewed included Chinese hypertension management guidelines (Liu & Writing group of 2005 Chinese GMH 2006; 2011); the training programme for community nurses in a COPD programme (Wang. S. L et al., 2008); The Omaha System (Martin, 2005), and a training outline for community nurses in China (NHFPC of RPC, 2007). The expert was an advanced practice nurse who runs a hypertension clinic in Hong Kong. The main contents of the training programme had previously been used 2010 in Hangzhou, China (Zhu, Wong, & Wu, 2014). The trainers in the present study included a doctoral student researcher, clinical experts in hypertension management, and professionals in chronic disease management.

The selected nurses:

a. were certified community nurses;

b. had at least three years working experience in community health service;

c. had an associate degree or above.

After eligible community nurses had been recruited, they were required to attend a training programme held in June and July 2012. The programme included theory and practice training. The contents included basic knowledge of hypertension and hypertension management, patient adherence and health education, self-empowerment and self-management, the Omaha System and its application, home visit and telephone follow-up, and hypertension case management (see Appendix 7 Training programme). At the end of the programme, the trainees who were community nurses had to pass an examination that tested their knowledge of both theory and practice. In the theory part, multiple-choice questions focusing on the subject matter tested whether trainees had gained the necessary knowledge for hypertension management. In the practice part, each trainee had to use the protocols established in the current study to complete the case of an eligible participant before the intervention programme commencement. The doctoral student researcher observed and recorded the trainees' performance on the protocols, and also discussed the protocols with the trainees to confirm they knew the standard practice. Trainees who completed the programme and passed the exit exam were awarded a certificate.

3.7.2.1.2.2 Intervention protocols

The protocols for home visits, telephone follow-ups, and referrals were drawn up after consulting the national guidelines for hypertension management (Liu &

Writing group of 2005 Chinese GMH, 2006; 2011), reported studies (Table 2.4), an expert, and the feasibility study conducted in 2010-2011 in a CHC in Hangzhou (Zhu et al., 2014). These evidence-based protocols were provided to the trained community nurses to help them make decisions in the management of hypertension.

3.7.2.1.2.3 Regular meetings

Regular meetings provided the chance for the trained community nurses to share any problems they encountered and discuss them with other team members. From August 2012 to February 2013, the team members attended monthly meetings and the trained community nurses attended biweekly meetings, then from March 2013 to August 2013, bimonthly meetings were held for the team members and monthly meetings for the trained community nurses.

3.7.2.1.3 Clinical information system

In this study, the clinical information system consisted of the CHC's patient health records in and the Omaha System (Chinese version) (Martin, 2005; Wong, 2012). The Chinese government requires patient health records be established for hypertensive patients (State Commission Office of Public Sectors Reform et al., 2006). These health records provide general health information for the healthcare providers, while the Omaha System focuses on providing nurse-led intervention information. The Omaha System was adopted in this study as the documentation method for recording patients' health problems, their status, any changes, as well as the intervention received. Compared with the CHC's current health recording system, the Omaha System is more systematic, specific and dynamic in recording health-related problems and intervention strategies. In American nursing practice, the System was adopted as early as 1992 as one of the standardised terminologies, and in

2014 in the United States, the System was adopted for use in electronic health records (EHR) (The Omaha System, 2015). Though it has not been adopted in China, the reliability and feasibility of the Chinese version of the Omaha System (Wong, Wang et al., 2010) in the recording of chronic diseases management has been proven. The trained community nurses used the Chinese version of the Omaha System to record the patient's current health problems as well as the results of evaluations of the patient's knowledge, his or her behaviour and the status of the identified health problems in the first visit and each follow-up. The trained community nurses could also record their interventions strategies, such as teaching / guidance / counselling, treatment and procedure, case management, and surveillance, that were conducted for each health problem in the first visit and each follow-up.

3.7.2.1.4 Self-management support

The delivery system, decision support, and clinical information system in the healthcare organisation were designed to support the trained community nurses to help patients' self-management. In this study, self-management mainly refers to self-care behaviours. The trained community nurses used the following strategies to help patients become knowledgeable and active partners in hypertension management.

a. helped patients to understand the importance of self-management;

b. encouraged patients to discuss their health conditions and set mutual goals (Appendix 5 Health Behaviour Contract);

c. helped patients to make action plans and perform self-monitoring;

d. provided information and facility resources for patients to manage their health problems;

e. provided a self-management booklet with intelligible text and pictures for patients to enhance their knowledge of and skills in self-management. This booklet was based on the Chinese National GMH (Liu & Writing Group of 2010 Chinese GMH, 2011; Wang & Yao, 2009) and was first used in the study conducted in Hangzhou, China in 2010 (Zhu et al., 2014).

3.7.2.2 Features of the nurse-led hypertension management model

The NHM model incorporated the Four-C features. The first 'C' is comprehensiveness, which was achieved through patient assessment and documentation by using the Omaha System (Martin, 2005), a standardised assessment-intervention-evaluation structure. This system can guide the trained community nurses to identify patients' health problems in the following domains: environmental, psychological, physical and health-related behaviour. The trained nurse can use a 5-point Likert scale in the Omaha system to evaluate patients' knowledge, behaviour and status for each identified healthcare problem. The intervention structure can also help the trained nurse to provide interventions for the targeted health problem.

The second 'C' is collaboration and is achieved through the trained community nurses working closely with other healthcare providers on the team to enhance patient health conditions.

The third 'C', coordination, involves the trained community nurses organising, facilitating and managing the available community and / or family resources to meet patients' health needs.

The fourth 'C' is continuity, which in the NHM begins with the home visit and regular telephone follow-ups. Whenever a patient is referred to the GP for

pharmacological treatment, the nurse continued to monitor the patient's health condition. Moreover, the intervention emphasised patients' self-management in order to help the patient continue to manage their health condition even after the end of the intervention.

3.7.2.3 Intervention fidelity

Fidelity is a critical factor for the implementation of evidence-based interventions in community settings. The definition of fidelity is consistency between the actual implementation of the intervention and the intervention programme intended (Breitenstein et al., 2010). Implementation fidelity is a critical step toward achieving the intended outcomes of the intervention. In the study, nurses' competency and nurses' adherence to protocols were two components of implementation fidelity that were monitored. Firstly, before the main study commenced, the nurses were required to attend the 36-hour training programme that was described above. After the training programme, the nurses were required to take a closed-book examination on what was taught in the training programme. Then they were asked to complete interventions on two patients according to the protocols. Secondly, the nurses' adherence to intervention protocols was assessed by self-report at the regular meetings, through observation, and by reviewing the records. In regular team member meetings, the trained community nurses were asked to report the implementation of intervention. The researcher also observed two home visits and one referral conducted by each trained community nurse in the current study. The researcher reviewed telephone records that were saved on a digital storage card to ensure that the trained community nurses were adhering to protocols in terms of the frequency and duration of the calls. The researcher also regularly reviewed case records to monitor the implementation of the protocols.

3.8 Sample size calculation

The calculation of study sample size was based on a change in SBP. G*Power 3.1 software was used to calculate the sample size. The calculations used these three parameters: desired power level (1-β), pre-specified significance level (α) and expected effect size. For the current study, we assumed that $\alpha = 0.05$ and power = 0.8. The sample size was obtained from literature on studies of similar design or intervention. In Chiu and Wong's study (2010), which involved intervention strategies similar to the current study, the effect size was 0.59. Chiu and Wong reported that the reduction of SBP mean was -7.97 (SD = 20.30) for the control group and -19.03 (SD = 16.91) for the study group. Based on their study, the calculated sample size would be 92. A total of 115 participants would allow for a 20% dropout rate.

When the effect size of 0.60 was assumed, based on a systematic review (Carter et al., 2009), in which the reduction of SBP mean was 4.8 (SD = 8.0), in a paired t-test study, a total of 48 participants would be required. Allowing for a 20% dropout rate brings the number to a total of 60 participants. Carter et al.'s study was adopted in the calculation of sample size because the reduction of SBP was close to 5 mmHg, which is considered clinically meaningful in hypertension management (Law et al., 2009).

When the middle-level of the effect size of 0.25 in repeated measures Analysis of Variance (ANOVA) was assumed, a total of 100 participants (50 in each group) would be required, according to the software for sample size calculation. Allowing for a 20% dropout rate, 126 patients would therefore need to be recruited.

3.9 Outcome measures

Outcome measures in this study were clinical outcome, functional outcome, satisfaction, and utilisation of healthcare service. Clinical outcomes were BP reading, BP reduction, and control rate of BP. Functional outcomes in this study were self-care behaviours, self-efficacy, and QoL. Utilisation of healthcare services was used as the indicator of cost. Patient satisfaction was the satisfaction indicator.

The primary outcome in this study was the difference between the two groups in the reduction of SBP and DBP immediately after intervention. The secondary outcomes were the differences between the two groups in changes in BP control, self-care behaviours, self-efficacy, QoL, utilisation of healthcare services and patient satisfaction. Information on the instruments of the outcome measures is summarised in Table 3.3. The details of the outcome measurements are described below.

Table 3.3 Description of the instruments of the outcome measures

Category	Indicator	Item	Instruments	Range
Clinical outcome	SBP /DBP	1	SBP and DBP were measured by a calibrated mercury sphygmomanometer	-
Functional outcome	Self-care behaviour	6	Self-care behaviour scale	-
	Self-efficacy	6	Short-form Chronic Disease Self-Efficacy Scale (Chinese Version)	1-10
	Quality of life		SF-36 (Chinese Version):	-
		10	Physical Functioning	0-100
		4	Role-Physical	0-100
		2	Bodily Pain	0-100
		5	General Health	0-100
		4	Vitality	0-100
		2	Social Functioning	0-100
		3	Role-Emotional	0-100
		5	Mental Health	0-100
Cost	Utilisation of healthcare services	6	Questionnaire of utilisation of healthcare services	-
Satisfaction	Patient satisfaction	8	Patients' Satisfaction Scale	-
Total items		63		

3.9.1 Blood pressure

SBP and DBP were measured twice using the same calibrated YUYUE sphygmomanometer and YUYUE stethoscope, and the average of the two BP readings was recorded. The way BP measurements were taken, including time intervals, body position, cuff application and size of cuff when taking a measurement, followed the hypertension guidelines (Aronow et al., 2011; Liu & Writing Group of 2010 Chinese GMH, 2011). In order to get a reliable BP measurement, at least two readings were taken once the patient was comfortable and settled for at least five minutes. BP was measured in the sitting position with the back supported, feet on the floor, arm supported in a horizontal position and the BP cuff at heart level. At the initial evaluation, BP was measured in each arm, and the arm with the highest BP used for reassessing BP. An appropriately sized cuff with a bladder that encircles at least 80% of the upper arm circumference was used. The interval of two sequential measurements was at least two minutes, as specified in China's national guidelines (Liu & Writing Group of 2010 Chinese GMH, 2011). These requirements ensured the reliability of the evaluation of the BP readings.

3.9.2 Self-care behaviours

Self-care behaviour is an indicator for evaluating a patient's ability in managing chronic disease. In this study, self-care refers to adherence to treatment recommendations, symptom response, and adoption of healthy lifestyles (Riegel, 2009). A scale of self-care behaviour used in previous studies (Chiu & Wong, 2010; Wong et al., 2005) was modified and used in this study (see Appendix 8 Scale of self-care behaviours). The measures of self-care behaviour in the study covered two aspects: adherence to prescribed anti-hypertensive drug behaviour (score ranged

from 0 to 3) and suggested non-pharmacological behaviour (score ranged from 0 to 8). A higher score meant better adherence.

The data collector recorded the name, dose, time and frequency of the prescribed anti-hypertensive drug at each time point of data collection. At T1 or T2, the number of participants whose prescription of anti-hypertensive drug was maintained, changed, increased or decreased was checked. When both the drugs and dose were the same as the previous record, it was regarded as calculated as 'drug maintained'; when the anti-hypertensive drug differed from the previous record, it was recorded as 'drug changed'; when the dose of previous prescribed anti-hypertensive drug was added, it was counted as 'drug increased' while the dose of previous drugs was reduced, it was treated as 'drug decreased'.

Patient adherence to prescribed anti-hypertensive drug behaviour was measured by having the data collector compare the previous paper records of drug prescriptions with the patient's self-reported medicine-taking behaviours in the three following aspects: time, frequency and dose. Each aspect was scored respectively. When patients' reports were completely consistent with the prescriptions in each of the aspects, the score of 1 was recorded; otherwise, the score of 0 was recorded. A total score of adherence to anti-hypertensive drugs ranged from 0 to 3.

Suggested non-pharmacological behaviours were smoking cessation, alcohol restriction, salt restriction, regular physical activity, and HBPM. Smoking cessation was defined as the patient having not smoked in the previous four weeks (0 = non-adherence, 1 = adherence). The definition of alcohol restriction was consuming less than 25 g of alcohol per day in the previous four weeks (0 = non-adherence, 1 = adherence). Salt restriction meant less than 6 g per day (0 = non-adherence, 1 =

partial adherence, 2 = full adherence). Regular activity referred to engaging in aerobic physical activity, such as brisk walking, for at least 20 minutes per day and at least three days per week in the previous four weeks (0 = non-adherence, 1 = partial adherence, 2 = full adherence). HBPM meant that a patient had monitored his or her BP at home at least once per day in the previous four weeks (0 = non-adherence, 1 = partial adherence, 2 = full adherence).

In addition, the adherence rate for each kind of behaviour was calculated by dividing the number of participants who fully adhered to their prescription or the suggestions by the total number of participants.

3.9.3 Self-efficacy

Self-efficacy refers to the patients' belief about their ability to participate in a given behaviour (Bandura, Freman, & Lightsey, 1999). In this study, patients' self-efficacy was measured using the Chinese version of the CDSES (Chow & Wong, 2014). This version of the scale was translated from Self-efficacy for Managing Chronic Disease 6-Item Scale (Lorig et al., 2001) and includes rating of a patient's confidence in general disease management and symptom management (see Appendix 9 Short-form Chronic Disease Self-Efficacy Scale). The rating scale for each item ranged from 1 (not at all confident) to 10 (totally confident). The Chinese version of the scale was tested in Hong Kong among elderly people with chronic diseases and found to be a reliable scale. Cronbach's alpha coefficient for the scale was 0.96, and the interclass correlation coefficient value was 0.98 in an examination of test-retest reliability (Chow & Wong, 2014).

3.9.4 Quality of life

QoL measures patients' perceived state of well-being. The Chinese version of the SF-36 (Fang, 2000) was used to measure patient's QoL in the study (see Appendix 10 SF-36). The SF-36 is a general health measure, not specific to any age, disease, or treatment group, that compares the relative burden of disease with the relative benefits of treatments. The SF-36 can easily be used for comparison across diseases and settings. This 36-item scale assesses the following eight domains of functional status: Physical Functioning (PF), Role-Physical (RP), Bodily Pain, General Health (GH), Vitality (VT), Social Functioning (SF), Role-Emotional (RE) and Mental Health (MH). The score for each domain ranges from 0 (worst possible health status) to 100 (best possible health status). The inter-rater reliability of the eight domains of SF-36 ranged from 0.63 to 0.94 among Chinese patients with chronic diseases in Fang's study (2000).

3.9.5 Utilisation of healthcare services

In this hypertension management study, utilisation of healthcare services refers to patients seeking and receiving healthcare services (see Appendix 11 Utilisation of Healthcare Services). For seeking healthcare services, the study focused on patients' behaviours in self-medication, medical visits, hospitalisations and going to the emergency room. For receiving healthcare services, the study looked at home visit and telephone follow-ups. The percentage and frequency of using these services was recorded and calculated.

3.9.6 Patient satisfaction

Patient satisfaction refers to the patient's perception of care. Patient satisfaction has become increasingly important in evaluating the performance of healthcare providers (NHFPC of PRC, 2011, April 25). In this study, patient satisfaction was

measured using a scale modified from the Patients' Satisfaction Scale employed by Wong et al. (2005) (see Appendix 12 Patients' Satisfaction Scale). The modified scale contains eight items, including hypertension-related knowledge, self-care skill, counselling, and provision of healthcare services in the community health setting. The items were ranked on a six-point scale (5 = very satisfactory, 4 = satisfactory, 3 = fair, 2 = unsatisfactory, 1 = very unsatisfactory, 0 = not applicable). In addition, the patient satisfaction rate was calculated by dividing the number of patients who scored "very satisfactory" and "satisfactory" for an item by the total number of participants.

3.9.7 Reliability and validity of the outcome measures

A reliable instrument is essential for outcome measurement. In this study, internal consistency, test-retest reliability, intra-rater reliability and inter-rater reliability of the outcome measures were examined before the main study commenced.

To test the reliability of the BP readings taken by the two research assistants, they were required to measure the same patient following the same BP measurement protocol and using the same calibrated mercury sphygmomanometer. The BP readings of 30 patients showed that ICC in the BP readings measured by the two research assistants was 0.96 in SBP and 0.97 in DBP. To test the reliability of the BP readings from the calibrated mercury sphygmomanometer, the BP of 30 patients was measured with the calibrated mercury sphygmomanometer as well as with an electronic sphygmomanometer (Omron 7152). The ICC was 0.94 and 0.90 in SBP and DBP, respectively, between the two BP measurement devices. The test-retest reliability of the Self-Care Behaviour Scale and the scale for the utilisation of healthcare services was examined by conducting a second test 7-10 days after the

first test was completed. The ICC was 0.92 in the Self-Care Behaviour Scale and 0.95 in the scale for the utilisation of healthcare services. Internal consistency with Cronbach's coefficient alpha α was tested for the CDSES for self-efficacy, the Patient Satisfaction Scale for patient satisfaction, and the SF-36 (Chinese version) for QoL among 73 participants in the previous feasibility study. The Cronbach's coefficient alpha α was 0.82 for the CDSES, 0.92 for the Patient Satisfaction Scale and 0.71-0.94 for the eight domains of the SF-36 (Chinese version). The results of the above reliability tests were reported in the feasibility study (Zhu et al., 2014). The findings indicated that the method and questionnaires used for outcome measures in the study were reliable.

There was a lack of standard objective methods of measuring validity of self-report survey scales such as patient self-care behaviours, self-efficacy, QoL, utilisation of healthcare services and patient satisfaction. In the current study, every effort was made to ensure reliable questionnaires were used. A panel of experts reviewed the questionnaires and all agreed that the contents of the questionnaires were adequate; thus, the content validity of the questionnaires was supported. Both the previous study and the feasibility study supported that the questionnaires used in the current study were acceptable and trustworthy.

3.10 Data collection

Data was collected from August 2012 to September 2013. The data collection period lasted for a full year to avoid any influence of seasonal effects on the study's results. Two community nurses who were blinded to the group assignment and the interventions were trained as research assistants for the chart interview and skills including taking measurements of BP, body weight and height. The two research

assistants' inter-rater reliability was greater than 0.9 when tested on five hypertensive patients before the study commenced.

After each patient had been recruited and signed a consent form, the research assistants collected the patient's demographic and clinical data and outcome data. The demographic data, including participants' gender, educational level, living arrangement, marital status, employment status, income, and age, were collected through interviews. Clinical data included co-morbidity, duration of hypertension, participants' BMI and WC. Co-morbidity and duration of hypertension were obtained through interviews and confirmed by reviewing the patients' health records, while patients' BMI and WC were measured by the research assistants using a standardised measuring tape. The research assistants measured the patients' BP. They also collected the other outcomes from the answers given by the patients responding to self-report questionnaires during the face-to-face interviews.

The research assistants collected all the participants' data in a clinic of the CHC. The research assistants telephoned each patient and reminded him or her of the time and date for each data collection. Data collection took, on average, about 30 minutes at each time point. The measurement schedule is shown in Table 3.4. Data of BP readings, self-care behaviour, self-efficacy, QoL and utilisation of healthcare services were collected at three time points: at baseline (T0), at 12 weeks after recruitment, immediately after the intervention (T1), and at 16 weeks after recruitment, four weeks after intervention completed (T2). Data on patient satisfaction were collected at T0 and T1. Collected data at baseline (T0), T1 and T2 were compared to detect the immediate and sustained intervention effects respectively.

Table 3.4 Measurement schedule

Measurement	T0	T1	T2
Socio-demographic characteristic (e.g. gender, living status etc.)	√	-	-
Clinical characteristic (e.g. comorbidity, duration of diagnosis, etc.)	√	-	-
SBP / DBP	√	√	√
Self-care behaviour	√	√	√
Self-efficacy	√	√	√
Quality of life	√	√	√
Utilisation of healthcare services	√	√	√
Patient satisfaction	√	√	-

T0: at recruitment, T1: at 12 weeks after recruitment, T2: at 16 weeks after recruitment

3.11 Ethical considerations

Prior to the commencement of the study, ethical approval was obtained from the Human Subject Ethics Sub-committee of the Hong Kong Polytechnic University (Project ID: HSEARS20120809001) (see Appendix 13 Ethical approval). Permission was also obtained from the CHC involved in the study. The CHC signed an agreement of cooperation which included consideration of the ethical issue.

Prior to the recruitment of patients, the research assistants orally introduced information about the study (see Appendix 14 Information sheet) face-to-face with potential participants. They were told about the study's aim, duration, and possible interventions for usual care or NHM. How the participants would be randomly assigned to either the control group or the study group was illustrated. Participants' rights were emphasised, and the potential participants were told that (a) their decision to participate or not would have no bearing on the usual care that they were entitled to receive, and (b) they had the right to withdraw at any time from the study without penalty. The potential participants were also assured that the data collected would only be used for academic purposes. All of this information was also provided to the potential participants in written form. After the potential patients verbally

agreed to participate, they were asked to sign a consent form (see Appendix 15 Consent Form).

To ensure confidentiality, participants' personal identities were protected; all data collected by the data collectors were identifiable by serial numbers alone. For the study group participants, their name appeared on the first page of their case record during the intervention period but the name was covered after the intervention was completed.

To ensure equal opportunity of receiving the same intervention, participants in the control group were given the option of receiving the NHM after the programme finished.

3.12 Data analysis plan

3.12.1 Missing data management

We performed intention-to-treat analysis (ITT), which means all randomised participants in the study were included in the analysis (Shao & Zhong 2003). The frequency and percentage of missing values are reported in Table 3.5. The percentage of missing values was less than 10% of values of observations of each measurement. Missing data in QoL was replaced by recommendation from the Chinese version of SF-36 Scale (Fang, 2000) which suggests that if respondents answered questions for at least half of the domain, the scores of missing items could be replaced by the average score of that domain. Meanwhile, if more than 50% of the items in a domain are missing, the statistical analysis should exclude this domain. The item response rates in this study were actually high; hence, no domain was excluded. Last observation carried forward was used in replacing the other missing data.

Table 3.5 Frequency and percentage of missing values in the data fields

Measurement	Variable	Value of observation	Missing value	
	n	n	n	%
Participants' characteristics	14	14 × 134 = 1876	0	0.0
Blood pressure readings	2	2 × 3 × 134 = 804	58	7.2
Self-care behaviours	6	6 × 3 × 134 = 2412	184	7.6
Self-efficacy	6	6 × 3 × 134 = 2412	204	8.5
Quality of life	36	36 × 3 × 134 = 14472	1080	7.5
Utilisation of healthcare service	6	6 × 3 × 134 = 2412	180	7.5
Patient satisfaction	8	8 × 2 × 134 = 2144	112	5.2
Total	**78**	**26532**	**1818**	**6.9**

3.12.2 Method of data analysis

All quantitative data were recorded and analysed using the IBM SPSS Statistics for Windows, Version 20.0 (IBM Corp. Armonk, NY). The types of statistical analysis and test for data are presented in Table 3.6.

When comparing demographic and clinical characteristics at baseline between the two groups, the Chi-square test was used for a categorical variable while unpaired t-test was used for continuous variables based on an assumption of normal distribution of the data.

Assuming the data was normally distributed, the repeated measures ANOVA were carried out to evaluate the effects of the intervention by comparing groups over time in outcome measures: BP, self-efficacy and QoL. In this kind of analysis, group (control group and study group) and time (T0: baseline, T1: 12 weeks after recruitment, T2: 16 weeks after recruitment) were entered as independent variables and the outcome measures entered as dependent variables. The repeated measures ANOVA was used to examine the within-group (time) effects, between-group (group) effects, and the interaction effects (time × group) to determine the difference between groups in terms of these outcomes over time. In the repeated measures

ANOVA, Mauchly's test of sphericity was performed to determine whether adjustments were needed for the repeated measures. If the Mauchly's test of sphericity was significant ($p < .05$), the Greenhouse-Geisser correction was used to adjust the test. When a significant difference showed up in the within-group, between-group or interaction group, the one-way repeated measures ANOVA was performed for each group. For further comparison of the within-group difference at different time points, the Bonferroni post hoc test was performed as a protection against Type I errors to adjust for the set of contrasts (T0 versus T1, T1 versus T2, T0 versus T2) (Portney & Watkins, 2009, p 489). Because a Bonferroni test from SPSS under 'post hoc comparisons' was required, each pair of means was adjusted so that the result was directly compared to 0.05. In addition, the unpaired t-test was used to compare the difference between the two groups at the same time points in BP outcome, self-efficacy and QoL. More important is that the mean difference of the change in each time period (T0 versus T1, T1 versus T2, T0 versus T2) between the study group and the control group was compared in the unpaired t-test.

In terms of BP control rate, the number of patients who had their BP controlled to below 140 / 90 mmHg was calculated. Since reducing SBP by 5 mmHg and 10 mmHg and DBP by 2 mmHg and 5 mmHg are regarded as clinically meaningful decreases that would contribute significantly to reducing the risk of CVDs (Carter et al., 2009; Lewington, Clarke, Qizilbash, Peto, & Collins, 2002), the number of patients who achieved this clinically significant reduction of their BP was calculated as well. The Chi-square test was used to compare differences in the BP control rate and the rate for this clinically significant reduction between the two groups at T1 and T2.

As for the outcome of self-care behaviour and frequency of utilisation of healthcare services in terms of self-prescription, outpatient department visits, emergency room visits, nights of hospitalisation, home visits, and telephone follow-ups, the Mann-Whitney test was used to determine the difference between the two groups at each time point. The Friedman test was used to examine the effects of intervention over time in each group. When a significant difference was detected, the Wilcox signed-ranks test was performed to test each set of contrasts (T0 versus T1, T1 versus T2, T0 versus T2) and the post hoc test was performed with Type I error to adjust at 0.0167 (0.05/3) for each pair (T0 versus T1, T1 versus T2, T0 versus T2).

The rate of self-care behaviour and utilisation of healthcare services in terms of self-prescription, outpatient visits, emergency room visits, nights of hospitalisation, and home visits, telephone follow-ups were calculated and the Chi-square test was performed to determine the difference between the two groups.

Table 3.6 Data collection and types of statistical tests

Measure	Time point	Statistical Test	
Socio-demographic characteristics	T0	Categorical variable Continuous variable	Chi-square test Unpaired t-test
Clinical characteristics	T0	Categorical variable Continuous variable	Chi-square test Unpaired t-test
Blood pressure readings	T0 T1 T2	Continuous variable	Two-way repeated measures ANOVA One-way repeated measures ANOVA Bonferroni post hoc test Unpaired t-test
Blood pressure reduction	T1 T2	Continuous variable	Unpaired t-test
Rate of blood pressure control and the reduction achieved a clinical meaning	T1 T2	Categorical variable	Chi-square test
Self-care behaviour	T0 T1 T2	Continuous variable	Friedman test Wilcoxon signed-ranks test Mann-Whitney U test
Self-care behaviour rate	T0 T1 T2	Categorical variable	Chi-square test
Self-efficacy	T0 T1 T2	Continuous variable	Two-way repeated measures ANOVA One-way repeated measures ANOVA Bonferroni post hoc test Unpaired t-test
Quality of life	T0 T1 T2	Continuous variable	Two-way repeated measures ANOVA One-way repeated measures ANOVA Bonferroni post hoc test Unpaired t-test
Utilisation of healthcare services	T0 T1 T2	Continuous variable Categorical variable	Friedman test Wilcoxon signed-ranks test Mann-Whitney U test Chi-square test
Patient satisfaction	T0 T1	Continuous variable	Mann-Whitney U test Wilcoxon signed-ranks test

ANOVA: Analysis of variance

3.13 Summary

This chapter focused on how the NHM model was established and how an RCT was designed to test the model's effectiveness. The details of the intervention, including the components of the intervention as well as performers, duration, frequency, examination methods and tools in the intervention, were presented. The next chapter presents the results of the study that was conducted according to the methodology presented in this chapter.

CHAPTER 4

RESULTS

4.1 Introduction

This chapter reports the results of this single-blinded RCT of the NHM programme. A description of the recruitment of participants, follow-up, and the attrition rate is provided. Then the participant characteristics and baseline data of outcomes are described. This chapter focuses on presenting the effects of the model on patient outcomes, which were BP outcome, self-care behaviours, self-efficacy, QoL, utilisation of healthcare services and patient satisfaction. Both the immediate and the sustained effects were considered.

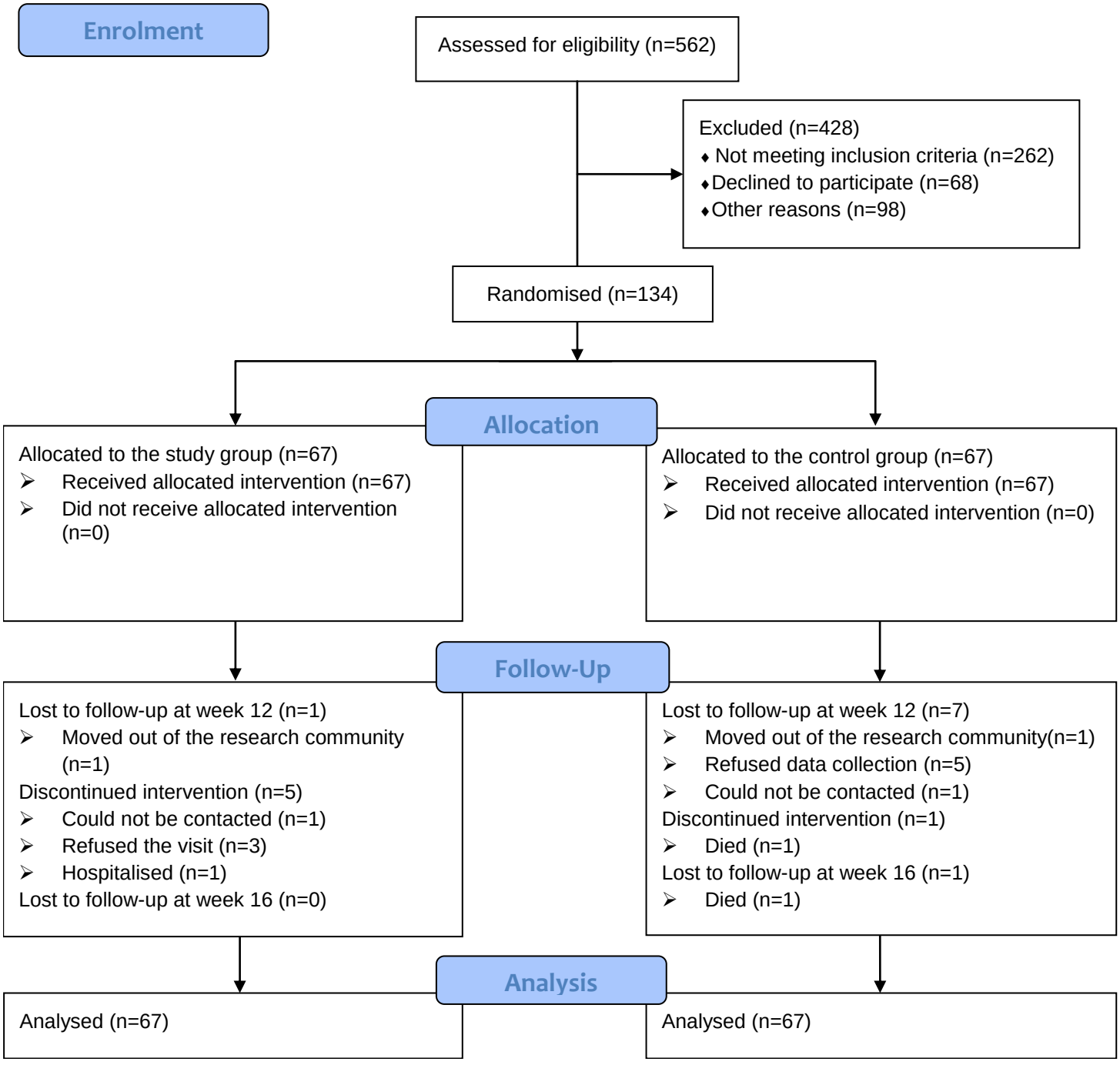
4.2 Participants recruitment

A total of 562 residents within the CHC service network attended the screening for eligibility in August 2012 and May 2013. A total of 428 potential participants could not be recruited into the current study for the following reasons: 262 did not meet the inclusion criteria, 98 met one or more of the exclusion criteria, and 68 refused to participate. Ultimately, 134 eligible patients agreed to join the study and signed a consent form. Sixty-seven participants were randomly assigned to the control group and 67 participants to the study group. (Figure 4.1)

A total of 120 (89.6%) participants ($n_{study} = 61$, $n_{control} = 59$) were assessed at T1 (immediately after the 12-week intervention). A total of 119 (88.8%) ($n_{study} = 61$, $n_{control} = 58$) participants completed data collection at T2 (4 weeks after the intervention completed). A total of 15 (11.2%) participants ($n_{study} = 6$, $n_{control} = 9$)

dropped out of the study. The reasons for dropping out were as follows. Two of the participants ($n_{study} = 1$, $n_{control} = 1$) moved out of the research community and could not return to the CHC for data collection. Two ($n_{study} = 1$, $n_{control} = 1$) could not be contacted. One was hospitalised ($n_{study} = 1$) due to acute hepatitis. Two ($n_{control} = 2$) died due to a cardiovascular incident. Three ($n_{study} = 3$) refused the home visit, and five ($n_{study} = 5$) refused to participate in the data collection at T1 (Figure 4.1). By using ITT analysis, all participants who dropped out during the study were included in the data analysis.

Figure 4.1 CONSORT 2010 Flow Diagram



See CONSORT TRANSPARENT REPORTING OF TRIALS website

http://www.consort-statement.org/

4.3 Participants' characteristics

Table 4.1 shows details of the socio-demographic and clinical characteristics of the participants. The mean age of the participants was 69 years (SD = 9.77). The distribution of males and females was balanced (male 49.3% versus female 50.7%). The majority of participants (73.1%) had received a secondary education or above while 5.2% had no formal education. More than four-fifths of participants (82.1%) were married, and 91.0% lived with their families or others. Eighty-seven percent were unemployed or retired. Nearly 95% of the participants reported that their income was equal to or greater than their expenditure.

In respect to clinical characteristics, the mean number of years of diagnosis with hypertension was 11 years (SD = 8.9). More than three-quarters of the participants (76.1%) had one or more comorbidities, including diabetes (23.9%), post-stroke (9.0%), and heart disease (25.4%). Ninety-one percent of the participants were currently being treated with anti-hypertensive drugs. More than half of participants (56%) had been prescribed one anti-hypertensive drug, 28.4% were taking two anti-hypertensive drugs, and 6.7% were on three or more. The most commonly used anti-hypertensive drug was a calcium channel blocker (68.0%), followed by an angiotensin receptor blocker (35.3%) and a beta-adrenergic-blocker (23.5%). In addition, 11.8% of participants were being treated with compound anti-hypertensive drugs. The mean BMI and WC of the participants were 24 kg / m^2 (SD = 3.30) and 87 cm (SD = 9.50), respectively.

A comparison of the characteristics of the study group participants and the control group participants was conducted to evaluate the results of randomization. Because of a normal distribution, the unpaired t-test was used to compare the differences between the two groups in participants' age, number of years diagnosed

with hypertension, as well as BMI and WC. The results showed that the two groups were comparable, and no statistically significant difference was found between the two groups in those characteristics. The Chi-square test also revealed that the two groups were similarly distributed for gender, education level, living status, marital status, employment, income, comorbidity, and use of anti-hypertensive drugs. In general, the two groups had equivalent socio-demographic and clinical characteristics (Table 4.1).

As for the 15 participants who dropped out of the study, their characteristics can be seen in Table 4.2. The socio-demographic and clinical characteristics of participants who dropped out did not differ from the participants who completed the study.

Table 4.1 Socio-demographic and clinical characteristics of participants in the control group and the study group

Characteristic	Total (n = 134)	Control group (n = 67)	Study group (n = 67)	t- test/ $\chi 2$ test	*p*-value
Socio-demographic characteristics					
Age (years), mean (SD)	69 (9.77)	69 (10.15)	69 (9.46)	-0.15	.881 [a]
Sex, n (%)					
Male	66 (49.3)	32 (47.8)	34 (50.7)	0.12	.730 [b]
Female	68 (50.7)	35 (52.2)	33 (49.3)		
Educational level, n (%)					
No formal education	7 (5.2)	5 (7.5)	2 (3.0)		.716 [c]
Primary education	29 (21.6)	15 (22.4)	14 (20.9)		
Secondary education	55 (41.0)	27 (40.3)	28 (41.8)		
Tertiary education	43 (32.1)	20 (29.9)	23 (34.3)		
Living status, n (%)					
Living alone	12 (9.0)	6 (9.0)	6 (9.0)	0.00	1.000 [b]
Living with others	122 (91.0)	61 (91.0)	61 (91.0)		
Marital status, n (%)					
Married	110 (82.1)	56 (83.6)	54 (80.6)	0.20	.652 [b]
Single/ Divorced / Widowed	24 (17.9)	11 (16.4)	13 (19.4)		
Employment, n (%)					
Employed	17 (12.7)	9 (13.4)	8 (11.9)	0.07	.795 [b]
Unemployed / Retirement	117 (87.3)	58 (86.6)	59 (88.1)		
Income, n (%)					
More than expenses	37 (27.6)	19 (28.4)	18 (26.9)		.526 [c]
Equal to expense	90 (67.2)	43 (64.2)	47 (70.1)		
Less than expenses	7 (5.2)	5 (7.5)	2 (3.0)		
Clinical characteristics					
Number of years with hypertension (years), mean (SD)	11 (8.90)	11 (8.22)	12 (9.52)	-1.11	.270 [a]
Comorbidity, n (%) [#]					

Yes	102 (76.1)	49 (73.1)	53 (79.1)	0.66	.418 [b]
Diabetes (yes)	32 (23.9)	13 (19.4)	19 (28.4)	1.48	.224 [b]
Post-stroke (yes)	12 (9.0)	6 (9.0)	6 (9.0)	0.00	1.000 [b]
Heart disease (yes)	34 (25.4)	15 (22.4)	19 (28.4)	0.63	.427 [b]
Use of anti-hypertensive drug, n (%)					
Number of anti-hypertensive drugs					
0	12 (9.0)	10 (14.9)	2 (3.0)		
1	75 (56.0)	35 (52.2)	40 (59.7)		
2	38 (28.4)	18 (26.9)	20 (29.9)		
≥3	9 (6.7)	4 (6.0)	5 (7.5)		
Class of anti-hypertensive drug [#]					
Use of calcium channel blocker (yes)	83 (68.0)	37 (64.9)	46 (70.8)	0.48	.489 [b]
Use of angiotensin receptor blocker (yes)	42 (35.3)	23 (40.4)	19 (29.2)	1.64	.197 [b]
Use of angiotensin converting enzyme inhibitor (yes)	7 (5.7)	3 (5.3)	4 (6.2)		.833 [c]
Use of Beta-adrenergic-blocker (yes)	28 (23.5)	10 (17.5)	18 (27.7)	1.77	.184 [b]
Use of thiazide-type diuretic (yes)	2 (1.6)	0 (0.0)	2 (3.1)		.496 [c]
Use of compound anti-hypertensive drugs (yes)	14 (11.8)	7 (12.3)	7 (10.8)	0.07	.794 [b]
Body mass index (kg / m^{-2}), mean (SD)	24 (3.30)	25 (3.39)	24 (3.23)	0.30	.768 [a]
Waist circumference (cm), mean (SD)	87 (9.50)	87 (10.01)	86 (9.00)	0.51	.610 [a]

a. Unpaired *t*-test, b. Pearson Chi-square, c. Fisher's Exact Test, # Participants can choose more than one option in these parameters

Table 4.2 Comparison of socio-demographic and clinical characteristics between completed and uncompleted participants

Characteristic	Total (n = 134)	Completed (n = 119)	Uncompleted (n = 15)	t-test /χ^2test	*p*-value
Socio-demographic characteristics					
Age (years), mean (SD)	69 (9.77)	69 (9.78)	69 (10.09)	0.23	.818 [a]
Sex, n (%)					
Male	66 (49.3)	61 (51.3)	5 (33.3)	1.71	.191 [b]
Female	68 (50.7)	58 (48.7)	10 (66.7)		
Educational level, n (%)					
No formal education	7 (5.2)	5 (4.2)	2 (13.3)		
Primary education	29 (21.6)	26 (21.8)	3 (20.0)		
Secondary education	55 (41.0)	51 (42.9)	4 (26.7)		
Tertiary education	43 (32.1)	37 (31.1)	6 (40.0)		
Living status, n (%)					
Living alone	12 (9.0)	12 (10.1)	0 (0.0)		.360 [c]
Living with others	122 (91.0)	107 (89.9)	15 (100.0)		
Marital status, n (%)					
Married	110 (82.1)	96 (80.7)	14 (93.3)	0.72	.397 [d]
Single/ Divorced / Widowed	24 (17.9)	23 (19.3)	1 (6.7)		
Employment, n (%)					
Employed	17 (12.7)	16 (13.2)	1 (7.7)	0.017	.896 [d]
Unemployed / Retired	117 (87.3)	105 (86.8)	12 (92.3)		
Income, n (%)					
More than expenses	37 (27.6)	32 (26.9)	5 (33.3)		
Equal to expense	90 (67.2)	80 (67.2)	10 (66.7)		
Less than expenses	7 (5.2)	7 (5.8)	0 (0.0)		
Clinical characteristics					
Mean duration of hypertension (years), mean (SD)	11 (8.90)	12 (9.1)	8 (6.0)	1.50	.135 [a]
Comorbidity, n (%) [#]					

Yes	102 (76.1)	92 (77.3)	10 (66.7)	0.35	.555 [d]
Diabetes (yes)	32 (23.9)	25 (21.0)	7 (46.7)	3.52	.061 [d]
Post-stroke (yes)	12 (9.0)	10 (8.4)	2 (13.3)	0.02	.880 [d]
Heart disease (yes)	34 (25.4)	32 (26.9)	2 (13.3)	0.68	.411 [d]
Use of anti-hypertensive drugs, n (%)					
Number of anti-hypertensive drugs					
0	12 (9.0)	10 (8.3)	2 (13.3)		.521 [c]
1	75 (56.0)	65 (54.6)	10 (66.7)		
2	38 (28.4)	35 (29.4)	3 (20.0)		
≥3	9 (6.7)	9 (7.6)	0 (0.0)		
Class of anti-hypertensive drug [#]					
Use of calcium channel blocker (yes)	83 (68.0)	72 (66.1)	11 (84.6)	1.09	.298 [b]
Use of angiotensin receptor blocker (yes)	42 (35.3)	39 (35.8)	3 (23.1)	0.36	.547 [d]
Use of angiotensin converting enzyme inhibitor (yes)	7 (5.7)	7 (6.4)	0 (0.0)		1.000 [c]
Use of Beta-adrenergic-blocker (yes)	28 (23.5)	26 (23.9)	2 (15.4)	0.11	.736 [d]
Use of thiazide-type diuretic (yes)	2 (1.6)	2 (1.8)	0 (0.0)		1.000 [c]
Use of compound anti-hypertensive drugs (yes)	14 (11.8)	13 (11.9)	1 (7.7)	0.00	1.000 [d]
Body mass index (kg / m^{-2}), mean (SD)	24 (3.30)	24 (3.14)	25 (4.47)	-0.11	.911 [a]
Waist circumference (cm), mean (SD)	87 (9.50)	87 (9.34)	86 (10.98)	0.15	.884 [a]

a. Unpaired t-test, b. Pearson Chi-square, c. Fisher's Exact Test, d. Continuity Corrected, # Participants can choose more than one option in these parameters

Table 4.3 Comparison of outcome measures at baseline between the control group and the study group

Outcome measure	Total (n = 134)	Control group (n = 67)	Study group (n = 67)	t-test /χ2test	p-value
Blood pressure reading (mmHg), mean (SD)					
Systolic blood pressure	151.78 (15.79)	149.65 (14.59)	153.90 (16.74)	-1.57	.119 [a]
Diastolic blood pressure	83.08 (11.43)	83.53 (11.45)	82.63 (11.47)	0.45	.652 [a]
Self-care behaviour, median [IQR]					
Anti-hypertensive drugs	3 [1-3]	3 [2-3]	3 [1-3]	-1.92	.055 [c]
HBPM daily	1 [1-1]	1 [1-2]	1 [1-1]	-0.46	.649 [c]
Smoking cessation	1 [1-1]	1 [1-1]	1 [1-1]	-1.21	.228 [c]
Alcohol restriction	1 [1-1]	1 [1-1]	1 [1-1]	-1.57	.117 [c]
Salt restriction	1 [1-1]	1 [1-1]	1 [1-1]	-0.83	.407 [c]
Physical activity	2 [1-2]	2 [1-2]	2 [1-2]	-0.66	.507 [c]
Self-efficacy, mean (SD)	6.33 (1.89)	6.71 (1.58)	5.95 (2.05)	2.46	.015 [b]
Quality of life, mean (SD)					
Physical Functioning	84.70 (13.88)	84.25 (14.04)	85.15 (13.82)	-0.37	.710 [a]
Role-Physical	66.60 (37.41)	70.90 (34.43)	62.31 (39.97)	1.33	.185 [a]
Bodily Pain	67.20 (23.69)	67.51 (23.35)	66.90 (24.20)	0.15	.882 [a]
General Health	49.67 (15.73)	50.91 (15.19)	48.42 (16.28)	0.92	.361 [a]
Vitality	69.66 (17.57)	71.64 (17.37)	67.69 (17.67)	1.31	.194 [a]
Social Functioning	82.84 (21.00)	84.89 (19.77)	80.78 (22.12)	1.13	.259 [a]
Role-Emotional	74.63 (37.73)	77.11 (36.33)	72.14 (39.18)	0.76	.447 [a]
Mental Health	77.31 (14.97)	78.69 (13.67)	75.94 (16.16)	1.06	.290 [a]
Utilisation of healthcare service					
Self-prescription, n (%)	30 (22.4)	12 (17.9)	18 (26.9)	1.55	.214 [b]
Frequency of self-prescription, median [IQR]	0 [0-0]	0 [0-0]	0 [0-1]	-1.32	.187 [c]

Visited outpatient department, n (%)	100 (74.6)	49 (73.1)	51 (76.1)	0.16	.691 [b]
Frequency of visiting outpatient department, median [IQR]	3 [1-3]	3 [0-3]	3 [1-3]	-0.62	.539 [c]
Visited emergency room, n (%)	6 (4.5)	2 (3.0)	4 (6.0)		.680 [d]
Frequency of visiting emergency room, median [IQR]	0 [0-0]	0 [0-0]	0 [0-0]	-0.83	.405 [c]
Hospitalised, n (%)	6 (4.5)	1 (1.5)	5 (7.5)		.208 [d]
Nights of hospitalised, median [IQR]	0 [0-0]	0 [0-0]	0 [0-0]	-1.75	.081 [c]
Received home visit, n (%)	1 (0.7)	1 (1.5)	0 (0.0)		1.000 [d]
Frequency of receiving home visits, median [IQR]	0 [0-0]	0 [0-0]	0 [0-0]	-1.00	.317 [c]
Received telephone follow-up, n (%)	9 (6.7)	6 (9.0)	3 (4.5)		.490 [d]
Frequency of receiving telephone follow-ups, median [IQR]	0 [0-0]	0 [0-0]	0 [0-0]	-1.02	.310 [c]
Patient satisfaction, median [IQR]	0 [0-8]	0 [0-8]	3 [0-15]	-1.35	.176 [c]

a. Unpaired t-test, b.χ^2test, c. Mann-Whitney U test, d. Fisher's Exact Test

4.4 Outcome measures

4.4.1 Baseline of patient outcomes

Table 4.3 shows a baseline of patient outcomes as well as the results of the comparisons of the two groups. The outcomes were BP reading, self-care behaviour, self-efficacy, QoL, patient satisfaction and utilisation of healthcare services.

The mean SBP of all participants at baseline was 151.78 mmHg (SD = 15.79), and DBP was 83.08 (SD = 11.43) mmHg. The study group had a little higher SBP reading (153.90 mmHg) than the control group (149.65 mmHg) but the difference was not statistically significant. The DBP in the control group (83.53 mmHg) was similar to the study group (82.63 mmHg).

As for self-care behaviour, there was no significant difference between the two groups in the median score of anti-hypertensive drugs, daily HBPM, smoking cessation, alcohol restriction, salt restriction, or physical activity.

The mean score of self-efficacy in all participants was 6.33 (SD = 1.89). The control group (6.71) was higher than the study group (5.95) (p = .015).

As far as QoL was concerned, among the eight domains of SF-36, the lowest score was 49.67 (SD = 15.73) in GH. The highest score was 84.70 (SD = 13.88) in PF, followed by 82.84 (SD = 21.00) in SF. The mean score of RE and MH was 74.63 (SD = 37.73) and 77.31 (SD = 14.97), and the mean score of RP, Bodily Pain and VT ranged from 66.60 to 69.66. Participants in the control group had a better QoL score in most domains, but there was no significant difference between the two groups.

Regarding utilisation of healthcare services, a total of 22.4% of participants ($n_{control} = 12$, $n_{study} = 18$) had exercised self-prescription in the previous 12 weeks while 74.6% of participants ($n_{control} = 49$, $n_{study} = 51$) used anti-hypertensive drugs prescribed by doctors in the outpatient department of the CHC or hospitals. The median of the frequency of self-prescription and visiting the outpatient department in all participants was 0 and 3, respectively. Only 4.5% of participants ($n_{control} = 2$, $n_{study} = 4$) visited the emergency room and 4.5% of participants ($n_{control} = 1$, $n_{study} = 5$) were hospitalised due to hypertension in the previous 12 weeks. One participant ($n_{control} = 1$) reported receiving hypertensive care at home, and nine participants ($n_{control} = 6$, $n_{study} = 3$) received phone follow-ups related to hypertension care from CHC healthcare providers. In general, the utilisation of healthcare services in the two groups was comparable at baseline.

Patient satisfaction ranged from 0 to 8. The median of the satisfaction score was 0 in the control group and 3 in the study group. There was no significant difference between the two groups.

In summary, outcome indicators at baseline in the study and control groups revealed that there were no significant differences in terms of BP readings, self-care behaviour, QoL, patient satisfaction, and utilisation of healthcare services. Nevertheless, there was a significant difference in terms of self-efficacy; therefore, the baseline self-efficacy was controlled as covariates in data analysis for the comparison of the effects of the intervention between the two groups.

4.4.2 Effects of intervention on patient outcomes

4.4.2.1 Effects of intervention on blood pressure outcome

The current study examined the effects of the intervention on BP outcomes, specifically, BP readings, BP reduction, and BP control rate.

4.4.2.1.1 Effects of intervention on blood pressure readings

The data of the participants' BP readings were normally distributed. A General Linear Model with repeated measures was used to detect within-group (time), between-group (control versus study), and interaction (time × group) effects of the intervention on BP readings. Table 4.4 displays the results of the comparisons of the two groups as well as the mean of SBP and DBP at baseline (T0), immediately after intervention (T1), and four weeks after the intervention was completed (T2). A significant interaction (time × group) effect was present in SBP ($F = 4.34$, $p = .015$), which means that the trend in mean SBP over time was different between the two groups. No significant between-group effect was found for SBP, but within-group effect showed a significant difference ($F = 32.58$, $p = .000$). By conducting a one-way repeated measures ANOVA, a significant time effect was revealed in both the control group ($F = 9.29$, $p = .000$) and the study group ($F = 26.36$, $p = .000$). The SBP was reduced significantly across time both in the control group (T0 149.65 mmHg, T1 144.55 mmHg, T2 140.43 mmHg) and in the study group (T0 153.90 mmHg, T1 139.53 mmHg, T2 139.18 mmHg). By using the Bonferroni test to adjust for multiple comparisons of SBP at different time points, a statistically significant decrease in SBP was also found in the study group from T0 to T1 ($p = .000$), as well as T0 to T2 ($p = .000$). Meanwhile, a statistically significant decrease in SBP was found in the control group from T0 to T1 ($p = .023$), as well as T0 to T2 ($p = .001$).

The DBP showed significant interaction (time × group) effect (F = 4.87, p = .009), which means the trend in mean DBP over time was different between the two groups. The DBP did not show a significant between-group effect, but did show a significant within-group effect (F = 39.21, p = .000). By conducting a one-way repeated measures ANOVA, a significant time effect was revealed both in the control group (F = 13.00, p = .000) and in the study group (F = 29.50, p = .000). The DBP was significantly reduced over time in the control group (T0 83.53 mmHg versus T1 80.84 mmHg versus T2 78.40 mmHg) and in the study group (T0 82.63 mmHg versus T1 75.28 mmHg versus T2 75.20 mmHg). By using Bonferroni corrections to adjust P values for multiple comparisons at different time points, a statistically significant decrease was found in the study group, from T0 to T1 (p = .000), as well as from T0 to T2 (p = .000). The control group also had a statistically significant decrease, from T0 to T1 (p = .019), as well as from T0 to T2 (p = .000).

Table 4.4 Comparison of mean blood pressure readings between the control group and study group at three time points

Outcome measure	Time			Within group (Time)		Between group (Group)		Time × Group		T_0:T_1	T_1: T_2	T_0: T_2
	T0	T1	T2	F	*p*-value	F	*p*-value	F	*p*-value	*p*-value	*p*-value	*p*-value
Systolic blood pressure (mmHg), mean (SD)				32.58	.000 [a]	0.07	.790 [a]	4.34	.015 [a]			
Control group (n = 67)	149.65 (14.59)	144.55 (19.10)	140.43 (22.69)	9.29	.000 [b]					.023 [c]	.164 [c]	.001 [c]
Study group (n = 67)	153.90 (16.74)	139.53 (16.05)	139.18 (17.66)	26.36	.000 [b]					.000 [c]	1.000 [c]	.000 [c]
t, *p*-value	-1.57, .119 [d]	1.65, .102 [d]	0.36, .723 [d]									
Diastolic blood pressure (mmHg), mean (SD)				39.21	.000 [a]	2.92	.090 [a]	4.87	.009 [a]			
Control group (n = 67)	83.53 (11.45)	80.84 (10.94)	78.40 (13.28)	13.00	.000 [b]					.019 [c]	.019 [c]	.000 [c]
Study group (n = 67)	82.63 (11.47)	75.28 (13.02)	75.20 (11.68)	29.50	.000 [b]					.000 [c]	1.000 [c]	.000 [c]
t, *p*-value	0.45, .652 [d]	2.68, .008 [d]	1.48, .143 [d]									

a. Two-way repeated measures ANOVA, b. One-way repeated measures ANOVA, c. Adjustment for multiple comparisons: Bonferroni, d. Unpaired t-test, T0 = baseline, T1 = 12 weeks after recruitment, T2 = 16 weeks after recruitment

4.4.2.1.2 Effects of intervention on blood pressure reductions

The primary outcome of the study was the difference in the reduction of SBP between the two groups from T0 to T1. Because the data fell within a normal distribution, the unpaired t-test was used to test this difference. As the results in Table 4.5 show, the reduction of SBP from T0 to T1 in the study group (-14.37 mmHg) was significantly greater than in the control group (-5.10 mmHg) (p = .003). Such a significant difference was also found in DBP between the study group (-7.43 mmHg) and the control group (-2.69 mmHg) (p = .002). Overall, SBP for the study group was reduced by 14.72 mmHg from T0 to T2, which was greater than the 9.22 mmHg in the control group, but the difference was not statistically significant (p = .113). In terms of DBP from T0 to T2, compared to the decrease in the control group (-5.14 mmHg), the study group saw a larger drop (-7.43 mmHg), but the difference was not significant (p = .159).

The above results point to a significant difference in the effects of the NHM model from the effects of usual care in SBP and DBP reduction at T1. The null hypothesis can thus be rejected.

Table 4.5 Comparison over time of the mean reduction of blood pressure between the control group and the study group

Outcome measures	T0 vs. T1	T1 vs. T2	T0 vs. T2
Reduction of systolic blood pressure (mmHg), mean (SD)			
Control group (n = 67)	-5.10 (15.17)	-4.13 (17.26)	-9.22 (19.89)
Study group (n = 67)	-14.37 (20.06)	-0.35 (16.53)	-14.72 (20.02)
t, *p*-value	3.02, .003	-1.29, .198	1.60, .113
Reduction of diastolic blood pressure (mmHg), mean (SD)			
Control group (n = 67)	-2.69 (7.79)	-2.45 (7.12)	-5.14 (9.65)
Study group (n = 67)	-7.43 (9.08)	-0.07 (9.15)	-7.43 (9.07)
t, *p*-value	3.20, .002	-1.68, .096	1.42, .159

T0 = baseline, T1 = 12 weeks after recruitment, T2 = 16 weeks after recruitment

4.4.2.1.3 Effects of intervention on blood pressure control rate and the rate of blood pressure reduction achieved clinical significance

The difference in the rates of the two groups was compared by using the Chi-square test at T1 and T2. All of the participants had uncontrolled BP at recruitment. The number of participants whose SBP was less than 140 mmHg and DBP was less than 90 mmHg was calculated. As shown in Table 4.6, at T1 47.8% of the study group had their BP controlled, which was greater than the control group (35.8%), but the difference between the two groups was not significant ($p = .161$). At T2, the BP control rates of the study group had increased to 50.7% while the control group's had risen to 47.8%. No statistically significant difference was observed between the two groups either at T2 ($p = .730$).

Reduction of SBP by 5 mmHg and 10 mmHg or DBP by 2 mmHg and 5 mmHg is viewed as a clinically meaningful change in practice (Schroeder et al., 2005; Verdecchia et al., 2010). The number of participants who achieved these clinically significant reductions was calculated and compared between the two groups at T1 and T2. A total of 65.7% of the study group ($n = 44$) and 47.8% of the control group ($n = 32$) had their SBP reduced by at least 5 mmHg at T1. Furthermore, 55.2% ($n = 37$) of the study group and 34.3% ($n = 23$) of the control group had decreased their SBP by at least 10 mmHg. The Chi-square test showed that the difference between the two groups in the number of patients with reduced SBP $\geq$ 5 mmHg ($\chi^2 = 4.38$, $p = .036$) and SBP $\geq$ 10 mmHg ($\chi^2 = 5.92$, $p = .015$) at T1 was statistically significant. However, the statistically significant difference disappeared at T2, although the study group still had more participants than the control group with reduced SBP $\geq$ 5 mmHg (65.7% of the study group versus 56.7%

of the control group) and ≥ 10 mmHg (61.2% of the study group versus 47.8% of the control group).

As for DBP, a total of 64.2% of the study group achieved at least a 2 mmHg reduction at T1, which was significantly greater than the 44.8% of the control group ($p = .024$). A total of 58.2% of the study group achieved at least a 5 mmHg reduction in DBP at T1 which was significantly greater than the 28.4% of the control group ($p = .000$). At T2, the study group still had more participants than the control group who had reduced their DBP by at least 2 mmHg (64.2% of the study group versus 56.7% of the control group) and 5 mmHg (53.7% of the study group versus 47.8% of the control group), but the difference was not statistically significant.

The above results indicate that there was no statistically significant difference between the effects of the NHM model and usual care in the BP control rate. The null hypothesis thus cannot be rejected.

Table 4.6 Comparisons of the rate of blood pressure control and rate of blood pressure reduction that achieved a clinical significance between the control group and study group

Outcome measures	T1	T2
Blood pressure control rate, n (%)		
Control group (n = 67)	24 (35.8)	32 (47.8)
Study group (n = 67)	32 (47.8)	34 (50.7)
χ^2, p-value	1.96, .161	0.12, .730
Reduction of systolic blood pressure achieved 5 mmHg or above, n (%)		
Control group (n = 67)	32 (47.8)	38 (56.7)
Study group (n = 67)	44 (65.7)	44 (65.7)
χ^2, *p*-value	4.38, .036	1.31, .287
Reduction of systolic blood pressure achieved 10 mmHg or above, n (%)		
Control group (n = 67)	23 (34.3)	32 (47.8)
Study group (n = 67)	37 (55.2)	41 (61.2)
χ^2, p-value	5.92, .015	2.44, .118
Reduction of diastolic blood pressure achieved 2 mmHg or above, n (%)		
Control group (n = 67)	30 (44.8)	38 (56.7)
Study group (n = 67)	43 (64.2)	43 (64.2)
χ^2, p-value	5.09, .024	0.78, .377
Reduction of diastolic blood pressure achieved 5 mmHg or above, n (%)		
Control group (n = 67)	19 (28.4)	32 (47.8)
Study group (n = 67)	39 (58.2)	36 (53.7)
χ^2, p-value	12.16, .000	0.48, .489

T1 = 12 weeks after recruitment, T2 = 16 weeks after recruitment

4.4.2.2 Effects of intervention on self-care behaviours

This study looked at the following indicators of self-care behaviours: adherence to anti-hypertensive drug treatment and non-pharmacological suggestions (daily HBPM, smoking cessation, alcohol restriction, salt restriction, and physical activity). The median score of these indicators was compared between the two groups at T0, T1 and T2 using the Mann-Whitney U test. The Friedman test was used to examine the changes of the median score over time in indicators of adherence for each group. The Wilcoxon signed-ranks test was used for comparisons at different time points within group. The results of the tests are shown in Table 4.7.

Table 4.7 Comparison of median score of self-care behaviour between the control group and study group at three time points

Outcome measures	T0	T1	T2	$\chi 2$	*p*-value	T0:T1, T1:T2, T0:T2 *p*-value [c]
Anti-hypertensive drug, median [IQR]						
Control group (n = 57)	3 [2-3]	3 [2-3]	3 [2-3]	0.64	.728 [a]	
Study group (n = 65)	3 [1-3]	3 [2-3]	3 [3-3]	31.94	.000 [a]	.001, .017, .000
Z, *p*-value	-1.92, .055 [b]	-0.94, .347 [b]	1.72, .086 [b]			
Home blood pressure monitoring, median [IQR]						
Control group (n = 67)	1 [1-2]	1 [1-1]	1 [1-1]	3.00	.223 [a]	
Study group (n = 67)	1 [1-1]	2 [2-2]	2 [1-2]	43.10	.000 [a]	.000, .010, .001
Z, *p*-value	-0.46, .649 [b]	-6.54, .000 [b]	-3.83, .000 [b]			
Smoking cessation, median [IQR]						
Control group (n = 67)	1 [1-1]	1 [1-1]	1 [1-1]		1.000 [a]	
Study group (n = 67)	1 [1-1]	1 [1-1]	1 [1-1]	0.67	.717 [a]	
Z, *p*-value	-1.21, .228 [b]	-1.45, .146 [b]	-1.21, .228 [b]			
Alcohol restriction, median [IQR]						
Control group (n = 67)	1 [1-1]	1 [1-1]	1 [1-1]	0.40	.819 [a]	
Study group (n = 67)	1 [1-1]	1 [1-1]	1 [1-1]	4.33	.115 [a]	
Z, *p*-value	-1.57, .117 [b]	-1.53, .125 [b]	-0.71, .481 [b]			
Salt restriction, median [IQR]						
Control group (n = 67)	1 [1-1]	1 [1-2]	2 [1-2]	15.73	.000 [a]	.024, .294, .001
Study group (n = 67)	1 [1 -1]	2 [1-2]	2 [1-2]	55.49	.000 [a]	.000, .268, .000
Z, *p*-value	-0.83, .407 [b]	-2.60, .009 [b]	-0.62, .536 [b]			
Physical activity, median [IQR]						
Control group (n = 67)	2 [1-2]	2 [1-2]	2 [2-2]	12.68	.002 [a]	.045, .295, .031
Study group (n = 67)	2 [1-2]	2 [1-2]	2 [2-2]	30.43	.000 [a]	.000, .470, .000
Z, *p*-value	-0.66, .507 [b]	-2.09, .037 [b]	-0.44, .662 [b]			
Non-pharmacological behaviour, median [IQR]						
Control group (n = 67)	5 [5-6]	6 [5-7]	6 [5-7]	16.76	.000 [a]	.008, .012, .000
Study group (n = 67)	5 [4-6]	7 [6-8]	7 [6-8]	64.19	.000 [a]	.000, .036, .000
Z, *p*-value	-0.90, .370 [b]	-4.86, .000 [b]	-2.28, .023 [b]			

a. Friedman Test, b. Mann-Whitney U test, c. Wilcoxon signed-ranks test, T0 = baseline, T1 = 12 weeks after recruitment, T2 = 16 weeks after recruitment

The number of participants with full adherence to anti-hypertensive drug, daily HBPM, smoking cessation, alcohol restriction, salt restriction, and regular physical activity was calculated in the adherence rate. Table 4.8 shows the adherence rate for anti-hypertensive drug, daily HBPM, smoking cessation, alcohol restriction, salt restriction, regular physical activity. Table 4.8 also shows the Chi-square test results of the comparison of the two groups at T0, T1 and T2.

Table 4.8 Comparison of adherence rate of self-care behaviours between the control group and study group at three time points

Outcome measures	T0	T1	T2
Anti-hypertensive drug, n (%)			
Control group (n = 57)	40 (70.2)	39 (68.4)	43 (75.4)
Study group (n = 65)	33 (50.8)	48 (73.8)	56 (86.2)
χ2, *p*-value	4.76, .029	0.44, .509	2.28, .131
Home blood pressure monitoring, n (%)			
Control group (n = 67)	18 (26.9)	12 (17.9)	13 (19.4)
Study group (n = 67)	13 (19.4)	51 (76.1)	40 (59.7)
χ2, *p*-value	1.05, .306	45.57, .000	22.76, .000
Smoking cessation, n (%)			
Control group (n = 67)	63 (94.0)	63 (94.0)	63 (94.0)
Study group (n = 67)	59 (88.1)	58 (86.6)	59 (88.1)
χ2, *p*-value [b]	1.46, .226	2.13, .144	1.46, .226
Alcohol restriction, n (%)			
Control group (n = 67)	64 (95.5)	64 (95.5)	64 (95.5)
Study group (n = 67)	59 (88.1)	60 (89.6)	63 (94.0)
χ2, *p*-value	2.48, .116	1.73, .189	1.15, .698
Salt restriction, n (%)			
Control group (n = 67)	14 (20.9)	27 (40.3)	35 (52.2)
Study group (n = 67)	11 (16.4)	41 (61.2)	39 (58.2)
χ2, *p*-value	0.44, .506	5.85, .016	0.48, .487
Physical activity, n (%)			
Control group (n = 67)	40 (59.7)	45 (67.2)	51 (76.1)
Study group (n = 67)	36 (53.7)	56 (83.6)	55 (82.1)
χ2, *p*-value	0.49, .486	4.87, .027	0.72, .395

Adherent to one suggestion, n (%)			
Control group (n = 67)	19 (28.8)	10 (14.9)	13 (19.4)
Study group (n = 67)	24 (35.8)	5 (7.5)	3 (4.5)
Adherent to two suggestions, n (%)			
Control group (n = 67)	19 (28.8)	10 (14.9)	13 (19.4)
Study group (n = 67)	24 (35.8)	5 (7.5)	3 (4.5)
Adherent to three suggestions			
Control group (n = 67)	27 (40.3)	29 (43.3)	22 (32.8)
Study group (n = 67)	27 (40.3)	12 (17.9)	15 (22.4)
Adherent to four suggestions			
Control group (n = 67)	17 (25.8)	19 (28.4)	25 (37.3)
Study group (n = 67)	8 (11.9)	23 (34.3)	28 (41.8)
Adherent to five suggestions			
Control group (n = 67)	2 (3.0)	5 (7.5)	7 (10.4)
Study group (n = 67)	2 (3.0)	25 (37.3)	18 (26.9)
$\chi 2$, *p*-value [b]	5.82, .213	23.10, .000	15.58, .004

[a] Binomial distribution used, [b] Continuity corrected, T0 = baseline, T1 = 12 weeks after recruitment, T2 = 16 weeks after recruitment

4.4.2.2.1 Effects of intervention on patient adherence to anti-hypertensive drug

There was no significant difference between the two groups in the median score of adherence to anti-hypertensive drugs at T0, T1, and T2. In the study group, a significant increase in the adherence score was found for anti-hypertensive drugs (χ^2 = 31.94, p = .000). A further comparison showed a significant difference at T0 versus T1 (p = .001) and T0 versus T2 (p = .000). No statistically significant difference over time was found in the control group.

As for the anti-hypertensive drugs adherence rate, the study group (50.8%) at T0 was less adherent than the control group (70.2%) (p = .029). After the intervention, a sustained increase appeared in the study group (T0 50.8%, T1 73.8%, T2 86.2%). At T1 and T2, the adherence rate in the study group surpassed that of the control group (T1 68.4%, T2 75.4%), but the difference between the two groups at T1 and T2 was not statistically significant.

4.4.2.2.2 Effects of intervention on patient adherence to daily home blood pressure monitoring

The median score of the study group was significantly higher than the control group for daily HBPM at T1 (Z = -6.54, p = .000) and T2 (Z = -3.83, p = .000). The study group showed a significant increase of the score (χ^2 = 43.10, p = .000). A further comparison found a significant difference at T0 versus T1 (p = .000), T1 versus T2 (p = .010) and T0 versus T2 (p = .001). The difference in the control group over time was not statistically significant.

The adherence rate of daily HBPM in the study group dramatically increased from 19.4% at baseline (T0) to 76.1% after intervention (T1) and slightly decreased

to 59.7% at four weeks after intervention (T2). In the control group, the adherence rate to daily HBPM slightly decreased from 26.9% at T0 to 17.9% at T1 and increased to 19.4% at T2. The study group had a significantly higher adherence rate than the control group at T1 ($p = .000$), as well as at T2 ($p = .000$).

4.4.2.2.3 Effects of intervention on patient adherence to smoking cessation and alcohol restriction

The median score of patient adherence to smoking cessation and alcohol restriction was comparable in the two groups at T0. The control group was unchanged and the study group had no significant change in both indicators during the study period. No statistically significant difference was found between the two groups on these two indicators.

The adherence rate of smoking cessation and alcohol restriction in the control group was stable at 94.0% and 95.5%, respectively. The study group registered a slight change in adherence to smoking cessation (T0 88.1%, T1 86.6%, T2 88.1%) and alcohol restriction (T0 88.1%, T1 89.6%, T2 94.0%) over time.

4.4.2.2.4 Effects of intervention on patient adherence to salt restriction

Based on the comparable baseline median score of adherence to salt restriction in the two groups, the study group presented a higher median score than the control group ($Z = -2.60$, $p = .009$) at T1 but not at T2 ($Z = -0.62$, $p = .536$). The study group had a significant increase in the adherence score ($\chi^2 = 55.49$, $p = .000$). A further comparison showed a significant difference at T0 versus T1 ($p = .000$) and T0 versus T2 ($p = .000$). Meanwhile, the control group also had a significant increase in the

adherence score (χ^2 = 15.73, p = .000). A further comparison showed a significant difference at T0 versus T2 (p = .001).

Patient adherence rate to salt restriction in the study group improved remarkably from 16.4% at T0 to 61.2% at T1, then decreased slightly to 58.2% at T2. In the control group, an increase was also observed from 20.9% at T0 to 40.3% at T1, and to 52.2% at T2. The study group had a significantly higher adherence rate to salt restriction than the control group at T1 (p = .016) but not at T2 (p = .487).

4.4.2.2.5 Effects of intervention on patient adherence to physical activity

In comparing the baseline median score of adherence to regular physical activity in the two groups, the study group presented a higher median score than the control group (Z = -2.60, p = .009) at T1 but not at T2 (Z = -0.62, p = .536). The study group had a significant increase in the adherence score (χ^2 = 30.43, p = .000). A further comparison showed a significant difference at T0 versus T1 (p = .000) and T0 versus T2 (p = .000). Meanwhile, the control group also had a significant increase of the adherence score (χ^2 = 12.68, p = .002) but a further comparison did not find a significant difference in any time pair.

The adherence rate to physical activity for the study group sharply increased at T1 (T0 53.7%, T1 83.6%) and was stable at 82.1% at T2. The control group had a sustained increase of adherence rate of physical activity from 59.7% at T0 to 67.2% at T1, then to 76.1% at T2. The study group exhibited a significantly greater rate of adherence than the control group at T1 (p = .027) but not at T2 (p = .395).

4.4.2.2.6 Effects of intervention on patient adherence to all non-pharmacological suggestions

The study group showed a significant increase in the adherence score of all non-pharmacological suggestions (χ^2 = 64.19, p = .000). A further comparison showed a significant difference at T0 versus T1 (p = .000) and T0 versus T2 (p = .000). Meanwhile, the control group also had a significant increase of adherence score (χ^2 = 16.76, p = .000) and a significant difference was found at T0 versus T1 (p = .008) and T0 versus T2 (p = .000). However, the median score of adherence to non-pharmacological suggestions in the study group was higher than the control group at both T1 (Z = -4.86, p = .000) and T2 (Z = -2.28, p = .023).

For the adherence rate to non-pharmacological suggestions, at baseline (T0), only 3% participants (n=4, 2 in the study group and 2 in the control group) adhered to all five non-pharmacological suggestions. After the intervention, a little improvement was found in the control group (T1 7.5%, T2 10.4%) while a significant improvement occurred in the study group (T1 37.3%, T2 26.9%). A significant difference was found between the two groups at T1 (χ^2 = 23.10, p = .000), as well as T2 (χ^2 = 15.58, p = .004).

The results of the study indicated that there was a significant difference between the effects of the NHM model and usual care on self-care behaviours in terms of patient adherence to non-pharmacological suggestions, especially in HBPM. The null hypothesis can thus be rejected.

4.4.2.3 Effects of intervention on self-efficacy

Table 4.9 presents the comparison of the mean score of self-efficacy within each group and between the two groups at three time points. Because of a significant

difference in the two groups at baseline (study group 5.94 versus control group 6.71, t = 2.46, p = .015), the baseline score was therefore controlled as covariates in the testing. A two-way repeated measures ANOVA did not detect an interaction effect (time × group) on self-efficacy (F = 2.50, p = .116). No between-group effect (F = 1.19, p = .227) or time effect (F = 1.84, p = .178) was found.

As for the mean difference at different time points in the two groups, the difference in change from T0 to T1 and T1 to T2 in the two groups was not significant. However, the results showed that from T0 to T2 there was a decrease of 0.24 in the control group and an increase of 0.59 in the study group. A significant difference was found between the two groups (t = -2.89, p = .005).

The results of the study indicated that there was not a statistically significant difference between the effects of the NHM model and usual care in self-efficacy. The null hypothesis, therefore, cannot be rejected.

Table 4.9 Comparison of the mean score of self-efficacy changes between the control group and study group at three time points

Outcome measure	Time			Within group (Time)		Between group (Group)		Time × Group	
	T0	T1	T2	F	*p*-value	F	*p*-value	F	*p*-value
Self-efficacy, mean (SD)				1.84	.178 [a]	1.19	.277 [a]	2.50	.116 [a]
Control group (n = 67)	6.71 (1.58)	6.67 (1.56)	6.48 (1.45)						
Study group (n = 67)	5.94 (2.05)	6.33 (1.70)	6.53 (1.62)						
***t, p*-value**	2.46, .015 [b]	1.21, .229 [b]	-0.21, .834 [b]						

a. Repeated measures ANCOVA adjusted by T0 = 6.33, b. Unpaired t-test, T0 = baseline, T1 = 12 weeks after recruitment, T2 = 16 weeks after recruitment

Table 4.10 Comparison of mean difference of self-efficacy between the control group and study group over time

Outcome measures	T0 vs. T1	T1 vs. T2	T0 vs. T2
Self-efficacy, mean (SD)			
Control group (n = 67)	-0.05 (1.45)	-0.19 (1.22)	-0.24 (1.25)
Study group (n = 67)	0.39 (1.73)	0.21 (1.18)	0.59 (1.99)
t, *p*-value	-1.58, .117 [a]	-1.91, .058 [a]	-2.89, .005 [a]

a. Unpaired t-test, T0 = baseline, T1 = 12 weeks after recruitment, T2 = 16 weeks after recruitment

4.4.2.4 Effects of intervention on quality of life

Table 4.11 displays the comparison of mean scores in eight domains of QoL measured by SF-36 at three time points within the group and between the two groups. No interaction effect (time × group) was observed in any of the eight domains of QoL when using two-way repeated measures ANOVA. A between-group effect in each domain was not evident. A within-group effect was found in RP, Bodily Pain, GH, SF, RE, MH. A one-way repeated measures ANOVA detected a time effect in six domains for the study group and in three domains for the control group. The study group showed a significant improvement over time in these domains: RP (T0 62.31 versus T1 74.25 versus T2 83.58, F = 12.47, p = .000), Bodily Pain (T0 66.90 versus T1 73.52 versus T2 75.64, F = 4.99, p = .008), GH (T0 48.42 versus T1 51.16 versus T2 54.13, F = 4.70, p = .014), SF (T0 80.78 versus T1 85.63 versus T2 89.37, F = 6.89, p = .001), RE (T0 72.14 versus T1 78.11 versus T2 86.07, F = 4.25, p = .016), and MH (T0 75.94 versus T1 79.88 versus T2 81.43, F = 4.87, p = .009). Using Bonferroni corrections to adjust P values for multiple comparisons within the study group, a statistically significant difference was found in the RP domain from T0 to T1 (p = .026), as well as T0 to T2 (p = .000). Furthermore, the six domains of RP, Bodily Pain, GH, SF, RE and MH all showed a statistically significant improvement from T0 to T2 but not for T0 to T1.

In the control group, a significant improvement over time showed up in the domains RP (T0 70.90 versus T1 72.76 versus T2 82.46, F = 5.40, p = .006), RE (T0 77.11 versus T1 85.57 versus T2 87.56, F = 5.70, p = .014), and MH (T0 78.69 versus T1 80.42 versus T2 82.03, F = 3.59, p = .035). When Bonferroni corrections were used to adjust p-values for multiple comparisons within the control group, only the domains RP and RE showed statistically significant increases from T0 to T2.

Table 4.12 shows the comparison of the changes of each time pair between the two groups. No statistically significant difference was found except for VT at T2 versus T1 (study group 3.13 versus control group -2.01, $t = -2.19$, $p = .030$).

The results of the study indicate that there was no significant difference between the effects of the NHM model and usual care on QoL. The null hypothesis, therefore, cannot be rejected.

Table 4.11 Comparison of mean score of quality of life between the control group and study group at three time points

Outcome measure	Time			Within group (Time)		Between group (Group)		Time × Group		T0: T1	T1: T2	T0: T2
	T0	T1	T2	F	*p*-value	F	*p*-value	F	*p*-value	*p*-value	*p*-value	*p*-value
Physical Functioning, mean (SD)				0.86	.410 [a]	0.06	.809 [a]	0.45	.639 [a]			
C (n = 67)	84.25 (14.04)	84.93 (14.73)	86.27 (14.81)									
S (n = 67)	85.15 (13.82)	86.27 (13.80)	85.75 (13.49)									
t, *p*-value	-0.37, .710 [d]	-0.55, 587 [d]	0.21, .831 [d]									
Role-Physical, mean (SD)				19.52	.000 [a]	0.15	.698 [a]	1.76	.177 [a]			
C (n = 67)	70.90 (34.43)	72.76 (35.55)	82.46 (31.98)	5.40	.006 [b]					1.000 [c]	.055 [c]	.018 [c]
S (n = 67)	62.31 (39.97)	74.25 (36.66)	83.58 (29.05)	12.47	.000 [b]					.026 [c]	.055 [c]	.000 [c]
t, *p*-value	1.33, .185 [d]	-0.24, .811 [d]	-0.21, .832 [d]									
Bodily Pain, mean (SD)				5.41	.006 [a]	0.45	.505 [a]	.88	.417 [a]			
C (n = 67)	67.51 (23.35)	70.07 (24.21)	70.88 (24.85)	0.78	.449 [b]							
S (n = 67)	66.90 (24.20)	73.52 (23.13)	75.64 (22.19)	4.99	.008 [b]					.057 [c]	1.000 [c]	.016 [c]
t, *p*-value	0.15, .882 [d]	-0.84, .401 [d]	-1.17, .244 [d]									
General Health, mean (SD)				4.52	.013 [a]	0.01	.942 [a]	1.34	.265 [a]			
C (n = 67)	50.91 (15.19)	50.99 (16.97)	52.33 (15.82)	0.44	.644 [b]							
S (n = 67)	48.42 (16.28)	51.16 (16.89)	54.13 (18.68)	4.70	.014 [b]					.382 [c]	.197 [c]	.032 [c]
t, *p*-value	0.92, .361 [d]	-0.06, .951 [d]	-0.60, .547 [d]									
Vitality, mean (SD)				0.77	.466 [a]	1.72	.194 [a]	2.08	.130 [a]			
C (n = 67)	71.64 (17.37)	73.28 (15.73)	71.27 (15.06)									
S (n = 67)	67.69 (17.67)	67.76 (18.28)	70.90 (14.17)									
t, *p*-value	1.31, .194 [d]	1.87, .063 [d]	0.15, .883 [d]									

Social Functioning, mean (SD)				7.79	.001 [a]	0.29	.593 [a]	1.27	.285 [a]		
C (n = 67)	84.89 (19.77)	87.69 (20.24)	88.43 (22.54)	1.55	.216 [b]						
S (n = 67)	80.78 (22.12)	85.63 (22.22)	89.37 (16.02)	6.89	.001 [b]					.172 [c]	.323 [c]	.000 [c]
t, *p*-value	1.13, .259 [d]	0.56, .577 [d]	-0.28, .783 [d]								
Role-Emotional, mean (SD)				9.30	.000 [a]	0.92	.341 [a]	.47	.623 [a]		
C (n = 67)	77.11 (36.33)	85.57 (30.28)	87.56 (28.92)	5.70	.014 [b]					.147 [c]	1.000 [c]	.014 [c]
S (n = 67)	72.14 (39.18)	78.11 (35.08)	86.07 (28.52)	4.25	.016 [b]					.740 [c]	.287 [c]	.010 [c]
t, *p*-value	0.76, .447 [d]	1.32, .190 [d]	0.30, .764 [d]								
Mental Health, mean (SD)				7.59	.001 [a]	0.37	.547 [a]	.72	.473 [a]		
C (n = 67)	78.69 (13.67)	80.42 (13.03)	82.03 (11.66)	3.59	.035 [b]					.483 [c]	.413 [c]	.065 [c]
S (n = 67)	75.94 (16.16)	79.88 (15.22)	81.43 (11.97)	4.87	.009 [b]					.105 [c]	.990 [c]	.024 [c]
t, *p*-value	1.06, .290 [d]	0.22, .827 [d]	0.29, .770 [d]								

a. Two-way repeated measures ANOVA，b. One-way repeated measures ANOVA，c. Adjustment for multiple comparisons: Bonferroni, d. Unpaired t-test, C = Control group, S = Study group, T0 = baseline, T1 = 12 weeks after recruitment, T2 = 16 weeks after recruitment

Table 4.12 Comparison of mean difference of quality of life between the control group and study group over time

Outcome measures	T1 vs. T0	T2 vs. T1	T2 vs. T0
Physical Functioning, mean (SD)			
Control group (n = 67)	0.67 (8.91)	1.34 (11.73)	2.01 (11.97)
Study group (n = 67)	1.12 (14.71)	-0.52 (7.89)	0.60 (14.18)
t, *p*-value	- .21, .832	1.08, .282	.63, .53
Role-Physical, mean (SD)			
Control group (n = 67)	1.86 (26.22)	9.70 (32.84)	11.57 (33.23)
Study group (n = 67)	11.94 (40.44)	9.33 (28.15)	21.27 (35.15)
t, *p*-value	-1.71, .090	0.07, .944	-1.64, .103
Bodily Pain, mean (SD)			
Control group (n = 67)	2.57 (20.13)	0.81 (22.34)	3.37 (26.34)
Study group (n = 67)	6.63 (22.57)	2.12 (23.48)	8.74 (24.83)
t, *p*-value	-1.10, .274	-0.33, .741	-1.22, .227
General Health, mean (SD)			
Control group (n = 67)	0.07 (13.99)	1.34 (14.48)	1.42 (13.21)
Study group (n = 67)	2.75 (14.55)	2.97 (12.99)	5.72 (17.84)
t, *p*-value	-1.08, .281	-0.68, .495	-1.59, .115
Vitality, mean (SD)			
Control group (n = 67)	1.64 (12.59)	-2.01 (10.30)	-0.37 (11.19)
Study group (n = 67)	0.07 (16.34)	3.13 (16.23)	3.21 (16.98)
t, *p*-value	0.62, .535	-2.19, .030	-1.44, .152
Social Functioning, mean (SD)			
Control group (n = 67)	2.80 (16.89)	0.74 (16.41)	3.54 (18.95)
Study group (n = 67)	4.85 (20.52)	3.73 (18.72)	8.58 (17.57)
t, *p*-value	-0.64, .526	-0.98, .328	-1.60, .113

Role-Emotional, mean (SD)			
Control group (n = 67)	8.46 (34.50)	1.99 (20.00)	10.45 (29.13)
Study group (n = 67)	5.97 (41.81)	7.96 (38.53)	13.93 (37.22)
t, *p*-value	0.38, .708	-1.13, .263	-0.60, .547
Mental Health, mean (SD)			
Control group (n = 67)	1.73 (10.00)	1.61 (8.78)	3.34 (11.64)
Study group (n = 67)	3.94 (14.97)	1.55 (12.95)	5.49 (16.44)
t, *p*-value	-1.00, .317	0.03, .975	-0.87, .384

a. Unpaired t-test, T0 = baseline, T1 = 12 weeks after recruitment, T2 = 16 weeks after recruitment

4.4.2.5 Effects of intervention on utilisation of healthcare services

Table 4.13 presents the comparison of the utilisation of healthcare services by the control group and the study group at three time points. The number of participants who engaged in self-prescription, visited the outpatient department, visited the emergency room, or were hospitalised was counted. It seemed that the rate of self-prescription in the study group was higher than the control group at T0 (control group 17.9% versus study group 26.9%) as was the rate of outpatient department visits at T1 (control group 77.6% versus study group 83.6%), but no statistically significant difference was detected using the Chi-square test. No significant difference between the two groups was detected in the rate of self-prescription, outpatient department visits, emergency room visits, or hospitalisation at T0, T1, and T2.

The frequency of participants engaging in self-prescription, visiting the outpatient department, visiting the emergency room, and being hospitalised in the past 12 weeks was calculated. The Friedman test was used to examine the changes of frequency of utilisation of healthcare services over time. In the study group, a significant decrease was found in the frequency of self-prescription ($Z = 14.95$, $p = .001$). By using the Wilcoxon signed-ranks test to detect the difference within the study group, a significant difference between T0 to T2 was observed ($p = .002$). Furthermore, the frequency of outpatient department visits substantially increased in both the study group ($Z = 30.84$, $p = .000$) and the control group ($Z = 42.29$, $p = .000$). The Wilcoxon signed-ranks test found a significant difference in the study group from T1 to T2 ($p = .000$), as well as T0 to T2 ($p = .000$). Other indicators, such as visiting the emergency room and hospitalisation, did not produce significant differences within the study group or the control group.

The results of the study indicate that there was no significant difference between the effects of the NHM model and usual care in the utilisation of healthcare services. The null hypothesis, therefore, cannot be rejected.

Table 4.13 Comparison of utilisation of healthcare services between the control group and study group at three time points

Outcome measures	T0	T1	T2	Z, *p*-value	T0 vs. T1 *p*-value	T1 vs. T2 *p*-value	T0 vs. T2 *p*-value
Self-prescription, n (%)							
Control group (n = 67)	12 (17.9)	9 (13.4)	9 (13.4)				
Study group (n = 67)	18 (26.9)	8 (11.9)	8 (11.9)				
χ^2, *p*-value	1.55, .214 [a]	0.07, .795 [a]	0.07, .795 [a]				
Frequency of self-prescription, median [IQR]							
Control group (n = 67)	0 [0-0]	0 [0-0]	0 [0-0]	2.26, .323 [b]			
Study group (n = 67)	0 [0-1]	0 [0-0]	0 [0-0]	14.95, .001 [b]	.046 [c]	.263 [c]	.002 [c]
Z, *p*-value	-1.32, .187 [d]	-0.17, .863 [d]	-0.79, .432 [d]				
Visited outpatient department, n (%)							
Control group (n = 67)	49 (73.1)	52 (77.6)	43 (64.2)				
Study group (n = 67)	51 (76.1)	56 (83.6)	53 (79.1)				
χ^2, *p*-value	0.16, .691 [a]	0.76, .382 [a]	3.67, .055 [a]				
Frequency of visiting outpatient department, median [IQR]							
Control group (n = 67)	3 [0-3]	3 [1-3]	0 [0-1]	42.29, .000 [b]	.766 [c]	.037 [c]	.345 [c]
Study group (n = 67)	3 [1-3]	3 [1-5]	1 [1-2]	30.84, .000 [b]	.047 [c]	.000 [c]	.000 [c]
Z, *p*-value	-0.62, .539 [d]	-0.99, .321 [d]	-1.74, .082 [d]				
Visited emergency room, n (%)							
Control group (n = 67)	2 (3.0)	1 (1.5)	0 (0.0)				
Study group (n = 67)	4 (6.0)	1 (1.5)	0 (0.0)				
***p*-value**	.680 [e]	1.000 [e]	1.000 [e]				
Frequency of visiting emergency room, median [IQR]							
Control group (n = 67)	0 [0-0]	0 [0-0]	0 [0-0]	3.00, .223 [b]			
Study group (n = 67)	0 [0-0]	0 [0-0]	0 [0-0]	5.20, .074 [b]			

Z, *p*-value	-0.83, .405 [d]	0.00, 1.000 [d]	0.00, 1.000 [d]	
Hospitalised, n (%)				
Control group (n = 67)	1 (1.5)	2 (3.0)	1 (1.5)	
Study group (n = 67)	5 (7.5)	1 (1.5)	0 (0.0)	
***p*-value**	.208 [e]	1.000 [e]	1.000 [e]	
Nights of hospitalised, median [IQR]				
Control group (n = 67)	0 [0-0]	0 [0-0]	0 [0-0]	2.00, .368 [b]
Study group (n = 67)	0 [0-0]	0 [0-0]	0 [0-0]	3.50, .174 [b]
Z, *p*-value	-1.75, .081 [d]	0.00, 1.000 [d]	0.00, 1.000 [d]	

a. Pearson Chi-square, b. Friedman Test, c. Wilcoxon signed-ranks test and *p*-value adjusted at 0.0167 (0.05/3), d. Mann-Whitney U test, e. Fisher's exact test, T0 = baseline, T1 = 12 weeks after recruitment, T2 = 16 weeks after recruitment

4.4.2.6 Effects of intervention on patient satisfaction

Patient satisfaction was examined at T0 and T1. Table 4.14 displays the comparison between the two groups of the median score of patients satisfied with hypertension care before and after the intervention. After the intervention, both groups reported an increase in satisfaction. The study group's satisfaction significantly improved from median 3 to 28 (Z = -6.49, p = .000), while the control group's satisfaction increased from median 0 to 7 (Z = -3.56, p = .000). Based on the comparable baseline data of patient satisfaction, satisfaction in the study group was obviously higher than the control group after intervention (Z = -3.56, p = .000). The null hypothesis can thus be rejected.

Table 4.14 Comparison of patient satisfaction between the control group and study group pre- and post-intervention

	T0	**T1**	**Z**	***p*-value**
Patient satisfaction, median [IQR]				
Control group (n = 67)	0 [0– 8]	7 [0–20]	-3.56	.039 [a]
Study group (n = 67)	3 [0–15]	28 [16-33]	-6.49	.000 [a]
Z, *p*-value	-1.35, .176 [b]	-5.47, .000 [b]		

a. Wilcoxon Signed-Ranks Test, b. Mann-Whitney Test, T0 = baseline, T1 = 12 weeks after recruitment

4.5 Results of process of care

4.5.1 Changes in the anti-hypertensive drugs treatment

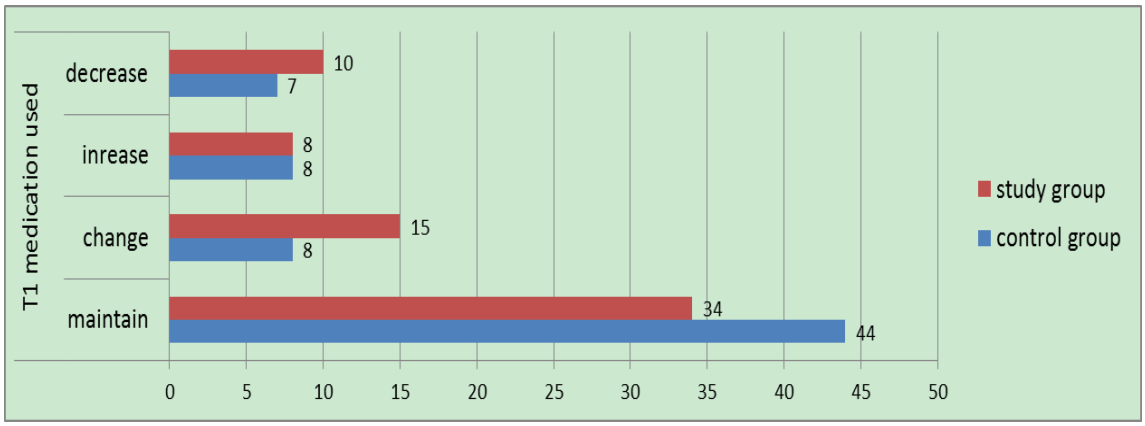
To distinguish the effects of the intervention from the effects of anti-hypertensive drugs, changes in pharmacological treatment during the intervention period and follow-up period were compared between the two groups. As shown in Table 4.15, a total of 50.7% of the study group (n = 34) and 65.6% of the control group (n = 44) maintained the previous pharmacological treatment at T1. Changes were made in the anti-hypertensive drugs treatment for 11.9% of the control group

participants (n = 8) and 22.4% (n = 15) of the study group participants. A total of 10.4% of participants (n = 7) in the control group and 14.9% (n = 10) from the study group decreased the dosage of their anti-hypertensive drugs while 11.9% of patients (n = 8) in the control group and 11.9% (n = 8) from the study group increased the dosage of their anti-hypertensive drug. No significant difference between the two groups was observed in the changes in anti-hypertensive drugs treatment during the intervention period ($\chi^2 = 6.75$, p = .087).

A total of 77.6% of the study group and 79.1% of the control group maintained their treatment during the T1 to T2 period (Table 4.16). The number of participants whose treatments changed was similar in the two groups ($\chi^2 = 0.121$, p = .989).

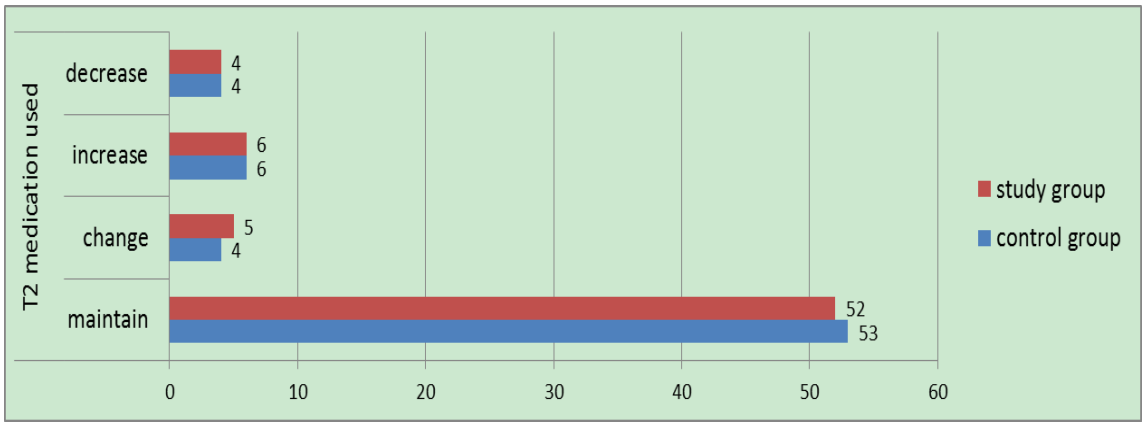
Based on the results of the comparison of changes in pharmacological treatment between the two groups, we can conclude that the effects of BP reduction did not result from changes of dose of pharmacological treatment.

Table 4.15 Comparison of pharmacological treatment from T0 to T1 for the study group and the control group



T0 = baseline, T1 = 12 weeks after recruitment

Table 4.16 Comparison of pharmacological treatment from T1 to T2 for the study group and the control group



T1 = 12 weeks after recruitment, T2 = 16 weeks after recruitment

4.5.2 Changes in blood pressure readings from home blood pressure monitoring

To observe the effects of NHM on BP readings, patients' BP readings from the home visit and during the six telephone follow-ups were recorded and analysed. BP readings from a total of 62 participants who received the NHM were recorded. A total of 4.6% of data were missing, the result of some patients failing to record all their BP readings. These missing data were replaced by the last observed BP reading.

Table 4.17 presents the results of the testing of BP readings at seven time points using one-way repeated measures ANOVA. The results showed a significant time effect in SBP ($F = 5.35$, $p = .000$), as well as in DBP ($F = 2.62$, $p = .035$). The results indicate that the SBP and DBP were reduced over time in the NHM model. Comparisons of each time pair were conducted using Bonferroni corrections to adjust p values. The SBP showed a significant decrease at T0 versus T3 ($p = .045$), T0 versus T6 ($p = .036$) as well as T0 versus T7 ($F = 2.62$, $p = .004$). The DBP did not show a significant difference for any time pair. The results show that NHM was effective in reducing patient BP readings.

Table 4.17 Comparison of blood pressure readings in the intervention period

	NO1	NO2	NO3	NO4	NO5	NO6	NO7	F	*p*-value
Blood pressure reading (mmHg), mean (SD), (N = 62)									
Systolic blood pressure	141.74 (16.26)	137.00 (13.60)	135.21 (13.88)	137.16 (13.62)	135.87 (13.07)	134.61 (12.63)	132.76 (12.75)	5.35	.000 [a]
t, *p*-value		.108 [a]	.045 [a]	.349 [a]	.085 [a]	.036 [a]	.004 [a]		
Diastolic blood pressure	77.00 (11.75)	74.92 (1 .23)	73.90 (1 .10)	74.77 (9.64)	75.00 (8.92)	74.42 (9.67)	73.71 (9.34)	2.62	.035 [a]
t, *p*-value		1.000 [a]	.445 [a]	1.000 [a]	1.000 [a]	.646 [a]	.264 [a]		

a. One-way repeated measures ANOVA, b. Adjustment for multiple comparisons: Bonferroni, NO1 at home visit, NO2 at 1st telephone follow-up, NO3 at 2nd telephone follow-up, NO4 at 3rd telephone follow-up, NO5 at 4th telephone follow-up, NO6 at 5th telephone follow-up, NO7 at 6th telephone follow-up

4.6 Summary

From the results of the examination of this RCT, we can conclude that, based on equivalent characteristics at baseline, the NHM model showed greater effects than usual care in reducing patients' SBP and DBP, increasing the number of patients who achieved a clinically significant reduction in BP, improving patient adherence to daily HBPM, salt restriction, regular physical activity, and improving patient satisfaction. In addition, the NHM model showed a trend of improving patient adherence to anti-hypertensive drugs and patients' QoL.

To conclude, the NHM model has shown better effects on most indicators of patient outcome than usual care. The impact of NHM was maintained at four weeks after intervention, but the difference between the NHM model and the usual care gradually disappeared due to the unexpected effects of usual care. The possible reasons are discussed in the next chapter.

CHAPTER 5

DISCUSSIONS

5.1 Introduction

Increasing efforts have been made to manage hypertensive patients at the community level, but an effective approach still needs to be explored and proven to be effective. Nurses, although indispensable among the ranks of healthcare providers, have always played a silent role in practice. Despite the fact that nurse-led intervention for hypertensive patients has been shown to be effective in some countries (Clark et al., 2010), the evidence from meta-analysis studies is inconsistent and evidence is scant from well-designed trials in communities of resource-poor countries. China is one of those resource-poor countries and has numerous hypertensive patients in the community setting. To date, evidence showing the contribution of nurses to hypertension management is lacking. The current study is an early attempt to establish an NHM model tailored to the community health setting in China. The NHM model was set up based on the CCM (Wagner 1998, Wagner et al., 2001) and the Four-C Model (Wong et al., 2005; Wong, Chow et al., 2010) with the features of comprehensiveness, collaboration, coordination, and continuity. In a two-arm and single-blinded RCT, the NHM model showed superior effects on patient outcomes.

This chapter discusses the impact of the NHM model in each of the following patient outcomes: BP outcome, self-care behaviours, self-efficacy, QoL, utilisation of healthcare services and satisfaction. We compared the results of this study to other

relevant studies and analysed the possible mechanisms of those positive outcomes and the likely reasons for the outcomes without positive results.

5.2 The difference between traditional hypertension management and the nurse-led hypertension management model

GPs have always played the leading role in traditional hypertension management, which is focused only on pharmacological treatments. When patients feel sick, they visit healthcare organisations to seek help from GPs. The fact is, however, that although many hypertensive patients take anti-hypertensive drugs, the majority of them have not controlled their BP (Table 2.2). Researchers have called for more healthcare professionals from various disciplines to collaborate in hypertension management so as to improve patient outcome (Carter et al., 2009; Hill et al., 2010; Nkansah et al., 2010). The NHM model incorporated both the nurses' role in non-pharmacological treatment and the GPs' traditional role in pharmacological treatment. More importantly, the NHM model emphasised the patients' role in their own care and was designed to support patient self-management. Unlike the majority of team-based intervention programmes which focused on the process of the intervention and overlooked structural factors such as the healthcare system, the NHM model includes the local healthcare organisation as an integral part of the system in areas such as delivery system design, decision support, and clinical information system to support nurse-led interventions in patients' self-care management.

5.3 Effects of the nurse-led hypertension management model on patient outcomes

5.3.1 Effects on blood pressure outcome

5.3.1.1 Effects on blood pressure reduction

The measurement of BP readings is a recognised outcome indicator when evaluating the impact of a programme or medicine on hypertensive patients. The following paragraphs discuss the effects of the NHM model on BP reduction, as well as the BP control rate. Lowering BP readings is closely related to the risk for CVDs (Lewington et al., 2002; Schroeder et al., 2005; Verdecchia et al., 2010). Therefore, BP reduction is a core indicator for evaluating hypertension intervention programmes, especially programmes targeting patients with elevated BP. The findings of the present study support the hypothesis that there is a difference in BP reduction between NHM and usual care. In terms of SBP reduction, NHM resulted in a reduction of 14.4 mmHg, from 153.9 mmHg at T0 to 139.5 mmHg at T1. This remarkable reduction of SBP was higher than the 9.1 mmHg reduction that resulted from BP-lowering medications reported in a meta-analysis of 354 RCTs (Law, Wald, Morris, & Jordan, 2003). In the current study, usual care also reduced SBP readings for hypertensive patients at T1, but only by 5.1 mmHg, from 149.7 mmHg at T0 to 144.6 mmHg. Verdecchia et al. (2010), in a meta-analysis study of thirty RCTs, concluded that each 5-mmHg reduction in SBP contributed to a 13% reduced risk for CVDs. Verdecchia et al.'s findings indicate that both NHM and usual care are helpful in reducing patients' risk for CVDs with clinical meaning. Furthermore, NHM helped 65.7% of patients to reduce SBP by at least 5 mmHg after the intervention, whereas only 47.8% of the patients in the control group achieved the same SBP reduction, a difference of 18 percentage points. Even at four weeks after

the intervention, 65.7% of the patients still maintained this reduction of SBP, which was 9 percentage points more than the percentage of usual care patients who did (56.7%). The results confirm that NHM is more effective than usual care in SBP reduction.

In terms of DBP, NHM in this study helped patients achieve a 7.4 mmHg-reduction (T0 82.6 mmHg versus T1 75.2 mmHg). Usual care also resulted in reducing DBP, but only by 2.7 mmHg, from 83.5 mmHg at T0 to 80.8 mmHg at T1. Since evidence has shown that a 2-mmHg reduction is related to a 12% reduction of the risk for CVDs (Verdecchia et al., 2010), the reduction of DBP in both NHM and usual care would benefit the promotion of long-term health in hypertensive patients. Furthermore, NHM helped 64.2% of patients achieve a 2-mmHg reduction of DBP while usual care helped 44.8% of patients achieve the same 2-mmHg reduction. That is, the percentage of patients who reduced their DBP by at least 2 mmHg of DBP was 20 percentage points higher for those under NHM than those receiving usual care. Even at four weeks after the intervention, 64.2% of patients in the NHM still maintained this 2-mmHg reduction of DBP, which was 7.5 percentage points more than the percentage of usual care patients who did (56.7%). It has been reported that a 5-mmHg reduction of DBP leads to a 38% reduction in strokes and a 16% reduction in coronary heart disease (Schroeder et al., 2005). In this current study, NHM helped 58.2% of patients reduce DBP by at least 5 mmHg reduction, which was 30 percentage points higher than the 28.4% of patients in the control group who achieved the same reduction. Even at four weeks after the intervention, 53.7% of patients in the study group had maintained this 5-mmHg DBP reduction, which was 6 percentage points more than the usual care patients who did (47.8%). These results prove that NHM was more effective than usual care in DBP reduction.

Few studies using nurse interventions on hypertensive patients have been conducted at the community level in China (Chiu & Wong, 2010; Ma et al., 2014). Ma et al. trained 12 clinical nurses to use nurse-led MI with 60 Chinese hypertensive patients. After the six-month intervention, the nurse-led MI had reduced SBP by 12 mmHg and DBP by 7 mmHg, significantly better than the reductions of SBP and DBP by 4 mmHg and 3 mmHg, respectively, for patients receiving usual care. Obviously, the present study achieved BP reductions that were somewhat better than those in Ma et al.'s study and did so within a shorter period of time. One possible reason for the success of the current study may be the use of a system-based approach that is supported by the local healthcare organisation. In Chiu and Wong's study, an experienced nurse provided face-to-face consultations with patients in the study group and then followed their health behaviours through telephone calls every 2-3 weeks. Compared to the control group, which received only a clinic consultation, the study group achieved a reduction of SBP / DBP by 19.0 / 11.7 mmHg, which was better than the control group results (SBP / DBP by 8.0 / 3.7 mmHg). It appears that the study carried out by Chiu and Wong was more successful in BP reduction than the current study and in a shorter time period. The likely reason is that the majority of the participants in Chiu and Wong's study were newly diagnosed patients, whereas, in the current study, the mean number of years with hypertension was 11 years. Newly diagnosed patients may be more responsive to behavioural intervention. Neither Ma et al.'s study nor Chiu and Wong's study examined the sustained effects of the intervention, so whether the effects were sustained or faded with time is unknown. The current study provided evidence that the effects of NHM were sustained for at least four weeks after the intervention. Based on the data for HBPM (Table 4.17), the current study also showed that the effects of NHM in significantly

reducing BP persisted at ten weeks after intervention and continued to decrease at 12 weeks.

5.3.1.2 Effects on blood pressure control rate

One of the targets in hypertension treatment is to bring down SBP and DBP to less than 140 / 90 mmHg (James et al., 2014; Liu & Writing Group of 2010 Chinese GMH, 2011; Mancia et al., 2014). When the number of patients who controlled their BP in the current study was calculated, the results showed insufficient evidence to support the hypothesis that there is a difference in BP control rate between the care provided by the NHM model and usual care. All the participants had uncontrolled BP at recruitment. After the intervention, NHM had helped 47.8% of the participants to control their BP, which was similar to the 47% achieved by a nine-month nurse-managed programme in Hebert et al.'s study in the United States (2012). In the current study, usual care also helped 35.8% of the patients to control their BP. No significant difference was detected between the two groups in the BP control rate. The results are in line with the meta-analysis study done by Clark et al. (2010) that found that nurse-led interventions produced a greater reduction in BP but not in achieving target BP. Although the NHM group had a better control rate, this rate was not optimal and still needs to be enhanced for optimal hypertension management. In an eight-week nurse-led intervention study in Hong Kong, China (Chiu & Wong, 2010), 75% of the patients were able to control their BP.

The findings from the present study proved that NHM produces a post-intervention reduction of BP that is both statistically and clinically significant, and at four weeks after intervention, the NHM patients maintained a lower BP than the usual care patients. The usual care group also achieved post-intervention BP reduction, which is to be expected since these participants were also under medical

care. NHM appears to have achieved a clinically significant effect on both SBP and DBP reduction that was sustained even after the intervention had ended.

5.3.1.3 Possible reasons for the sustaining effect after intervention

NHM helped the patients significantly reduce SBP and DBP readings not just immediately after the intervention but even at four weeks after the NHM had ended, meaning their BP readings still remained under 140 / 90 mmHg. In the current study, at four weeks after the completion of the intervention, the effects of the NHM model on BP outcomes were still evident but they were not statistically significantly different from the usual care effects. The continued post-intervention decrease in the mean BP of the usual care group and increase in their BP control rate resulted in no statistically significant differences between the usual care and the study groups. A similar situation also appeared in the study by Hebert et al. (2012). There are several possible reasons for this. The first is that usual care can have effects on BP outcomes. This is not uncommon in mainland China in both the current study and other studies (X. J. Chen et al., 2014; X. H. Liang et al., 2014). The second is the possibility of contamination between the two groups. Although some measures were employed to try to prevent contamination between the two groups, such as making appointments to collect data in private one-on-one sessions, nonetheless, it was still possible that the patients might find their interventions were different since they lived in the same community. When the control group participants realised that the study group participants received closer follow-up, they might have sought other treatments outside of the centre on their own. Especially after the second data collection time point, the control group participants might have observed that their BP reductions were not as good as the study group's, they might have learned knowledge and skills from the study group participants and possibly adopted these self-management

behaviours. Thirdly, the improvement in the usual care group may have been an effect of having social support in the form of the data collectors contacting the usual care patients three times to collect data in person, including measuring their BP. This is particularly likely to have resulted from the third data collection, which was conducted at T2, four weeks after T1, and was an additional point of contact compared to the usual 12-week medical appointment schedule. Although the data collector was blinded to the patient's group assignment, the patient might have viewed the data collection as an intervention because it took place in the CHC.

5.3.2 Effects on self-care behaviours

Hypertensive patients have to struggle to keep their BP normal to reduce the long-term risk for mortality and loss of mobility. Patient self-care behaviours are essential to effective hypertension management. The results of this study support the hypothesis that NHM enhances patients' self-care behaviours more than usual care. These self-care behaviours are HBPM, salt restriction, regular physical activities and total adherence to non-pharmacological suggestions. A sustained difference was shown in HBPM and total adherence to non-pharmacological suggestions four weeks post intervention.

5.3.2.1 Adherence to pharmacological treatment

Poor adherence directly impacts the effects of treatment and results in wasted resources. Poor adherence to anti-hypertensive drugs is common worldwide (WHO, 2003). Many efforts have been made to improve patient adherence to anti-hypertensive drugs. In some countries or regions, such as Canada (Gee et al., 2012) and the UK (Schroeder et al., 2005), patient adherence to anti-hypertensive drugs was reported to be as high as 90% or more. In this study, we found that 50.8% of patients fully adhered to prescribed anti-hypertensive drugs in terms of time, dose,

and frequency. This result is similar to the 55% - 61% adherence rate in Beijing, China (Cai et al., 2012; Y. J. Liang et al., 2014) and the 56% adherence rate among Chinese in Canada (Liu et al., 2014). The NHM model increased the adherence rate of anti-hypertensive drugs from 50.8% at T0 to 73.8% at T1 and to 86.2% at T2. Although this study did not detect a significant difference between the two groups in patient medication adherence, the study group showed a trend of improved adherence whereas the control group did not. A GP-led group-based intervention programme conducted by Gao et al. (2013) in the community of Shanghai, China, found that after the six-month intervention programme, the patient medication adherence rate increased from 46% to 61%. Compared to Gao et al.'s study, the results of the current study indicate that the contribution of nurses on the team improved patient medication adherence (Hill et al., 2010).

5.3.2.2 Adherence to non-pharmacological suggestions

Non-pharmacological suggestions such as HBPM, salt restriction, physical activities, smoking cessation and alcohol restriction are closely related to BP control. However, due to various barriers, patients' self-care behaviours are suboptimal. In this study, only 3% of participants were adherent to all non-pharmacological suggestions at baseline. NHM provided interventions on patient self-care behaviours and successfully enhanced the patient adherence rate to non-pharmacological treatment from 3.0% to 37.3% after intervention, which was 30 percentage points higher than the adherence rate of the usual care patients (T0 3.0% versus T1 7.5%). Even at four weeks after intervention, those under NHM had a 26.9% adherence rate to all the non-pharmacological suggestions, which was higher than the rate of the usual care patients (10.4%). The effect of NHM in each non-pharmacological behaviour is discussed below.

5.3.2.2.1 Adherence to salt restriction

Salt restriction is closely associated with BP reduction and mortality related to CVDs (Adler et al., 2014; He, Li, & MacGregorr, 2004). He et al. in a meta-analysis study involving more than 20 trials proved that a reduction of salt intake can reduce SBP by 5.4 mmHg and DBP by 2.8 mmHg. Excessive consumption of salt seems to be a global problem. WHO recommends a sodium intake of no more than 2000 mg per day (about 5 g of salt) but the International Study of Macro／Micro-nutrients and Blood Pressure (INTERMAP) found that per capita sodium consumption per day in the United Kingdom, the United States, Japan and China ranges from 3400 mg to 4600 mg (about 8.5 g - 11.5 g of salt) (Anderson et al., 2010), which is higher than the WHO recommendation. The study also showed that the Chinese population consumes 3991 mg sodium (about 10 g of salt) per day in their diet. Following the recommendations to reduce salt intake from 9-12 g / day to 5-6 g / day would have a significant effect in lowering BP and the risk of CVDs (He et al., 2004). In this study, the aim was to reduce patient salt intake to less than 6 g / day, as recommended in the Chinese National GMH (Liu & Writing Group of 2010 Chinese GMH, 2011). At baseline, a total of salt restriction adherence rate was about 20%, which is far less than the rate of 65% reported in a Turkish study of hypertensive patients (Uzun et al., 2009).

Many measures can reduce salt intake. In this study, we focused on salt intake in cooking because the majority of salt consumption in China is from home cooking (Anderson et al., 2010). In the NHM programme, the patients were provided with a salt-restriction spoon and a salt container with a scale and the trained community nurses demonstrated how to use both. As a result, the percentage of patient adhering to salt intake restriction increased from 16.4% before the intervention to 61.2% post-

intervention, and 58.2% remained compliant at four weeks post-intervention. The result was supported by Chen et al. (2014) who asserted that the salt-restriction spoon and the individual's understanding of how to use it were the keys to whether patients in the community adopted the behaviour of restricting their salt intake.

5.3.2.2.2 Adherence to physical activities

Research findings have provided evidence to show that physical activities have an effect on lowering patient BP and reducing the risk for CVDs. The review by Baena et al. (2014) found that the intervention of physical activity resulted in a reduction of SBP by 11.4 mmHg and DBP by 6.5 mmHg. In this study, 57% of participants engaged in regular physical activities at baseline. Hu et al.'s investigation (2013) also showed that 52% of Chinese hypertensive patients participated in regular physical activity. In this study, the trained community nurses conferred with the patients to find feasible and acceptable physical activities for them. The NHM programme managed to increase the regular physical activity rate to 83.6% immediately after intervention, and it remained at 82.1% at four weeks after intervention. The results of NHM were more promising than usual care, which increased the rate of physical activities by 16.4 percentage points (T0 59.7% versus T1 67.2% versus T2 76.1%). This study exceeded the group-based intervention that only enhanced the pre-intervention physical activity adherence rate of 44% to 53% post-intervention (Gao et al., 2015).

5.3.2.2.3 Adherence to smoking cessation and alcohol restriction

Smoking is a major public health problem. After making numerous efforts, China has managed in recent decades to increase its rate of adherence to cessation of tobacco use (X. H. Liang et al., 2014). The 91% of non-smokers in this study was

similar to prior published data from the United States in which 89% of elderly adhered to smoking cessation (Miller et al., 2005). The results of this study also showed high adherence to alcohol moderation, in that 92% of participants were adherent to alcohol restriction. Neither NHM nor usual care showed any significant effects on improving adherence to smoking cessation or moderation of alcohol consumption. The negative results may be related to the fact that the high adherence rates at baseline meant there was little room for improvement.

5.3.2.2.4 Adherence to suggested home blood pressure monitoring

National and international guidelines all recommend HBPM (Liu & Writing group of 2010 Chinese GMH, 2011; Mancia et al., 2013; Pickering, Miller et al., 2008), but HBPM is not commonly practised in China. It has been reported that 80% of Chinese patients do not monitor their BP at home (Hu et al., 2013). The main reason for such a low rate of HBPM is a lack of BP monitoring devices and skills (Hu et al., 2013). In recent years, more of China's population can afford a BP monitoring device. In the present study, about 70% of participants had a BP monitor device, yet the HPBM rate was only 21%. Most of the participants did not measure their BP at home because they lacked the confidence and skills. In the NHM model, the trained community nurses focused on teaching patients the skills of HBPM. In addition, the trained community nurses also coordinated loans of electronic BP monitoring devices from the CHC to the hypertensive patients. As a result, the HBPM rate in the study group increased from 20% to 76% and stayed at 60% at four weeks post-intervention while the control group showed a slight decline at four weeks post-intervention.

5.3.3 Effects on self-efficacy

Some studies have shown that the self-efficacy of a hypertensive patient is closely related to some patient self-care behaviours (Lewis, Schoenthaler, & Ogedegbe, 2012; Mansyur et al., 2013; Warren-Findlow, Seymour, & Brunner, 2012). Lewis et al. and Warren-Findlow et al. found that high self-efficacy is associated with high medication adherence. Mansyur et al. also found that good self-efficacy was helpful for reducing smoking and increasing physical activity but had no impact on following dietary suggestions. Warren-Findlow et al. found that high self-efficacy was associated with consuming a low-salt diet, increasing physical activity, smoking cessation, and weight management but not with restricting alcohol consumption. In the NHM programme, MI techniques, such as nonjudgmental, empathetic communication, were used to inspire patients to adopt self-care behaviours along with mutual goal setting that sought to improve patients' self-care behaviours (Hibbard, Mahoney, Stock, & Tusler, 2007; Warren-Findlow et al., 2012). However, the evidence from the current study was insufficient to support the hypothesis of a difference in patient self-efficacy between the care provided by NHM and usual care immediately after intervention. Nevertheless, NHM did show better effects in patients' self-care behaviour than usual care. The findings seem consistent with those from Ma et al.'s study (2014), in which nurse intervention resulted in improved patient adherence but was not accompanied by enhanced self-efficacy. The non-significant results of the effects of self-efficacy may be related to the fact that the participants had a long history of hypertension (mean 11 years) and had not successfully controlled their BP control before they joined this programme, and these characteristics increased the difficulties of changing self-efficacy. However, since a significant difference in changes of self-efficacy from T0 to T2

between NHM and usual care was detected (Table 4.10), the NHM model may show its strength in the improvement of patient self-efficacy in long-term follow-ups.

5.3.4 Effects on quality of life

Improving or maintaining patients' QoL is an ultimate aim of care. Optimal intervention should be the maintenance of a reduced BP reading without decreasing the individual's QoL. The evidence in this study was insufficient to support the hypothesis of a difference in QoL between the care provided by the NHM model and usual care. However, some domains of QoL, such as RP, Bodily Pain, GH, SF, RE and MH, showed a tendency toward improvement over time for those who received the NHM model. These results were inconsistent with other lifestyle intervention programmes (Young et al., 2010) and MI intervention programmes (Ma et al., 2014). Young et al. demonstrated that a six-month lifestyle intervention programme improved patient QoL in GH, RE, VT, and MH. They also found that dietary changes and physical activity were related to improving QoL. In the current study, although the intervention of dietary changes and physical activities showed significant results, a significant difference in QoL was not observed between groups. Ma et al.'s study (2014) found that a six-month intervention programme resulted in a significant improvement in patients' QoL in PF, GH, VT and MH.

The main factor affecting QoL of hypertensive patients was the severe complications of hypertension (Poljičanin et al., 2010). The period of 12 weeks may be too short to follow-up and detect the complications of hypertension. Thus, we did not find a significant difference in QoL between the two groups.

5.3.5 Effects on utilisation of healthcare services

There was not enough evidence to support the hypothesis of a difference in utilisation of healthcare services between the care provided by the NHM model and usual care. In this study, after receiving the care guided by the NHM model, participants seemed to be more likely to reduce the frequency of self-prescription and increased the frequency of outpatient visits, but no statistically significant difference was found.

Since more home visits and telephone follow-ups were provided for the NHM group than the usual care group, the direct cost of the intervention was calculated. A home visit, five to six follow-up telephone calls and referrals were provided to each participant in the NHM group in addition to usual care. We calculated the direct cost of NHM based on the cost of the community nurses' labour. Their training time and the time spent in direct delivery care was included calculating the labour cost. Firstly, the four community nurses spent a total of 144 hours in the training programme (36 hours for each nurse). Secondly, the four trained community nurses provided a total of 62 home visits and 310 phone calls and made 23 referrals. Based on the records, an assumption was made based on a mean of 60 minutes for each home visit, a mean of 10 minutes on each call and a mean of 60 minutes for each referral, resulting in a total of 136.7 hours spent on direct intervention in this study. Assuming RMB 45 (about US$ 7.3) per hour as the midpoint salary of a community nurse, the intervention programme cost RMB12, 630 (about US$ 2,037). The cost of this intervention programme can be used as a reference point for the implementation of the NHM model in other similar nurse-led intervention programmes.

5.3.6 Effects on patient satisfaction

Patient satisfaction is the patient's perception of care. The researcher has asserted that satisfied patients are more likely to adhere to the recommendations of healthcare professionals (Barbosa et al., 2012). The results of this study support the hypothesis that the NHM model results in higher patient satisfaction when compared to usual care.

Many patients are more accustomed to consulting medical doctors than nurses when they have health problems. But now, with the introduction of advanced roles for nurses, patients are increasingly accepting of nurses' consultation and treatment in primary care (Caldow et al., 2007). Two meta-analysis studies showed that nurse-led care had a higher level of satisfaction in the primary care setting than doctor-led care for patients with chronic diseases (Keleher et al., 2009; Laurant et al., 2005). The findings of the current study are consistent with a study by Chiu & Wong's (2010) that found that nurse-led hypertension follow-ups resulted in an increase in patients' satisfaction. This finding may be attributed to the nurses spending more time with patients in consultations than is the case with routine medical consultations (Bebb et al., 2007; Caldow et al., 2007). The positive outcome may also be related to patients' sense of achievement in reducing their BP and the fact that the NHM model adopted a patient-centred intervention approach. In NHM, the trained community nurses comprehensively assessed a patient's health problems at his or her home to facilitate care; the trained community nurses coordinated with the GPs to provide treatment, thus reducing appointment wait times and overlapping treatments; the trained community nurses also continued to follow the patient's health condition through phone calls to connect fragmentary care; and the trained community nurses also coordinated health resources to facilitate care. This kind of active hypertension

management increased patients' satisfaction with the care provided by the trained community nurses in the CHC.

5.4 The nurse-led hypertension management model

In the current study, an NHM model was developed in which trained nurses were supported by other team members in conducting home visits, telephone follow-ups and initiating referrals as appropriate. In this model, the healthcare system was involved in such aspects as delivery system design, decision support, and patient health documentation. In addition, the patient's role in NHM was emphasised. Components were adopted from the CCM (Wagner 1998; Wagner et al., 2001), which has been proven to have effects on improving the quality of care and patient outcomes in chronic diseases and conditions (Coleman, Austin, Brach, & Wanger, 2009). The CCM is a flexible model, so users can use one or more components and integrate them into their practice or healthcare system. Although most studies use only one CCM component, and very few studies use all its components, intervention programmes that combine more components always result in more positive outcomes (Coleman et al., 2009). However, most of the evidence comes from the Unites States, with some from Europe, Canada, and Australia (Coleman et al., 2009). There is little evidence from MICs and scarce evidence from China. The current study is the first study in mainland China to adopt the components of the CCM to set up the NHM model and examine its effects.

In NHM, self-management support is supposed to directly impact patient outcome. The delivery system design, decision support, and clinical information system were used to support NHM. The following paragraphs describe how these components were tailored for use in the healthcare system of mainland China.

5.4.1 Self-management in the nurse-led hypertension management model in China

China, an MIC country, faces a heavy burden in providing hypertension care. Hypertension management has been a priority policy, but BP control is still at a relatively low level. Studies focusing on drug therapy using Chinese hypertensive drugs show that BP control can be achieved. Clinical studies such as Syst-China (Liu, Wang, Gong, Liu, & Staessen, 1998) and STONE (Gong et al., 1996) have demonstrated that calcium channel blockers are efficacious in lowering BP and in preventing strokes for Chinese people. Chinese guidelines for hypertension management also provide clear guidance for treatment algorithms with Chinese characteristics. However, the availability and affordability of pharmacological treatment is a significant challenge for China, a country that is demographically getting old before getting rich. By contrast, safe cost-effective measures and self-care behaviour-related interventions, such as adherence to treatment algorithms, engaging in physical activity, and moderating salt in the diet, are often undervalued. The current study is in line with previous studies in showing that in-community patients had relatively low rates of adherence to healthy behaviours. Since hypertensive patients often face multiple challenges in sticking with healthy behaviours, targeting a single lifestyle intervention to lower BP among in-community hypertensive patients is not always preferable. Evidence has shown that interventions that combine multi-lifestyle behaviours are more promising for lowering BP (Baena et al., 2014). The present study adds further evidence of the effectiveness of using a combination of interventions, such as salt restriction, promotion of physical activity, to bring about positive outcomes in BP management.

The usual care group was given a medical consultation; these clinic consultations traditionally were used to help patients control their BP with drug

prescriptions and on-site health education. However, many factors should be considered, such as the patient's beliefs and skills, that would mediate the effects of drug and health education to bring about the outcome of BP control. Health information is helpful to improve patient knowledge, but it does not necessarily result in improved patient adherence and BP control (Glynn, Murphy, Smit, Schroeder, & Fahey, 2010; Schroeder et al., 2004). In the present study, in addition to getting a booklet with information on self-management, the patients had opportunities to consult the trained community nurses during home visits and telephone follow-ups. The trained community nurses demonstrated skills such as the use of the salt-spoon, pill box, and HBPM, and ensured that patients acquired these skills through face-to-face demonstrations in the patients' homes. In addition, mutual goals were set to help patients have a sense of "taking charge" of their health condition, thus fostering patient self-management. The self-management knowledge and skills the patients acquired not only brought about the desired positive outcomes but also resulted in health cost savings. The NHM programme did not show an enhancement in patient self-efficacy, which will need further exploration in subsequent studies. Although trained community nurses used MI techniques in the current study, these may not be enough to promote patient self-confidence in hypertension management. Promoting patient self-management is inevitably an important intervention strategy for managing such a massive population of hypertensive patients as that in China.

5.4.2 Healthcare system in the nurse-led hypertension management model in China

Since 1999, China has issued a series of policies to support the establishment and reform of a healthcare system for hypertension management. Some healthcare systems are closely related to the NHM model.

5.4.2.1 Delivery system design

The policies and guidelines on hypertension management in China support the CHCs to manage hypertensive patients but are vague on how to organise the health resource, such as who is involved in management (Liu & Writing group of 2010 Chinese GMH, 2005; 2011; NHFPC of the PRC, 2009, October 10; 2011, April 25). GPs are responsible for routine hypertension management, but the role of other healthcare providers such as nurses is not mentioned (NHFPC of the PRC, 2009, October 10; 2011, April 25). Recent studies have reported the effects of GPs on hypertension management at the community level (X. J. Chen et al., 2014; X. H. Liang et al., 2014). But the lack of a control group for comparison makes the evidence of these studies inadequate to prove that the BP reduction and BP control rate that were achieved resulted from the GPs' contributions. Even were the GP-led approach effective, China's GP-to-population ratio of 1.46: 1000 (WHO, 2014) is far from adequate to manage the nation's considerable numbers of hypertensive patients. It is necessary to recruit more personnel from other disciplines into hypertension management. One researcher (Gao et al., 2013) tried to adopt a group-based approach to hypertension management and tested it in an RCT. In Gao et al.'s study, each group consisted of 18-20 patients, a physician, a nurse, and a health worker. The physician conducted health education and consultations while the nurse worked as an assistant to the physician, performing tasks such as taking patients' BP or scheduling appointment times. The health worker facilitated the health education of the group. The results showed that such a group-based approach was better than usual care in improving patient self-efficacy, BP control, and self-care behaviours.

Nurses are indispensable in practice, but their roles are usually restricted to assisting medical doctors (Guo et al., 2006). China's national policy requires nurses

to conduct health education, home visits, telephone follow-ups and chronic diseases management in the community healthcare setting (Ministry of Health of the PRC, 2002). Only a few studies have involved nurses in hypertension management in China (Gao et al., 2013; Ma et al., 2014) and fewer still involved the healthcare system at the community level. The current study established an NHM model and demonstrated that nurses were effective in improving patient outcomes, including BP control, self-care behaviours, and satisfaction.

In the current study, the trained community nurses were selected from those who had an associate degree or above. According to recent data, 51.3% of nurses in mainland China had an associate bachelor degree or higher (NHFPC of the PRC, 2011, December 31). This means that most of the nurses in China could be trained to lead a team in hypertension management. Furthermore, as the nurse-to-population ratio improves as a result of national policies encouraging nurse training (NHFPC of the PRC, 2011, December 31), the shortage of nursing personnel will be ameliorated. Expanding the NHM model in mainland China would enhance China's healthcare system.

5.4.2.2 Decision support

New hypertension guidelines backed by research-based evidence are being issued to provide information to healthcare providers in making decisions in hypertension management. In China, many guidelines for hypertension management have been published and updated in recent years (Liu & Writing Group of 2010 Chinese GMH, 2006; 2011; Wu, Huo, Wang, Zhao, & Zhu, 2014). Some specific guidelines are also now available, such as the GMH at the community level (Liu & Writing Group of 2010 Chinese GMH, 2009), the guideline for health education for hypertensive patients (Wu et al., 2014), and the guideline for BP monitoring (Wang

et al., 2011). However, GPs may not always be up-to-date in their knowledge of these hypertension guidelines for a variety of reasons, such as lack of time and training (Ren, 2004). J. Chen et al. (2014) reported that only 49% of GPs had accurate hypertension-related knowledge, such as treatment and community management requirements. They also found that nearly 90% of GPs wanted to attend training courses on hypertension prevention, including health education for hypertensive patients and improvement of patient adherence (J. Chen et al., 2014). The 36-hour training programme developed in the present study may meet the needs of GPs. This training programme was developed based on integrating updated information from guidelines and literature. More importantly, the training programme targeted improving health education skills such as MI techniques in communication, and skills to guide self-care behaviours during a home visit and telephone calls.

Guidelines and other research-based evidence can provide support for managing hypertensive patients, but too many guidelines with extensive information will make decision-making more difficult. In addition, the guidelines are intended for nationwide use and are not tailored to local use, and they do not provide details on the implementation of management. When healthcare providers manage hypertensive patients, the implementation of guidelines is varied and the effects of management are uncertain. The present study extracted the most important sections, such as goals and principles of pharmacological and non-pharmacological treatment, from the guidelines (Liu & Writing Group of 2010 Chinese GMH, 2006; 2011; Wu et al., 2014), and supplemented them with features of the local community healthcare setting to develop a series of protocols, such as for conducting home visits and telephone follow-ups. These established protocols provided a standardised process

for implementing hypertension management, and they increased the use of evidence-based information, including guidelines and research results, within the local healthcare context. Although the adherence rate of hypertension guidelines in the community setting has been reported to be low (Ren, 2004), the implementation rate of the protocols in the current study was high, based on the paper records and tape recordings. Strictly implementing guidelines or protocols was the main factor that resulted in reducing BP in NHM as well as other nurse-led intervention programmes (Fahey, Schroeder, & Ebrahim, 2005; Hill et al., 2010).

When healthcare providers apply the protocols to patients, they also need to focus on the patient's health conditions. Comprehensively assessing patients' health conditions is an essential step in healthcare providers' ability to make effective decisions for their patients. In the current study, the Omaha System, an assessment-intervention-evaluation structure, was used to guide the trained community nurses in identifying patient health problems, evaluating the health conditions and recording the intervention strategies. Firstly, the trained community nurses used the problem classification scheme of the Omaha System to assess patients' health problems, including common physiological problems such as circulation. The trained community nurses also assessed patients' health-related behaviours problems, such as nutrition and physical activity. In addition, environmental problems such as income were assessed, as well as psychosocial problems such as mental health. Secondly, the trained community nurses used the intervention scheme of the Omaha System to record the intervention they delivered. The information on intervention was not confined to pharmacological treatment but also included non-pharmacological interventions, such as self-care skills guidance, and the case management conducted, such as referral information. Thirdly, the Omaha System's

problem rating scale for the outcome was used by the trained community nurses to assess patients' knowledge, behaviour and status on identified health problems during the home visit and follow-ups. This comprehensive and individual health information helped the trained community nurses to make appropriate and effective patient care decisions.

5.4.2.3 Clinical information system

The clinical information system is an indispensable component of the healthcare system even though no obvious evidence supports its effects on patient outcome (Tsai, Morton, Mangione, & Keeler, 2005). Large health information systems can outline the general health conditions of residents and is helpful in identifying the key population in health or diseases management. At the individual level, an optimal clinical information system can provide healthcare providers with patients' individual, comprehensive and latest health-related information.

In mainland China, traditionally the only sources of patients' clinical information available to CHC healthcare providers is patients' self-report and medical records, because information related to patients' treatments is recorded on paper in personal medical records, which are kept by patients themselves. If a patient loses or forgets to bring his or her medical records, the therapy may be interrupted. Furthermore, in mainland China, patients can autonomously decide to visit hospitals or CHCs. Since each healthcare organisation has its own medical records system, when patients visit different healthcare organisations, they will get different forms of medical records. This results in overlapping or fragmentary recording of the patient's clinical information. Furthermore, traditional medical records only provide information on pharmacological treatments, omitting other health-related information, such as health-related behaviours. In 2009, the NHFPC of the PRC

(2009, October 10; 2009, September 1) required CHCs to adopt standardised health records for residents, especially for the elderly with diagnoses such as hypertension, diabetes and so on. In 2011, the NHFPC of the PRC encouraged CHCs to establish an EHR system for sharing health information within the healthcare system. Now, the majority of CHCs have set up paper health records or EHRs for most of their hypertensive patients, and the existing health records can provide general health information, such as health and medical history, medication and hospitalisation history, for healthcare providers. However, some problems have emerged in the existing health records, such as difficulties in information-sharing due to different terminologies and incompatible software and difficulties in evaluating changes due to a lack of quantitative information. These problems reduce the value of health records.

In the present study, a record-keeping method based on the Omaha System (Martin, 2005) was adopted into the clinical information system. The Omaha System is an international standardised taxonomy and has been translated into different languages and used in many countries. By using this system, the hypertension management information can be shared and exchanged internationally. The current study may be the first to adopt all the components of the Omaha System; these components were the problem classification scheme, intervention scheme and the problem rating scale for outcome in hypertension management in mainland China. Although there is, to date, no experimental trial to support the impact of the Omaha System combined with paper health records or EHRs on patient outcome in China, the records based on the Omaha System have their advantages, such as providing comprehensive and dynamic health information, so it was welcome in practice. The present study used paper-and-pen records of the Omaha System. To get more

comprehensive information, the trained community nurses would have needed to spend more time on the records, which would have increased their workload. Using the Omaha System computer software would solve this problem. In the United States, the state of Minnesota in 2014 adopted the Omaha system for its EHRs. In a future study, how the Omaha System software can connect EHRs in China should be considered.

5.5 Summary

The differences in the effects of NHM and usual care indicate that NHM significantly reduces BP, helps more patients achieve clinical reduction of BP, increases patient self-care behaviour, and improves patient satisfaction. Some insignificant outcomes, including BP control, self-efficacy, QoL and utilisation of healthcare services, suggest that further effective intervention strategies should be considered. As a result of analysing the healthcare system in China, we found that the NHM model is practicable and propagable in the Chinese healthcare system.

CHAPTER 6

CONCLUSION

6.1 Introduction

The present study is an early attempt to develop an NHM model to guide hypertension management in the community healthcare setting in mainland China. The present study has demonstrated, through an RCT design, that the NHM model produces better immediate post-intervention effects than usual care on patient outcomes, such as BP reduction, self-care behaviour, and patient satisfaction. The results of this study provide evidence that the contribution of nurses to hypertension management in the MIC's healthcare setting improves patient outcome. However, the study suffered some limitations, which are outlined in this chapter along with measures that were employed to prevent these limitations. Since the current study demonstrated the effectiveness of the NHM model, both the implications of the research study and its implications for clinical practice are discussed in this chapter. Some recommendations for nursing practice and further studies are outlined as well.

6.2 Major outcomes and contributions achieved

The aim of the study was to develop an NHM model and evaluate its effects on patient outcomes in mainland China. The objective of the study was to examine the difference between the effects of an NHM model and of usual care on patient outcomes in terms of BP reduction, BP control rate, self-care behaviour, self-efficacy, QoL, the utilisation of healthcare services, and patient satisfaction.

The main achievement of the study was the development of an NHM model to guide management of hypertensive patients in the community healthcare setting in mainland China. This was the first nurse-led model that incorporated components of the healthcare system, namely decision support, clinical information system and delivery system design, to back up nurse-led intervention to support patients' self-management. The contents of each component were organised on the basis of evidence from guidelines or literature and tailored to the context of China's community healthcare setting. The NHM model focused on demonstrating the effects of non-pharmacological treatment in hypertension management, such as involvement of patient self-management, and highlighting the roles of nurses, whose contributions are often overlooked in clinical practice. The NHM model was designed to demonstrate these features of nursing intervention: comprehensiveness, collaboration, coordination and continuity (Wong et al., 2005).

In the NHM model, a series of protocols and guidance booklets were developed. The protocols were the training protocol, home visit protocol, telephone follow-up protocol, and referral protocol. A self-management booklet and a case manager booklet were also developed. Through an RCT, the study demonstrated that the NHM model was superior to usual care in improving patient BP reduction, self-care behaviours, and patient satisfaction.

6.3 Limitations

As with other research studies, the present study suffered from some limitations, despite measures that were taken to try to avoid these limitations.

Firstly, the present study was unable to obtain sufficient evidence to prove that the NHM model was superior to usual care in the BP control rate, patient self-

efficacy, QoL and utilisation of healthcare services. The follow-up period of 12 weeks might have been too short to show these effects of the model. Therefore, a long-term follow-up should be conducted to examine the impact of these outcomes.

Secondly, the NHM model was tested in a single CHC only, which may affect the generalisability of the results. The research centre was a typical urban CHC in mainland China, but it is not known whether the NHM model is suitable for rural healthcare settings. As a consequence of China's rapid industrialisation and urbanisation, the differences between the rural healthcare setting and the urban healthcare setting are going to diminish, making the model more likely to become widely applicable in the near future. Furthermore, the research centre was located in southern China, where the hypertension prevalence rate, treatment rate and control rate are different from that in northern China (Table 2.2). Further multi-centre trials should be undertaken to test the effects of the model across varying geographic locales.

Thirdly, this study was a single-blinded one. Like other behaviour intervention studies, it was impossible to blind the participants and intervention implementers to the intervention strategies, so a single-blinded study is acceptable (Portney & Watkins, 2009). A challenge with this condition is that the patients may find their intervention different from others. Patients living within the same community might have exchanged the experiences of their healthcare with one another. Especially for patients in the usual care group, if they realised that the study group received closer follow-up than themselves, they may have sought other treatments outside of the research centre on their own. They also may have acquired knowledge and skills from patients in the study group if they happened to know each other. Though contamination across study arms could not be avoided, some measures were taken to

reduce this bias; for instance, the trained community nurses provided intervention one-on-one in a room, and the data collector also collected the participants' data one-on-one.

Lastly, the current study used the self-report questionnaire, the reliability and validity of which has been tested in previous studies, to measure patient adherence behaviours. From the perspective of cost, the self-report questionnaire is a feasible and affordable method. When compared to an objective measure such as an electronic medication monitoring, the data based on patients' self-report may suffer from a bias resulting from inaccurate patient recall or the influence of social desirability. In further studies, objective measures should be considered in measuring patients' medication adherence. Despite the study's limitations, they are unlikely to change our overall finding that the NHM model can be feasibly implemented in the Chinese community and showed its effectiveness at the patient level.

6.4 Implications

6.4.1 Implications for the research study

The NHM model established in the study enhances the effects of traditional hypertension management at the community level. The results of the study confirmed that application of the model in a community healthcare setting benefits massive numbers of hypertensive patients with poorly controlled BP.

The model supports patients as informed, prepared and motivated partners in self-care behaviour, thus filling the gap between the massive numbers of hypertensive patients and limited health resources. Given the increasing prevalence of hypertension and our inability to achieve satisfactory BP control, it is of increasing importance to implement interventions that support patients' self-care

behaviours. Since self-care behaviours not only help patients control their BP but also directly result in reducing CVDs, interventions that support patients' self-care behaviours can reduce to some extent the demands for high-cost health services due to hypertension complications such as stroke and heart disease.

The NHM model was established by translating research-based evidence into practical protocols that are supported by scientific evidence. The findings of the current study further supported the importance and value of nurses' contributions to hypertension management not only in HICs but also in countries with poor resources. A series of evaluated protocols in the current study can guide the implementation of non-pharmacological treatments, which are only briefly described in hypertension guidelines. These protocols can, in practice, be supplementary materials to the guidelines.

6.4.2 Implications for clinical practice

The current study was an early attempt to innovate the practice of hypertension management based on the present community healthcare setting in mainland China. The model provides an efficient supplementary approach for managing numerous hypertensive patients in a community-level setting in which there is a shortage of GPs. The intervention protocols in the established model can be adopted into the centre's routine work to help more hypertensive patients with uncontrolled BP improve their health outcomes.

In the model that was developed, the training programme provided a structured curriculum for nurses to enhance their ability to make decisions, and this training curriculum can be applied to the training of nurses in mainland China. Already, the

main contents of the training curriculum have been used to train community nurses and GPs in the cities of Shenzhen, Guangzhou, and Hangzhou in China.

In the model that was developed, the nurse's traditional role (e.g., as an assistant to the GP) in hypertension management was expanded, and more independent roles, such as in assessment and counselling, are suggested. Nurses can also perform these roles in advanced health services for patients with other chronic conditions or diseases. In the research centre, for instance, these trained community nurses have launched advanced healthcare services for the elderly.

6.5 Recommendations for further research

As mentioned in the limitations section, this study was conducted in a single CHC. Further studies should be carried out in multiple CHCs to test the effects on patient outcomes.

The ultimate aim of hypertension management is to reduce the complications caused by hypertension and improve patients' QoL. The health condition of the participants in this study would have to be examined to test the long-term effects of the NHM model on prevention of hypertension-related complications and the risk factors for CVDs.

Multiple factors will influence the impact of the NHM model. It is necessary to identify these factors and take measures to maximise the effects of the model in the future.

In the future, community resources, such as family members and volunteers, should be explored and examined for their potential to augment the services provided by healthcare providers.

6.6 Summary

This study was an early attempt to establish an NHM model in China's community healthcare setting. The NHM model was developed by translating a great deal of evidence into a series of practicable protocols. Subjecting the model to an RCT resulted in findings that demonstrated that the NHM model is feasible and effective in China's community setting. As for patient outcome, the results of subjecting the model to an RCT showed that the model had a great effect on patient BP reduction, self-care behaviours, and satisfaction. A long-term study should be conducted to test the effect of the model on more patient outcomes. Though the study suffered from some limitations, they did not change the conclusion that NHM is an effective approach for hypertension management in China.

APPENDICES

Appendix 1 Studies involved community-based interventions on hypertensive patients in China (Published in Chinese)

Author (year)	Design	Sample and sample size	Model	Study group	Control group	Duration	Data collection	Outcomes	Questionnaire
Xiao, et al. (2000)	RCT (?)	Sn=168 vs. Cn=166	×	BP monitoring weekly within 3m system recording per week provided consultant*3 times individualized instruction health education for patients and community health care providers performer? time?	blank	3y	pre & post	drug treatment + BP reading +	×
Wu & Xu (2001)	RCT (single blinded)	uncontrolled Sn=74 vs. Cn=74	×	health education leaflet knowledge competitions monthly lecture*4 bimonthly video watching*2 performer?	health education leaflet knowledge competitions	4m	pre & post	BP reading + Knowledge +	scale had been used in previous study
Wang (2002)	RCT (?)	Sn=121 vs. Cn=122	×	health education booklet weekly BP monitoring in outpatient department monthly home visit by trained GPs (1 GP vs.18-20 cases) bimonthly group lecture time?	unknown	3y	pre & post	BP control status + BP reading + complication + scl-90 +	scl 90 self-design scale described BP measure
Chen (2002)	RCT (?)	uncontrolled Sn=35 vs. Cn=33	×	content: comprehensive nursing intervention time? performer? frequency?	anti-hypertensive drug	18m	pre & post	BP reading + lifestyle modification +	×
Yu et al. (2003)	RCT (?)	Sn=118 vs. Cn=110	self efficacy	trained lay leader performed weekly*7	unknown	7week	pre & 4m	Knowledge + behavior + use of anti-hypertensive drug + BP - BMI + self-management behavior + health symptom + use of health care resource +	chronic disease management questionnaire described BP et al.measure method

Appendix 1 Studies involved community-based interventions on hypertensive patients in China (Published in Chinese)

Huang et al. (2004)	RCT (?)	Sn=90 vs. Cn=90	×	content:anti-hypertensive drug + knowledge education time? performer? frequency	anti-hypertensive drug	6m	Pre & post	BP reading + BMI + Salt intake + Alcohol intake + Smoking + TG + TC +	×
Xiao (2004)	RCT (?)	discharge from a hospital Sn=58 vs. Cn=46	×	content time? performer? frequency	unknown	6m	pre & post	drug adherence ratio +	Morisky drug adherence questionnair
Wang (2004)	RCT (?) admitted poor quality of RCT	uncontrolled BP Sn=55 vs. Cn=62	×	trained doctors performed 1 doctor vs.18-20 cases monthly home visit dietary,exercise, behaviour	usual care included anti-hypertensive drug	1y	pre & post	SBP + DBP + Salt intake + Alcohol intake and Smoking + Exercise +	×
Zhang et al.(2004)	RCT (according to consequence of visit)	uncontrolled BP Sn=45 vs. Cn=45	×	health education nurse intervention team perfomed weekly telephone follow up and consultant quarterly visit	health educaiton	2y	post	return visit + dietary + drug treatment + BP monitoring + exercise +	described BP measure self design scale
Fu et al. (2005)	RCT (?)	Sn=111 vs. Cn=108	self-efficacy	training for lay leader to conducted weekly group (15-20 person/group) lecture*6 using hypertension self-management guideline monthly group activity support from trained doctors by using telephone and consultant	usual hypertensive care	6m	pre & post	health status + use of health resource + BP reading + BP control rate + Self-management behavior + Self-efficacy +	chronic disease self-management study measures
Wang (2004)	RCT (?)	Sn=205 vs. Cn=195	×	doctors performed health education lecture booklet consultant with GP time? frequency?	did not provide community intervention	3m	pre & post	smoking + alcohol intake + use of anti-hypertensive drug + blood lipid + blood sugar + BP control rate +	×

Appendix 1 Studies involved community-based interventions on hypertensive patients in China (Published in Chinese)

Zhang (2005)	RCT (?)	Sn=125 vs. Cn=122	×	docotors performed monthly service time?	unknown	4y	pre & post	BP control rate +	discribed BP measure
Zhu (2005)	RCT (double blinded)	Sn=100 vs. Cn=100	×	doctors performed quarterly health education lecture monthly BP monitoring	blank	2y	post	BP control status + inhospital rate + death rate -	×
Zhu et al. (2005)	RCT (according to sequence of visiting)	outpatient department Sn=102 vs. Cn=102	×	2 experienced nurses 2 home visits(1m and 3m) at least 2 telephone follow-up	outpatient service did not provide community based intervention	1m	pre & post	BP control rate +	×
Yang et al.(2010)	RCT (?)	Sn=101 vs. Cn=97	×	health education health education conducted for families biweekly follow up for high risk patient until BP control rate achieved 90% → monthly follow up monthly follow up for middle and low risk level patient until BP control rate achieved 90% → every 2 month follow up for middle risk and quarterly follow up for low risk performer? time?	health education	1y	post	KAP + BP control status + complication -	unknown scale
Sun et al. (2005)	RCT (single-blinded)	Sn=185 vs. Cn=178	×	doctors: treatment therapy performer? Biweekly meeting lasted 2 hours at least 10 times	doctors: treatment therapy	6m	pre & post	BP control rate + BP reading + drug adherence +	×
Zhao et al. (2006)	RCT (?)	Sn=185 vs. Cn=179	×	performer? NAH(3 kinds of antihypertensive drugs) monthly follow-up	unknown	1y	pre & post	knowledge + smoking + alcohol intake + overweight + salt intake + exercise + regular BP monitor + BP control rate +	self-design scale
Du et al. (2006)	RCT (?)	outpatient department Sn=20 vs. Cn=20	×	team based(doctor and nurse) weekly or biweekly appointment(doctor) monthly home visit(doctor) contract(doctor)	outpatient visit	6m	pre & post	outcome status including BP and risk factors +	×

Appendix 1 Studies involved community-based interventions on hypertensive patients in China (Published in Chinese)

Dai (2006)	RCT (×)	Sn=50 vs. Cn=50	×	leaflet weekly telephone follow-up and BP monitoring *4 2 lectures performer?	unknown	4week	post	knowledge + drug adherence rate + BP monitoring + self confidence + BP control rate +	self-design scale describe BP measure method
Zhu (2006)	RCT (?)	outpatient department Sn=58 vs. Cn=50	×	face to face 10-20min in outpatient department monthly or bimonthly visit in outpatient department 2 times BP monitoring per week(some patients can chose other method) performer?	usual health education	2y	pre & post	attitude + adherence rate(drug,BP monitoring, BMI,salt intake and emotion) +	self-design scale
Li (2006)	RCT (single-blinded)	Sn=43 vs. Cn=47	×	treatment therapy anti-hypertensive drug booklet dietary+exercise+pshcological intervention performer? frequency? time?	treatment therapy anti-hypertensive drug booklet	2y	pre & post	BP reading + BP control rate + exercise adherence rate + dietary adherence rate + complication +	×
Wu et al. (2006)	RCT (?)	Sn=? vs. Cn=?(N=137)	×	anti-hypertensive drug health education 3 times high risk: monthly follow-up middle risk: at least 9 times follow-ups low risk：biweekly follow-ups health education prescription performer?	anti-hypertensive drug	1y	pre & post	BP control rate + risk level + behavior change +	described BP measure
Cai et al. (2007)	RCT (?)	Sn=103 vs. Cn=103	×	trained performer(doctor or nurse?) self-management booklet and record consultant service monthly lecture	did not provide service provided in the study group	1y	pre & post	BP reading	×
Xie (2007)	RCT (?)	outpatient department Sn=110 vs. Cn=110	×	knowledge discribed performer? time? frequency?	usual anti-hypertensive treatment	1y	pre & post	adherence + BP control rate + BP reading +	×

Appendix 1 Studies involved community-based interventions on hypertensive patients in China (Published in Chinese)

Pen (2007)	RCT (?)	outpatient department uncontrolled Sn=44 vs. Cn=43	×	health education in hospital community intervention: appointment,regular phone or home visit, lecture, reminder,instruction performer? time? frequency?	health education in hospital	1y	pre & post	BP reading + BP control rate + exercise + low salt dietary + alcohol intake + smoking cessation - drug use +	self-design scale
Zhu (2011)	RCT (?)	Sn=94 vs. Cn=94	×	health education regular follow up monthly satisfaction investigation monthly adherence investigation performer? time?	unknown	unknown	pre & post	BP reading + Adherence rate dietary, use of drug, smoking cessation and alcohol intake, BP monitoring, exercise)+	unknown scale
He (2012)	RCT (?)	Sn=50 vs. Cn=50	×	booklet monthly meeting drug instruction dietary education exercise education psychological education self monitoring education performer? time? frequency?	blank	unknown	unknown	(no data report) known rate + control rate + use of anti-hypertensive drug +	×
Wu & Liu (2007)	RCT (?)	discharge of a hospital uncontrolled Sn=60 vs. Cn=60	×	nurse performed instruction health recording self-management education booklet 1 phone in 2 week after discharge monthly outpatient visit receive phone consultant	instruction health recording without community nursing service part of them visit outpatient department	6m	post	self-management + BP reading + TC + TG +	self-design scale

Appendix 1 Studies involved community-based interventions on hypertensive patients in China (Published in Chinese)

Yu (2007)	RCT (according to sequence of visiting)	outpatient department uncontrolled Sn=60 vs. Cn=60	×	health education booklet biweekly lecture consultant phone weekly home visit for unable to attend the lectures or some patients with questions BP monitoring and recording monthly weight measure perfomer?	usual care in outpatient department	6m	pre & post	adherence rate + BP reading + BMI +	self-design scale
Hu (2007)	RCT (?)	Sn=100 vs. Cn=100	×	anti-hypertensive drug health education education provided for families：knowledge, behavior,psychological providie weekly BP monitoring performer? time? frequency?	anti-hypertensive drug health education	unknown	post	BP reading + BP control status +	×
Wang (2007)	RCT (?)	rurual elderly Sn=100 vs. Cn=101	×	health care provider performed (nurse? or doctor?) bimonthly health education by face to face or home visit or telephone follow up at least 5 times	unknown	1y	pre & post	knowledge + drug adherence rate + BP monitoring + HBP treatment rate + BP control rate +	scale used in previous study but did not report validity and reliability
Zhang et al. (2007)	RCT (?)	uncontrolled BP Sn=38 vs. Cn=38	×	community service persons anti-hypertensive drug health education booklet monthly meeting BP monitoring 1-2 times per week	anti-hypertensive drug	6m	pre & post	BP reading + BMI +	×
Wang (2007)	RCT (?)	uncontrolled BP Sn=140 vs. Cn=140	×	usual treatment therapy health education reported content and methods performer? time? frequency?	usual treatment therapy	1y	pre & post	drug adherence + BP control status +	Morisky drug adherence questionnair

Appendix 1 Studies involved community-based interventions on hypertensive patients in China (Published in Chinese)

Cheng et al. (2008)	RCT (?)	uncontrolled BP Sn=136 vs. Cn=136	IKAP	biweekly intervention based on assessement performer? time?	unknown	1y	pre & post	knowledge + BP reading +(6m, 12m) social support +	self-design scale reported validity and reliablity SRSS
Deng et al.(2008)	RCT (?)	Sn=462 vs. Cn=213	×	management BP monitoring at least once per month health education behaviour intervention performer? time? frequency?	unknown	3y	pre & post	behavior + risk factor + BP reading +	×
Yang & Liu (2008)	RCT (introduce the method)	Sn=179 vs. Cn=175	×	monthly lecture conducted by GP health education booklet follow-up(outpatient visit+phone) exercise prescription performer? time?	unknown	12m	pre & post	smoking + alcohol intake + over weight + low salt dietary + exercise + treatment + BP control + complication +	×
Li et.al. (2008)	RCT (?)	Sn=92 vs. Cn=93	×	health education and self-management booklet monthly lecture BP monitoring performer? time?	blank	3m	pre & post	BP control rate + knowledge + health belief + drug adherence + exercise + weight control + dietary +	×
Zhu (2008)	RCT (cluster sampling)	rural uncontrolled BP Sn=228 vs. Cn=189	×	doctor performed health education poster health education prescription monthly lecture	usual care	1y	pre & post	BP control status + drug adherence + exercise - smoking + alcohol intake + low salt +	×

Appendix 1 Studies involved community-based interventions on hypertensive patients in China (Published in Chinese)

Wei et al. (2008)	RCT (?)	Sn=150 vs. Cn=150	×	trained community health care provided making treatment therapy with patient weekly outpatient department visit or home visit before BP uncontrolled monthly home visit after BP controlled	level to level management(describe management content in different level)	1y	pre & post	BP reading + BP control rate + drug adherence + return visit + over weight + lifestyle behavior - emotion -	×
Xu et al. (2008)	RCT (?)	Sn=65 vs. Cn=65	KAP	trained nurse performed quarterly lecture lasted for 1 hour physical examination consultant 1 time weekly in the first month home visit 30min biweekly home visit 30min a total of 26 times	usual care	1y	pre & post	knowledge + self management +	self design scale
Yang & Zhou (2008)	RCT (?)	Sn=193 vs. Cn=193	×	health education booklet quarterly lecture BP monitoring performer? time?	blank	3m	pre & post	Knowledge + BP reading + TC + TG + HDL + BMI +	×
Chen (2008)	RCT (?)	uncontrolled BP Sn=60 vs. Cn=60	×	health education performer? time? frequency? method?	usual care	1y	pre & post	Knowledge +	×
Yang (2008)	RCT (according to sequence of visiting×)	outpatient department Sn=100 vs. Cn=100	×	health education booklet lecture monthly telephone follow up time? frequency? peformer?	unknown	6m	pre & post	knowledge + drug adherence +	self design scale

Appendix 1 Studies involved community-based interventions on hypertensive patients in China (Published in Chinese)

Su (2008)	RCT (?)	outpatient department uncontrolled BP Sn=56 vs. Cn=50	×	community nurse performed weekly home visit in first month + monthly home visit risk factor analysis individualized instruction family assessment health education for families	risk factor analysis individualized instruction	6m	3 time points, baseline,0.5 y & 1y	6m: SBP +/smoking +/dietary +/ exercise + 12m: SBP +/DBP +/ BMI -/TC +/smoking +/alcohol intake +/exercise +/BP monitoring monthly +	×
Wang et al. (2008)	RCT (?)	Sn=202 vs. Cn=198	×	usual follow up health education lecture bimonthly * 4 times perfomer?	usual follow-up	8m	pre & post	drug adherence + BP control rate + knowledge +	×
Xie (2008)	RCT (according to sequence of visit)	Sn=89 vs. Cn=87	×	drug treatment health education preformer? time? frequency?	drug treatment	6m	post	BP control rate + BP control status +	×
Dai & Qu (2009)	RCT (double blinded)	Sn=396 vs. Cn=390	×	health education performer? Content? time? frequency? method?	blank	1y	post	BP control rate	×
Gong (2009)	RCT (?)	uncontrolled BP Sn=396 vs. Cn=391	×	health education performer? time? frequency? method?	unknown	2y	pre & post	BP reading + adherence +	×
Hu et al. (2009)	RCT (?)	uncontrolled BP Sn=589 (HBP 171) vs. Cn=583(HBP 135)	×	trained health care providers performed return visit, telephone follow up and home visit (time? frequency?) one to one until achieved goals	monthly follow up medicine instruction health lifestyle instruction	3y	3 time points, baseline,1.5 y & 3y	BP reading + weight + BMI + WC + - TG + - TC + - BP control rate + complication +	×

Appendix 1 Studies involved community-based interventions on hypertensive patients in China (Published in Chinese)

Li & Liu (2009)	RCT (?)	uncontrolled BP Sn=55 vs. Cn=51	×	monthly follow up and BP monitoring health education including exercise,dietary,smoking cessation, alcohol intaking, drug treatment performer? time? frequency?	monthly follow up and BP monitoring		study group pre & post	smoking + alcohol intake + dietary + exercise + drug treatment + BP control +	×
Wang & Wang (2009)	RCT (?)	Sn=32 vs. Cn=32	×	drug treatment instruction weely follow up performer? time?	drug treatment instruction	1y	post	BP control rate + knowledge + drug adherence +	×
Shu & Lin (2009)	RCT (single blinded)	Sn=350 vs. Cn=350	×	trained community nurses or doctors drug treatment health record monthly follow up weekly BP monitoring health education(self management instruction,dietary instruction, exercise instruction, psychological instruction, weight control) weekly BP monitoring performer? time?	drug treatment monthly follow up healt record weekly BP monitoring	2y	pre & post	BP reading + BP control + knowledge + dietary + complication +	×
Wei et al. (2009)	RCT (?)	Sn=61 vs. Cn=61	×	health recording professional performed health education(nurse?Doctor?) drug treatment regular follow up：at least 2 times per month time? frequency?	usual care	1y	pre & post	drug adherence rate + exercise adherence rate + salt intake adherence rate + weight control adherence rate + BP reading +(6m, 12m)	×
Feng et al. (2009)	RCT (?)	Sn=320 vs. Cn=320	×	GPs and community nurses drug treatment health education (described content) time? frequency?	drug treatment	18m	post	treatment adherence status + behavior change rate + smoking - BP reading + BP control rate +	self design scale

Appendix 1 Studies involved community-based interventions on hypertensive patients in China (Published in Chinese)

Wang (2009)	RCT (?)	Sn=478 vs. Cn=512	×	regular health education performer? time? frequency?	blank	1y	post	BP control rate + DBP reading and difference +	×
Yao (2009)	RCT (?)	Sn=38 vs. Cn=38	×	drug treatment health education	drug treatment	6m	post	BP control status	×
Yang (2009)	RCT (?)	Sn=100 vs. Cn=100	×	health education booklet individualized instruction performer? time? frequency?	health education booklet	unknown	pre & post	treatment adherence rate + BP reading + BP control status + health lifestyle +	×
Li et al. (2009)	RCT (?)	18-35 years old Sn=58 vs. Cn=52	×	quarterly intervention for low risk patient monthly intervention for middle risk patient weely intervention for high risk patient reminder patient using computer system performer? time?	usual care	1y	pre & post	lifestyle behavior + knowledge + BP reading +	Morisky drug adherence questionnair
Lan (2009)	RCT (?)	Sn=50 vs. Cn=50	×	described health education content performer? time? frequency?	blank	1y	pre & post	knowledge + dietary + weight control - smoking - alcohol intake + exercise + emotion control + SBP reading + DBP reading -	×
Li (2009)	RCT (?)	uncontrolled BP Sn=100 vs. Cn=100	×	every 2 week BP monitoring performer? time? frequency?	usual care	unknown	post	treatment adherence rate + BP reading + BP control status +	×

Appendix 1 Studies involved community-based interventions on hypertensive patients in China (Published in Chinese)

Zhu et al.(2009)	RCT (simple randomized)	uncontrolled BP Sn=185 vs. Cn=184	×	trained 8 teams performed biweekly health education *7 times(90min per time) within 3 months	usual hypertension management	6m	pre & post	emotion control + dietary + low salt + alcohol intake + self-management behavior + self efficacy + health status + health service utilization + BMI - BP reading +	scales had been used in previous study
Wang & Deng (2009)	RCT (1：1)	Sn=183 vs. Cn=183	×	one to one consultant drug treatment hypertension guideline weekly telephone follow up biweekly outpatient visit health education: knowledge,drug instruction,dietary,exercise,sleeping,psychological instruction,weight control, self monitoring performer? time?	received drug treatment and in waiting list	3m	pre & post	BP reading + BP control rate + knowledge + health behavior +	×
Yan et al. (2009)	RCT (?)	Sn=60 vs. Cn=60	×	health recording education team(nurse?Doctor?) monthly health education lecture health education booklet BP monitoring for all families	health recording education team(nurse？Doctor？) monthly health education lecture health education booklet BP monitoring only for patient	6m	post	BP reading + BP control rate + health behavior +	self design scale CPAT
Zeng & Wang (2009)	RCT (?)	Sn=60 vs. Cn=60	×	community nurse performed regular follow up and instruction helath education booklet and lecture time? Frequence?	blank	unknown	post	knowledge + self management + BP control rate +	×

Appendix 1 Studies involved community-based interventions on hypertensive patients in China (Published in Chinese)

Xia et al. (2009)	RCT (randomized table)	Sn=65 vs. Cn=65	×	drug treatment health education bimonthly lecture health education booklet regular follow up performer? time?	drug treatment	1y	pre & post	BP reading + BP control rate + low salt dietary - smoking cessation + alcohol intake + exercise + drug treatment + drug adherence +	self design
Liu (2009)	RCT (?)	Sn=40 vs. Cn=40	×	drug treatment health education psychological intervention dietary education drug instruction performer? time?	drug treatment	6m	pre & post	knowledge + drug treatment rate + BP control rate + BP reading +	×
Wang & Li (2009)	RCT (?)	Sn=60 vs. Cn=60	×	drug treatment community nurse performed one nurse in charge of 15 cases weekly home visit or telephone follow up or lecture time? Frequence?	drug treatment monthly group lecture 90min per time health education booklet	6m	post	knowledge + control rate +	×
Ye et al. (2010)	RCT (?)	Sn=104 vs. Cn=82	×	health education (discribed contents) performer? time? frequency?	health education	2y	pre & post	adherence ? BP control status + BP reading +	×
Tan (2010)	RCT (?)	Sn=300 vs. Cn=300	×	team based(doctor and nurse et al) biweekly health education lecture * 7 times	unknown	12m	pre & post	BP reading + BP control classification + drug adherence rate + lifestyle +	×
Zhang et al. (2010)	RCT (?)	Sn=206 vs. Cn=109	×	biweekly health education lecture described health education content GPs vs.18-20 cases time? frequency?	usual care	1y	pre & post	BP reading + KAP +	unknown scale

Appendix 1 Studies involved community-based interventions on hypertensive patients in China (Published in Chinese)

He et al. (2010)	RCT (?)	discharge from a hospital Sn=99 vs. Cn=99	×	health education in hospital monthly follow up * 6 telephone follow up et al. performer? time? frequency?	health education in hospital	6m	post	dietary adherence rate + drug treatment + self monitoring + exercise - BP control status +	
Guo et al. (2010)	RCT (?)	discharge from a hospital Sn=99 vs. Cn=99	×	community health care providers(doctor or nurse?) psychological counseling 4-5 times weekly BP monitoring 120 times per case weekly video monthly health education lecture time?	drug treatment monthly BP monitoring 30-36 times per case	3y	post	BP reading + BMI + complication +	×
Wang et al.(2010)	RCT (according to discharge consequence)	discharge from a hospital Sn=39 vs. Cn=39	×	health education inhospital monthly home visit within 6 month monthly BP monitoring at least 15 times telephone contact inregular performer?	health education in hospital	6m	post	dietary adherence rate + drug treatment + self monitoring + exercise - BP reading +	×
Huang et al. (2010)	RCT (?)	Sn=50 vs. Cn=50	×	weekly telephone monthly home visit performer? time?	unknown	6m	pre & post	BP reading + BP control status +	described BP measure
Zhang (2010)	RCT (?)	outpatient Sn=50 vs. Cn=50	×	biweekly outpatient visit and BP monitoring drug treatment performer? time? frequency?	drug treatment	6m	post	adherence rate + BP control status +	described adherence measure
Zhu (2010)	RCT (?)	Sn=98 vs. Cn=70	×	making mutual treatment therapy biweekly home visit	outpatient treatment	6m	post	BP control status + Knowledge + health behavior +	described BP measure
Cai (2010)	RCT (?)	Sn=76 vs. Cn=76	×	usual care and drug treatment weekly BP monitoring monthly outpatient visit health education (15min?)	usual care and drug treatment monthly BP monitoring	1y	pre & post	adherence rate + BP control status +	×

Appendix 1 Studies involved community-based interventions on hypertensive patients in China (Published in Chinese)

Li et al. (2010)	RCT (?)	Sn=208 vs. Cn=205	self-management model	weekly lecture *6 times health education guideline group discussion support from doctors performer?	level-to-level management accordance to guideline	6m	pre & post	BP reading + BP control rate + classification +	×
Bao et al. (2010)	RCT (?)	Sn=124 vs. Cn=90	×	drug treatment monthly health education lecture lifestly modification exercise intervention performer? time? frequency	drug treatment	2y	pre & post	Bp reading + Complication +	×
Peng (2010)	RCT (1:1 matched general information)	outpatient department Sn=60 vs. Cn=60	×	trained team based including 1 doctor and 3 nurses weekly home visit and telephone follow up in the first month biweekly home visit and telephone follow up in the second month 1 time home visit and 2 telephone follow up every 3 weeks in the third and fourth month	usual care and health education lecture	4m	post	drug adherence rate + exercise adherence rate + BP monitor adherence rate + dietary adherence rate + weight control adherence rate + BP control rate + knowledge +	Morisky drug adherence questionnair Discribed adherence measure
Tan (2010)	RCT (?)	discharge of a hospital Sn=93 vs. Cn=93	×	telephone counseling performer? time? frequency?	blank	3m	post	adherence rate + dietary adherence rate + exercise adherence rate + drug adherence rate + stress + substance abuse + BP monitoring + side effects monitoring + return visit +	self design scale

Appendix 1 Studies involved community-based interventions on hypertensive patients in China (Published in Chinese)

Xia & Liu (2010)	RCT (according to room NO.)	uncontrolled BP Sn=300 vs. Cn=210	×	health recording：doctor performed health education：monthly health education lecture, regular home visit performer? time? frequency?	blank	5y	post	BP control status + complication +	×
Yang et al.(2010)	RCT (?)	Sn=412 vs. Cn=412	×	GP performed 10-20min instruction per day discribed health education contents time? frequency?	usual care	6m	post	over weight + emotion + smoking + dietary + exercise + alcohol intake +	self design scale
Wang (2010)	RCT (?)	outpatient uncontrolled BP Sn=80 vs. Cn=76	×	drug treatment health education face to face families support performer? time? frequency	drug treatment	6m	post	without data smoking + alcohol intake + low salt dietary +	×
excluded same as 092	RCT (?)	Sn=262 vs. Cn=180	×	drug treatment community service performer? time? frequency	drug treatment health education	6m	post	over weight + emotion + smoking + dietary - exercise + alcohol intake +	self design scale

Sn: sample size in the study group
Cn: sample size in the control group
GP: general practitioner
BP: blood pressure
RCT: randomised controlled trial

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Original Article

Development and evaluation of a nurse-led hypertension management model in a community: a pilot randomized controlled trial

Xuejiao Zhu[1,2], Frances Kam Yuet Wong[1], Lai Har Wu[1]

[1]*School of Nursing, The Hong Kong Polytechnic University, Hong Kong Special Administrative Region, P. R. China;*
[2]*Hangzhou Normal University, Hangzhou 310018, Zhejiang, P. R. China*

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Abstract: This study aims to develop a nurse-led hypertension management model in the community setting and pilot it to an experimental trial. A total of 73 recruited participants were randomly allocated into two groups. The study group received a home visit and 2-4 telephone follow-ups from the trained community nurses assisted by nursing student volunteers. The control group received doctor-led hypertension management. Data was collected at recruitment and immediately after the 8-week program. Outcome measures included blood pressure readings, self-care adherence, self-efficacy, quality of life, and patient satisfaction. Participants from the study group led by nurses had significant improvement in self-care adherence, patient satisfaction post-intervention than those from the control group led by doctors. However, there were no statistical significant differences in blood pressure readings, quality of life and self-efficacy between the two groups. The findings show that the nurse-led hypertension management appears to be a promising way to manage hypertensive patients at the community level, particularly when the healthcare system is better integrated.

Keywords: Community, hypertension management, nurse-led, pilot study, randomized controlled trial

Introduction

Hypertension has a high prevalence rate and low control rate worldwide. Finding a way to improve blood pressure (BP) control is a major challenge. Anti-hypertensive drugs and lifestyle modifications are well recognised as effective BP control measures, and are thus recommended in the guidelines of many countries and regions [1-7]. Unfortunately, the rates of adherence to the BP control measures and implementation of the guidelines remain low [5, 8]. Effective hypertension management should therefore incorporate essential elements to improve patient adherence. In conventional medical treatment, physicians play a primary role in BP control. However, physicians are more likely to focus on pharmacological treatment and overlook the strategies for BP control, such as interventions that involve lifestyle modifications and the provision of structured follow-ups to monitor the effects of treatment or intervention. There is evidence to show that interdisciplinary team-based care involving such professionals as nurses can exert positive effects on hypertension management [9]. Studies on nurse-led care show higher patient adherence and satisfaction rates compared with doctor-led care in the primary care setting, with similar effects on mortality and quality of life (QoL) [10, 11]. The intervention strategies in successful nurse-led hypertension care programmes include counselling and health education [12-18], and self-management such as BP monitoring [12, 13, 16-18]. Compared with pharmacological treatment, these nurse-led non-pharmacological intervention strategies are lower in cost but can contribute to reducing systolic blood pressure (SBP) by 4.8 mmHg [9]. Nurse-led intervention has thus been suggested as a promising way to manage hypertensive patients, although it lacks consistent international evidence. Accordingly, researchers [19, 20] have called for further evaluation of nurse-led care's efficacy in hypertension management. As Clark et al. [20] point out, since the

existing evidence comes mostly from the United States, it is necessary to obtain hypertension management evidence from other countries and regions.

In this study, a randomized controlled trial (RCT) was conducted to develop, and experimentally evaluate the effects of a model designed to guide the practice of nurse-led hypertension management in the community. The preliminary nurse-led hypertension management model was tested in practice, thereby providing evidence of and valuable insights into its feasibility and efficacy. The study has examined the difference in BP reading, self-care adherence, self-efficacy, QoL and patient satisfaction between patients who received care guided by the nurse-led hypertension management model and those who received care guided by doctor-led hypertension management.

Materials and methods

Enrolment of participants in RCT

The RCT study was conducted in a community health centre (CHC) in Hangzhou, China, with 73 participants recruited (36 in the study group and 37 in the control group). Ethical approval was obtained from the CHC involved in the study. All information was provided to the participants in written form. Signed consent forms were obtained from all participants. The inclusion criteria for study participation were: (a) a diagnosis of hypertension, (b) ≥35 years old and (c) living within the health service network of the CHC. The exclusion criteria were: (a) inability to communicate, (b) inability to be contacted by phone, (c) terminal illness, (d) co-morbidities in contradiction with the intervention programme (e.g. exercise) and (e) pregnancy.

Interventions

The study involved an 8-week intervention. The control group in the study received hypertensive care guided by the traditional doctor-led model. Such care included unstructured and irregular follow-ups with pharmacological treatment by general practitioners. These follow-ups occurred when patients visited general practitioners to get supplemental medicines in the centre. The control group received health education leaflets published by local department and the bimonthly health education lectures provided by the centre.

The study group received nurse-led hypertension management designed on the basis of the 4-C (comprehensiveness, collaboration, coordination, and continuity) framework developed by Wong et al. [21]. Comprehensiveness was assured in patient assessment and health documentation by using the Omaha System [22]. Its use allowed patients' health problems in the environmental, psychosocial, physiological and health-related behaviours domains to be assessed, and the results of all assessments, intervention implementation and changes in health condition to be recorded systematically and dynamically. Collaboration was assured by having the trained community nurses work with other team members such as general practitioners, nursing student volunteers, coordinator and the patients themselves to manage the latter's health condition. Coordination involved the trained community nurses organising and facilitating available resources to meet patients' needs. The trained community nurses provided home visits. After the home visit, the trained community nurse and a nursing student volunteer provided follow-up for every patient by telephone, thereby enhancing the effects of intervention. Two monthly telephone follow-ups were provided to those whose BP at recruitment was lower than 140/90 mmHg. Four biweekly telephone follow-ups were provided to those whose BP at recruitment was 140/90 mmHg or higher. These interventions and the training offered to the community nurses were based on protocols developed with reference to guidelines [23], literature review [16] and expert consultation.

Effects of interventions

The outcome measures included systolic blood pressure (SBP) and diastolic blood pressure (DBP), self-care adherence, self-efficacy, QoL, and patient satisfaction. SBP and DBP were measured twice using a calibrated YUYUE sphygmomanometer, with patients' average BP readings recorded [23] by the research assistants, who also collected the remainder of the outcomes through patient self-reports during face-to-face interviews carried out in the outpatient department of the CHC.

Self-care adherence was measured using the adherence form adopted in previous studies [16, 21], which includes adherence to smoking cessation, alcohol restriction, salt restriction, regular physical activity, home blood pressure monitoring (HBPM) and the use of anti-hyper-

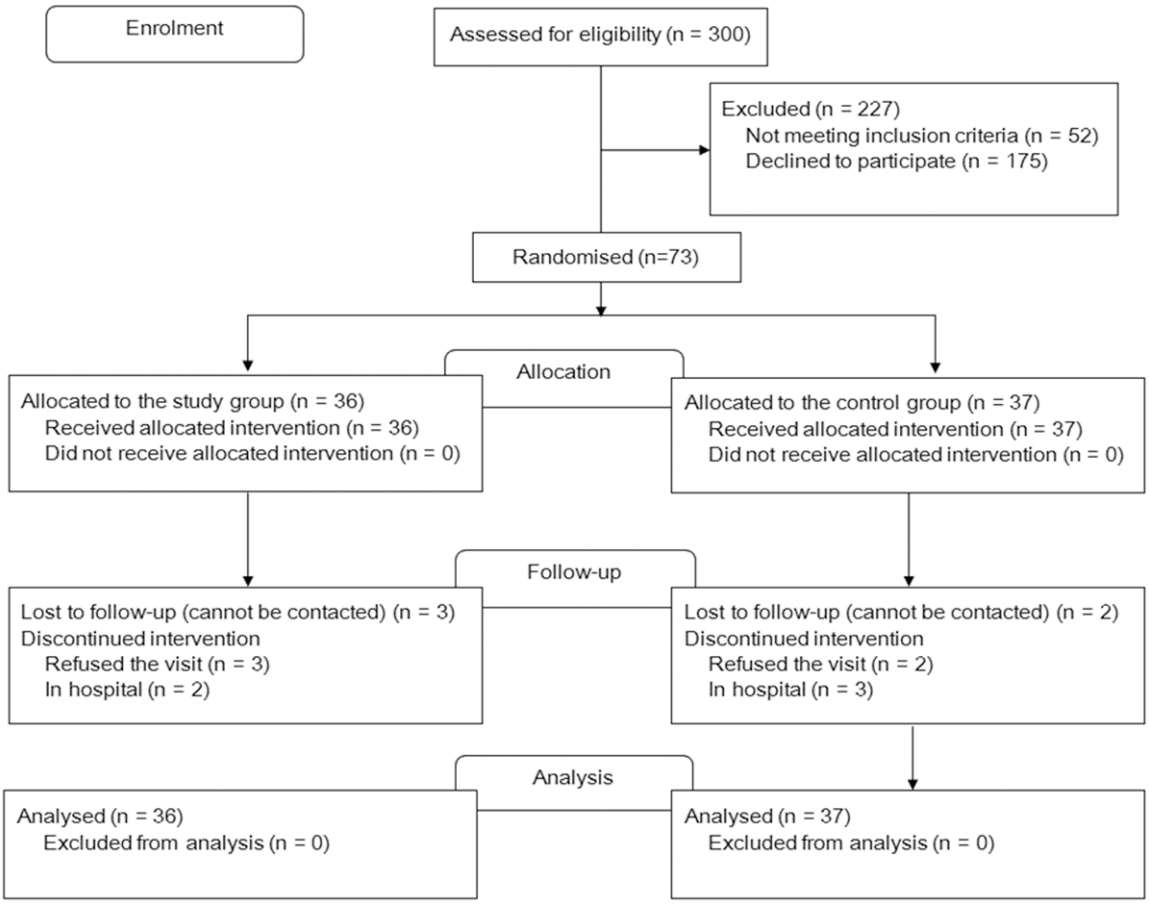

Figure 1. Patient allocation and experimental design.

tensive drugs. For smoking cessation and alcohol restriction, a score of 2 was given for adherence and a score of 1 for non-adherence. With respect to the remainder of adherence, a score of 3 was assigned for complete adherence, 2 for partial adherence and 1 for non-adherence. A high rate of inter-rater reliability, i.e. 0.92, was achieved for this measure.

Participants' self-efficacy was measured using the Chinese version of the Short-form Chronic Disease Self-Efficacy Scale (CDSES) [24]. The CDSES includes six items, each of which is rated on a scale ranging from 1 (not at all confident) to 10 (totally confident). The scale's Cronbach's alpha coefficient in this study was 0.82.

QoL was measured using the Chinese version of the Short-Form Health Survey (SF-36) [25]. The SF-36 includes eight domains of functional status: physical functioning, role-physical, bodily pain, general health, vitality, social functioning, role-emotional and mental health. The score for each domain ranges from 0 (worst possible health status) to 100 (best possible health status). In this study, the questionnaire's Cronbach's alpha coefficient ranged from 0.71 to 0.94.

Patient satisfaction was measured using a scale modified from the Patients' Satisfaction Scale employed by Wong et al. [21]. The modified scale contains ten items, ranked on a 6-point scale (5 = very satisfactory, 4 = satisfactory, 3 = fair, 2 = unsatisfactory, 1 = very unsatisfactory, 0 = not applicable). The scale's Cronbach's alpha coefficient in this study was 0.92.

Data analyses

All data were recorded and analysed using the Statistical Package for the Social Sciences, version 17.0. Baseline data were compared using a chi-square test for categorical data and independent t-tests for continuous data. A paired t-test was used for BP readings, self-efficacy, and QoL to test for within-groups differences and an independent t-test to test for between-

Table 1. Comparison of the characteristics of the two groups (n = 73)

Variable	Total n = 73 (%)	Study group n = 36 (%)	Control group n = 37 (%)	χ^2/*t*-test (*p* value)
Sex				
Male	27 (36.99)	15 (41.67)	12 (32.43)	0.67* (0.472)
Female	46 (63.01)	21 (58.33)	25 (67.57)	
Educational level				
No formal education	9 (12.32)	5 (13.89)	4 (10.81)	3.96* (0.139)
Primary education or below	14 (19.18)	10 (27.78)	4 (10.81)	
Secondary education or above	50 (68.49)	21 (58.33)	29 (78.38)	
Living status				
Live alone	10 (13.70)	5 (13.89)	5 (13.51)	0.00* (1.000)
Live with others	63 (86.30)	31 (86.11)	32 (86.49)	
Marital status				
Married	49 (67.12)	24 (66.67)	25 (67.57)	0.01* (1.000)
Single	24 (32.88)	12 (33.33)	12 (32.43)	
Income				
Below average	61 (83.56)	29 (80.56)	32 (86.49)	0.41* (0.750)
Average or above	12 (16.44)	7 (19.44)	5 (13.51)	
Age (years)				
Mean (SD)	69.13 (9.72)	70.42 (10.63)	67.81 (8.82)	1.13# (0.262)
[Range]	[47-89]	[47-89]	[51-84]	
Co-morbidity				
No co-morbidity	17 (23.29)	7 (19.44)	10 (27.03)	0.59* (0.581)
One or more co-morbidities	56 (76.71)	29 (80.56)	27 (72.97)	
Body mass index				
Mean (SD)	24.56 (2.89)	24.33 (2.82)	24.89 (2.91)	-1.46# (0.146)
[Range]	[16.24-32.53]	[16.22-29.34]	[20.42-32.53]	
Waist circumference				
Mean (SD)	86.54 (9.32)	86.46 (8.99)	86.53 (9.45)	-0.09# (0.927)
[Range]	[64-123]	[64-108]	[66-123]	

Note: *, Chi-square test; #, Independent sample *t-test*.

group differences. A Wilcoxon signed-rank test was used to compare self-care adherence and patient satisfaction pre- and post-intervention, and a Mann-Whitney U-test was performed to compare the ranked scores between the two groups. Missing data were replaced by last observation values according to previously reported method [26], and the intention-to-treat analysis was performed. Two-tailed *p* values of < 0.05 were considered significant.

Results

Demographic and health characteristics

Of the 73 participants recruited (36 in the study group and 37 in the control group) in this RCT study, 15 (eight in the study group and seven in the control group) were lost to follow-up or discontinued the programme. Results relative to the 15 participants were analyzed by the intention-to-treat analysis according to previous report [26]. The patient allocation is illustrated in **Figure 1**. There were no statistically significant differences between the demographic and health characteristics of the patients who dropped out and those who completed the study. The participants in the study and control groups received nurse-led and doctor-led hypertension managements, respectively.

Table 1 presents the participants' demographic and health characteristics. It can be seen that the majority of the participants were female (46, 63.0%). The mean age was 69.1 (SD = 9.7; range = 47-89) and more than half (68.5%) had a secondary school or above level of education. In addition, the majority of participants (76.7%) had one or more co-morbidities, with a mean

Table 2. Comparison of the blood pressure readings of the two groups (n = 73)

	Study group n = 36	Control group n = 37	Independent t-test	
	Mean (SD)	Mean (SD)	t value	*p* value
Systolic blood pressure				
Pre-test	130.92 (10.14)	131.95 (11.67)	-0.401	0.689
Post-test	130.83 (9.94)	132.24 (13.86)	-0.498	0.620
Paired t-test, t, *p*-value	0.069, 0.945	-0.128, 0.899		
Diastolic blood pressure				
Pre-test	74.31(6.23)	76.05 (8.10)	-1.032	0.306
Post-test	72.75 (6.64)	75.35 (6.86)	-1.646	0.104
Paired t-test, t, *p*-value	1.324, 0.194	0.587, 0.561		

Table 3. Comparison of self-care adherence between the two groups (n = 73)

Variables	Study group n = 36	Control group n = 37	Mann-Whitney U-test	
	Median (Interquartile Range)	Median (Interquartile Range)	Z value	*p* value
Smoking cessation				
Pre-test	2 (2-2)	2 (2-2)	-0.433	0.665
Post-test	2 (2-2)	2 (2-2)	-0.433	0.665
Wilcoxon signed-rank test, Z, *p*-value	0.000, 1.000	0.000, 1.000		
Alcohol restriction				
Pre-test	2 (2-2)	2 (2-2)	-0.052	0.959
Post-test	2 (2-2)	2 (2-2)	-0.723	0.470
Wilcoxon signed-rank test, Z, *p*-value	0.000, 1.000	-1.000, 0.317		
Salt restriction				
Pre-test	2 (1-2)	2 (1-2)	-0.588	0.557
Post-test	3 (2-3)	2 (1-2)	-2.366	0.018
Wilcoxon signed-rank test, Z, *p*-value	-2.357, 0.018	-0.235, 0.814		
Regular physical activity				
Pre-test	2 (2-3)	2 (2-2)	-0.751	0.453
Post-test	2 (2-3)	2 (2-2)	-1.185	0.236
Wilcoxon signed-rank test, Z, *p*-value	-0.504, 0.614	-0.000, 1.000		
Home blood pressure monitoring				
Pre-test	3 (2-3)	2 (2-3)	-0.536	0.592
Post-test	3 (2-3)	2 (2-3)	-3.101	0.002
Wilcoxon signed-rank test, Z, *p*-value	-2.646, 0.008	-1.000, 0.317		
Use of anti-hypertensive drugs				
Pre-test	2 (1-3)	2 (1-3)	-1.042	0.297
Post-test	3 (3-3)	2 (1-3)	-4.626	0.000
Wilcoxon signed-rank test, Z, *p*-value	-4.179, 0.000	-1.265, 0.206		

body mass index (BWI) of 24.6 (SD = 2.9) and a mean waist circumference (WC) of 86.5 (SD = 9.3). There were no statistically significant differences between the study and control groups at baseline data. No statistically significant differences in the participants' BP readings (**Table 2**) were found between the two groups after the 8-week intervention.

Self-care adherence

Although the two groups had equivalent adherence scores (**Table 3**), the study group displayed significant improvements in salt restriction (Z = -2.357, $p = 0.018$), HBPM (Z = -2.646, $p = 0.008$) and drug use (Z = -4.179, $p = 0.000$) post-intervention. These results suggest that

Table 4. Comparison of self-efficacy between the two groups (n = 73)

Variable	Study group n = 36	Control group n = 37	Independent *t*-test	
	Mean (SD)	Mean (SD)	*t* value	*p* value
Pre-test	6.20 (1.93)	5.77 (1.98)	0.957	0.342
Post-test	6.73 (1.63)	5.87 (2.18)	1.904	0.061
Paired t-test, *t* value (*p* value)	-1.497 (0.143)	-0.306 (0.761)		

Table 5. Comparison of quality of life between the two groups (n = 73)

Variables	Study group n = 36	Control group n = 37	Independent t-test	
	Mean (SD)	Mean (SD)	t value	*p* value
Physical functioning				
Pre-test	85.56 (12.86)	84.05 (16.62)	0.431	0.668
Post-test	84.03 (16.12)	82.84 (19.49)	0.285	0.777
Paired t-test, t, *p*-value	0.544, 0.590	0.367, 0.716		
Role physical				
Pre-test	68.75 (41.99)	74.32 (42.28)	-0.565	0.574
Post-test	67.36 (42.18)	78.38 (38.26)	-1.169	0.246
Paired t-test, t, *p*-value	0.158, 0.875	-0.498, 0.621		
Bodily pain				
Pre-test	74.78 (19.14)	72.86 (26.14)	0.357	0.722
Post-test	75.58 (23.99)	75.78 (23.61)	-0.036	0.971
Paired t-test, t, *p*-value	-0.201, 0.842	-0.564, 0.576		
General health				
Pre-test	46.53 (11.57)	49.89 (22.24)	1.237	0.220
Post-test	55.94 (19.43)	46.22 (12.81)	2.532	0.014
Paired t-test, t, *p*-value	2.515, 0.017	0.818, 0.419		
Vitality				
Pre-test	71.11 (13.94)	72.70 (17.50)	-0.429	0.669
Post-test	72.78 (15.65)	75.95 (14.57)	-0.896	0.374
Paired t-test, t, *p*-value	-0.634, 0.530	-1.366, 0.180		
Social functioning				
Pre-test	85.42 (16.77)	91.55 (12.17)	-1.786	0.079
Post-test	85.76 (16.13)	88.51 (20.49)	-0.636	0.527
Paired t-test, t, *p*-value	-0.133, 0.895	0.893, 0.378		
Role emotional				
Pre-test	74.07 (41.49)	79.28 (36.30)	-0.571	0.570
Post-test	73.15 (41.27)	81.08 (36.47)	-0.871	0.387
Paired t-test, t, *p*-value	0.122, 0.903	-0.264, 0.793		
Mental health				
Pre-test	79.89 (17.12)	85.84 (11.22)	-1.751	0.085
Post-test	83.56 (13.62)	87.68 (10.77)	-1.432	0.157
Paired t-test, t, *p*-value	-1.162, 0.253	-0.954, 0.347		

8-week nurse-led intervention program can effectively enhance patients' adherence to both prescriptions of anti-hypertensive drugs and recommendations of lifestyle modifications such as salt restriction.

Patient self-efficacy

As given in **Table 4**, there was a slight increase in the mean score of patient self-efficacy in the study group after intervention in comparison

Table 6. Comparison of patient satisfaction between the two groups (n=73)

	Study group n = 36	Control group n = 37	Mann-Whitney U-test	
	Median (Interquartile Range)	Median (Interquartile Range)	Z value	*p* value
Pre-test	35.50 (0.00-48.00)	34.00 (0.00-40.00)	-0.583	0.560
Post-test	40.00 (24.00-49.00)	32.00 (0.00-40.00)	-2.054	0.040
Wilcoxon sinned ranks test, Z value (*p* value)	-2.303, (0.021)	-0.430, (0.667)		

with the control group (6.73 versus 6.20). **Table 5** shows the mean scores of eight domains of QoL in the two groups. After intervention, in the domain of general health, the mean score increased by 9.41 (from 46.53 to 55.94) in the study group (P = 0.017). When compared to the control group, a significant difference also was observed (P = 0.014). These results suggest that intervention guided by nurse-led hypertension management model is more effective on enhancing patients' general health than the control doctor-led management.

Patient satisfaction

As given in **Table 6**, the intervention effected no significant change in this domain in the control group, whereas a significant post-intervention increase was observed in the study group (t = -2.303, *p* = 0.021). There was also a significant difference between the groups after the intervention (t = -2.054, *p* = 0.040). The significant difference was detected within the study group (*p* = 0.021) as well as between two groups after intervention (*p* = 0.040). These results suggest that hypertensive patients were more satisfied with nurse-led hypertension management than the control doctor-led management.

Discussion

In the doctor-led CHCs, doctors dominate hypertension management. This study has reported the nurse-led hypertension management model to compare its effects with a traditional doctor-led model in an experimental trial in China. In the study, we have established a nurse-led hypertension management model guided by 4-C framework [21]. When subjected to an RCT, our nurse-led model resulted in greater patient self-care adherence, satisfaction, and outcomes in some domain of QoL than the doctor-led model. Though we could not provide sufficient evidence of nurse-led intervention on reducing BP and improving self-efficacy, our study proved that the community nurses could be trained to play a key role in hypertension management at community level and contribute to improvement of patient outcome.

The study suffered two major limitations. First, just like other non-profit intervention studies conducted in the doctor-led health care organisations, it is difficult to conduct a large-scale trial. Thus, relatively small sample size in the study might affect evaluation of effects of the intervention in this study. Second, as with all single-centre study, the generalisability of our results to other healthcare settings is unknown, although the centre is a typical community health care organization.

Patient adherence is associated with clinical outcomes and health care cost. Improving patient adherence is a vital factor of effective BP control. In this study, trained community nurses enhanced patient adherence by using effective strategies such as home visit and telephone follow-ups [27]. The finding that the nurse-led intervention achieved greater patient adherence than the doctor-led control is consistent with the result of a meta-analyses study [11].

The nurse-led hypertension management model is practicable in guidance of managing hypertensive patients at the community level, while its effects on patient BP readings still need to be evaluated. In further study, efforts should be made to improve structural factors such as the health system in order to maximize the effectiveness of the nurse-led model.

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Disclosure of conflict of interest

None.

Address correspondence to: Dr. Frances Kam Yuet Wong, School of Nursing, The Hong Kong Polytechnic University, Hunghom, Kowloon, Hong Kong Special Administrative Region, P. R. China. Tel: 852-2766-6419; Fax: 852-23649663; E-mail: frances.wong@polyu.edu.hk

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Appendix 3

奥马哈系统
The Omaha System

填表说明：

Instructions:

1. 以下表中包含 4 个领域 42 个问题，其中：第一个领域为环境领域，包括第 1-4 个问题；第二个领域为心理社会领域，包括第 5-16 个问题；第三个领域为生理领域，包括第 17-34 个问题；第四个领域为健康相关行为领域，包括第 35-42 个问题。每个问题有各自的子项目。在家访或者电话随访时，就针对评估发现的问题在相应的子项目右侧一栏内打√，没有发现的问题无须标注，同时在眉栏填写相应的日期。

The following table is comprised of 42 health problems across four domains. The first domain is the environmental domain including NO.1 to NO.4 health problems. The second domain is the psychosocial domain including NO.5 to NO.16 health problems. The third domain is the physiological domain including NO.17 to NO.34 health problems. The fourth domain is the health-related behaviours domain including NO. 35 to 42 health problems. Each health problem has its sub-items. For each problem identified, please tick √ in the column on the right side of the corresponding sub-items. Please fill the date of home visit and each telephone follow-up.

2. 请针对个案健康问题的 K/B/S 给出评分，K 代表认知；B 代表行为；S 代表状况。评分内容中计分方式如下：

K：1=缺乏认知　2=少许认知　3=基本认知　4=足够认知　5=充分认知

B：1=不恰当　2=甚少恰当　3=间有恰当　4=通常恰当　5=一贯恰当

S：1=极严重的症状和体征　2=严重的症状和体征　3=中度的症状和体征　4=轻微的症状和体征　5=无症状和体征

Please rate the case's knowledge, behaviour and status in each identified health problem. The rating scale is as follows:

Knowledge

1 = No knowledge

2 = Minimal knowledge

3 = Basic knowledge

4 = Adequate knowledge

5 = Superior knowledge

Behaviour

1 = Not appropriate behaviour

2 = Rarely appropriate behaviour

3 = Inconsistently appropriate behaviour

4 = Usually appropriate behaviour

5 = Consistently appropriate behaviour

Status

1 = Extreme signs/symptoms

2 = Severe signs/symptoms

3 = Moderate signs/symptoms

4 = Minimal signs/symptoms

5 = No signs/symptoms

3. 如针对个案的某个健康问题实施了干预，请在相对应的干预的类别 E/T/C/S 前的□内打√，E 代表教育/指导和咨询，T 代表治疗和程序，C 代表个案管理，S 代表监测，针对同一个问题可有多种干预类别的干预。没有实施的干预类别毋须标注。

Please tick √ in the □ of E/T/C/S for those interventions implemented for each health problem of cases in the corresponding category. E stands for teaching/guidance and counselling. T stands for treatments and procedures. C stands for case management, and S stands for surveillance. More than one category can be chosen for the same health problem.

奥马哈系统
The Omaha System

	项目编号 Case number:	No. 1	No. 2	No. 3	No. 4	No. 5	No. 6	No. 7
	问题 Problem	月 日	月 日	月 日	月 日	月 日	月 日	月 日
1	收入 Income	K B S	K B S	K B S	K B S	K B S	K B S	K B S
		E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□
1.1	低/没有收入 Low/no income							
1.2	无医疗保险 Uninsured medical expenses							
1.3	仅够购买生活必需品 Able to buy only necessities							
2	卫生 Sanitation	K B S	K B S	K B S	K B S	K B S	K B S	K B S
		E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□
2.1	居住环境肮脏 Soiled living area							
2.2	食物储存/处置不当 Inadequate food storage/disposal							
3	住宅 Residence	K B S	K B S	K B S	K B S	K B S	K B S	K B S
		E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□
3.1	楼梯陡峭/不安全 Steep/unsafe stairs							
3.2	生活空间杂乱 Cluttered living space							
3.3	家电/设备不安全 Unsafe appliances/equipment							
4	邻里/工作场所的安全 Neighborhood/workplace safety	K B S	K B S	K B S	K B S	K B S	K B S	K B S
		E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□
4.1	游乐/运动的场地不足/不安全 Inadequate/unsafe play/exercise areas							
5	联络社区资源 Communication with community resources	K B S	K B S	K B S	K B S	K B S	K B S	K B S
		E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□
5.1	不熟悉获取服务的选项/程序 Unfamiliar with options/procedures for obtaining services							
5.2	难以理解服务提供者的角色/规定 Difficulty understanding roles/regulations of service providers							
5.3	对服务不满意 Dissatisfaction with services							
6	社交 Social contact	K B S	K B S	K B S	K B S	K B S	K B S	K B S
		E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□
6.1	有限的社交接触 Limited social contact							
6.2	极少外界刺激/休闲活动 Minimal outside stimulation/leisure time activities							
7	角色改变 Role change	K B S	K B S	K B S	K B S	K B S	K B S	K B S
		E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□
7.1	承担新的角色 Assumes new role							
7.2	失去先前的角色 Loses previous role							
8	人际关系 Interpersonal relationship	K B S	K B S	K B S	K B S	K B S	K B S	K B S
		E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□
8.1	不一致的价值观/目标/期望/计划安排 Incongruent values/goals/expectations/schedules							
8.2	人际沟通技巧不足 Inadequate interpersonal communication skills							
9	灵性 Spirituality	K B S	K B S	K B S	K B S	K B S	K B S	K B S
		E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□
9.1	灵性信仰与医疗/健康照顾方案有冲突 Conflicting spiritual beliefs and medical/health care regimen							
10	哀伤 Grief	K B S	K B S	K B S	K B S	K B S	K B S	K B S
		E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□
11*	精神健康 Mental health	K B S	K B S	K B S	K B S	K B S	K B S	K B S
		E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□
11.1	忧虑/不明的恐惧 Apprehension/undefined fear							
11.2	失去兴趣/参与活动/自我照顾 Loss of interest/involvement in activities/self-care							
11.3	易怒的/激动的/攻击的 Irritable/agitated/aggressive							
11.4	处理压力困难 Difficulty managing stress							
11.5	处理愤怒困难 Difficulty managing anger							
11.6	躯体性主诉/疲乏 Somatic complaints/fatigue							
11.7	情绪波动 Mood swings							
12	性 Sexuality	K B S	K B S	K B S	K B S	K B S	K B S	K B S
		E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□
12.1	不满性关系 Dissatisfied with sexual relationships							
13	照顾/育儿 Caretaking/parenting	K B S	K B S	K B S	K B S	K B S	K B S	K B S
		E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□
13.1	难以提供预防性和治疗性的健康照顾 Difficulty providing preventive and therapeutic health care							
13.2	对（所承担的）责任不满意/有困难 Dissatisfaction/difficulty with responsibilities							

K: 知识 Knowledge B: 行为 Behaviour S: 状态 Status
E: 教育/指导和咨询 Teaching/Guidance/Counseling
T: 治疗和程序 Treatments and Procedures
C: 个案管理 Case management
S: 监测 Surveillance

	项目编号 Case number:	No. 1	No. 2	No. 3	No. 4	No. 5	No. 6	No. 7
14	疏忽 Neglect	K B S	K B S	K B S	K B S	K B S	K B S	K B S
		E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□
14.1	医疗照顾不足/延误 Inadequate/delayed medical care							
15	虐待 Abuse	K B S	K B S	K B S	K B S	K B S	K B S	K B S
		E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□
16	成长和发育 Growth and development	K B S	K B S	K B S	K B S	K B S	K B S	K B S
		E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□
16.1	与年龄不符的行为 Age-inappropriate behavior							
17	听觉 Hearing	K B S	K B S	K B S	K B S	K B S	K B S	K B S
		E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□
17.1	听正常语调困难 Difficulty hearing normal speech tones							
17.2	对声音的反应缺失/异常 Absent/abnormal response to sound							
18	视觉 Vision	K B S	K B S	K B S	K B S	K B S	K B S	K B S
		E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□
18.1	看小的字体/刻度困难 Difficulty seeing small print/calibrations							
18.2	看远物困难 Difficulty seeing distant objects							
18.3	看近物困难 Difficulty seeing close objects							
19	说话和语言 Speech and language	K B S	K B S	K B S	K B S	K B S	K B S	K B S
		E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□
20	口腔卫生 Oral health	K B S	K B S	K B S	K B S	K B S	K B S	K B S
		E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□
20.1	牙齿缺失/损坏/畸形 Missing/broken/malformed teeth							
20.2	牙龈疼痛/肿胀/出血 Sore/swollen/bleeding gums							
21	认知 Cognition	K B S	K B S	K B S	K B S	K B S	K B S	K B S
		E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□
21.1	回忆近期事件受限 Limited recall of recent events							
21.2	回忆远期事件受限 Limited recall of long past events							
22	疼痛 Pain	K B S	K B S	K B S	K B S	K B S	K B S	K B S
		E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□
22.1	表达不适/疼痛 Expresses discomfort/pain							
22.2	脉搏/呼吸加快/血压升高 Elevated pulse/respirations/blood pressure							
22.3	苍白/出汗 Pallor/perspiration							
23	意识 Consciousness	K B S	K B S	K B S	K B S	K B S	K B S	K B S
		E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□
24	皮肤 Skin	K B S	K B S	K B S	K B S	K B S	K B S	K B S
		E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□
24.1	损伤/压疮 Lesion/pressure ulcer							
24.2	瘙痒 Pruritus							
24.3	切口愈合延迟 Delayed incisional healing							
25	神经-肌肉-骨骼功能 Neuro-musculo-skeletal function	K B S	K B S	K B S	K B S	K B S	K B S	K B S
		E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□
25.1	活动范围受限 Limited range of motion							
25.2	平衡减弱 Decreased balance							
26	呼吸 Respiration	K B S	K B S	K B S	K B S	K B S	K B S	K B S
		E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□
26.1	咳嗽 Cough							
26.2	发绀 Cyanosis							
26.3	呼吸音异常 Abnormal breath sounds							
27*	循环 Circulation	K B S	K B S	K B S	K B S	K B S	K B S	K B S
		E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□
27.1	水肿 Edema							
27.2	脉率减少 Decreased pulses							
27.3	皮肤变色 Discoloration of skin							
27.4	晕厥发作（晕倒）/眩晕 Syncopal episodes (fainting)/dizziness							

K: 知识 Knowledge B: 行为 Behaviour S: 状态 Status
E: 教育/指导和咨询 Teaching/Guidance/Counseling
T: 治疗和程序 Treatments and Procedures
C: 个案管理 Case management
S: 监测 Surveillance

	项目编号 Case number:	No. 1	No. 2	No. 3	No. 4	No. 5	No. 6	No. 7
27.5	血压读数异常 Abnormal blood pressure reading							
27.6	心率不规律 Irregular heart rate							
27.7	心率过快 Excessively rapid heart rate							
27.8	心率过慢 Excessively slow heart rate							
27.9	心音异常/杂音 Abnormal heart sounds/murmurs							
27.10	心脏实验室检查结果异常 Abnormal cardiac laboratory results							
28	消化-水合 Digestion-hydration	K B S	K B S	K B S	K B S	K B S	K B S	K B S
		E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□
28.1	恶心/呕吐 Nausea/vomiting							
28.2	消化不良 Indigestion							
28.3	贫血 Anemia							
29	排便功能 Bowel function	K B S	K B S	K B S	K B S	K B S	K B S	K B S
		E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□
29.1	大便频率/软硬度异常 Abnormal frequency/consistency of stool							
29.2	排便痛苦 Painful defecation							
30	泌尿功能 Urinary function	K B S	K B S	K B S	K B S	K B S	K B S	K B S
		E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□
30.1	排尿烧灼感/疼痛 Burning/painful urination							
30.2	尿失禁 Incontinent of urine							
30.3	尿急/尿频 Urgency/frequency							
30.4	尿量异常 Abnormal amount							
30.5	尿液实验室检查结果异常 Abnormal urinary laboratory results							
31	生殖功能 Reproductive function condition	K B S	K B S	K B S	K B S	K B S	K B S	K B S
		E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□
31.1	处理绝经期/男性更年期困难 Difficulty managing menopause/andropause							
34	传染/感染情况 Communicable/infectious condition	K B S	K B S	K B S	K B S	K B S	K B S	K B S
		E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□
34.1	发热 Fever							
34.2	不遵循感染控制方案 Does not follow infection control regimen							
35*	营养 Nutrition	K B S	K B S	K B S	K B S	K B S	K B S	K B S
		E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□
35.1	超重 Overweight							
35.2	过轻 Nnderweight							
35.3	超出每日热量/液体摄取量的既定标准 Exceeds established standards for daily caloric/fluid intake							
35.4	饮食不均衡 Nnbalanced diet							
35.5	没有遵循推荐的营养计划 Does not follow recommended nutrition plan							
35.6	原因不明的/渐进性的体重减轻 Unexplained/progressive weight loss							
35.7	低血糖 Hypoglycemia							
35.8	高血糖 Hyperglycemia							
36	睡眠和休息型态 Sleep and rest patterns	K B S	K B S	K B S	K B S	K B S	K B S	K B S
		E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□
36.1	睡眠/休息型态干扰家庭 Sleep/rest pattern disrupts family							
36.2	夜间频繁醒来 Frequently wakes during night							
36.3	相对年龄/身体状况的睡眠/休息不足 Insufficient sleep/rest for age/physical condition							
37*	身体活动 Physical activity	K B S	K B S	K B S	K B S	K B S	K B S	K B S
		E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□
37.1	久坐不动的生活方式 Sedentary life style							
37.2	不适当/不一致的运动常规 Inadequate/inconsistent exercise routine							
37.3	与年龄/身体状况不相配的运动类型/量 Inappropriate type/amount of exercise for age/physical condition							
38	个人照顾 Personal care	K B S	K B S	K B S	K B S	K B S	K B S	K B S
		E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□
38.1	不愿意/不能/忘记完成自我照顾的活动 Unwilling/unable/forgets to complete personal care activities							
39*	物质滥用 Substance use	K B S	K B S	K B S	K B S	K B S	K B S	K B S
		E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□
39.1	滥用非处方/处方药 Abuses over-the-counter/prescription medications							
39.2	滥用酒精 Abuses alcohol							
39.3	吸烟/使用烟草制品 Smokes/uses tobacco products							
39.4	暴露于香烟/雪茄烟雾 Exposure to cigarette/cigar smoke							

K: 知识 Knowledge B: 行为 Behaviour S: 状态 Status
E: 教育/指导和咨询 Teaching/Guidance/Counseling
T: 治疗和程序 Treatments and Procedures
C: 个案管理 Case management
S: 监测 Surveillance

	项目编号 Case number:	No. 1	No. 2	No. 3	No. 4	No. 5	No. 6	No. 7
40	计划生育 Family planning	K B S	K B S	K B S	K B S	K B S	K B S	K B S
		E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□
40.1	对计划生育方法的认识不恰当/不充分 Inappropriate/insufficient knowledge about family planning methods							
41*	健康照顾督导 Health care supervision	K B S	K B S	K B S	K B S	K B S	K B S	K B S
		E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□
41.1	未能按症状所需寻求评估/治疗 Fails to seek care for symptoms requiring evaluation/treatment							
41.2	未能按照健康照顾提供者的要求复诊 Fails to return as requested to health care provider							
41.3	不能协调多个就诊预约/治疗计划 Inability to coordinate multiple appointments/treatment plans							
41.4	治疗计划不足 Inadequate treatment plan							
42*	药物治疗方案 Medication regimen	K B S	K B S	K B S	K B S	K B S	K B S	K B S
		E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□	E□T□C□S□
42.1	不遵从推荐的剂量/时间表 Does not follow recommended dosage/schedule							
42.2	药物副作用/不良反应的证据 Evidence of side effects/adverse reactions							
42.3	药物储存不当 Improper storage of medication							
42.4	未能得到适当的药物补充 Fails to obtain refills appropriately							
42.5	药物治疗方案不足 Inadequate medication regimen							

K: 知识 Knowledge B: 行为 Behaviour S: 状态 Status
E: 教育/指导和咨询 Teaching/Guidance/Counseling
T: 治疗和程序 Treatments and Procedures
C: 个案管理 Case management
S: 监测 Surveillance

Appendix 4

家访干预导向及具体内容

Intervention Targets and Contents

类别 **Categories**	**导向** **Targets**	**具体内容** **Contents**
Teaching，guidance and counselling 教育/指导/咨询	解剖和生理 Anatomy/physiology	1 什么是血压，收缩压和舒张压 Definition of blood pressure, systolic blood pressure and diastolic blood pressure
		2 高血压的成因 Causes of hypertension
		3 控制血压的重要性 Importance of blood pressure control
		4 高血压常见的并发症 Complications of hypertension
		5 血压值的判断 Judgment of blood pressure readings
		6 其它 Other
	行为修正 Behaviour modification	1 生活行为对于控制高血压和心血管疾病的重要性 Importance of lifestyle to control of high blood pressure and cardiovascular diseases
		2 识别需要修正的生活行为 Identifying lifestyles needed to be modified
		3 其它 other
	连续护理 Continuity of care	1 自我管理的重要性 Importance of self-management
		2 自我管理手册的使用 Use of the booklet of self-management
		3 随访计划及其重要性 Plan of the follow-ups and its importance
		4 血压自我监测的指导 Guidance of blood pressure monitoring
		5 其它 Other
	饮食管理 Dietary management	1 饮食和高血压的关系 Relationship between dietary and hypertension
		2 低钠、高钙、高钾、高镁饮食对于控制血压的重要性 Importance of dietary with low-sodium, high-calcium, high-potassium, and high-magnesium to control blood pressure
		2 低钠、高钙、高钾、高镁食物的选择 Choice of dietary with low-sodium, high-calcium,

		high-potassium, and high-magnesium
		3 体重、体质指数和腹围的判断 Judgment of body weight, body mass index and waist circumference
		4 均衡饮食的判断 Judgment of balanced dietary
		5 每日额外摄入钠盐低于 6g 的判断 Judgment of 6g sodium salt
		6 减少钠盐摄入的方法 Methods of reducing sodium intake
		7 其它 Other
	运动 Exercises	1 有氧运动对于控制高血压的益处 Benefits of aerobic exercises
		2 有氧运动的种类的选择 Choice of aerobic exercises
		3 有氧运动的强度的判断 Judgment of the intensity of aerobic exercises
		4 有利于控制高血压的有氧运动的次数，持续时间 Times and lasting time of aerobic exercises for controlling blood pressure
		5 运动的注意事项 Notes of the exercise
		6 其它 Other
	终止物质滥用 Substance use cessation	1 吸烟对自己和他人的影响 Impacts of smoking
		2 过量饮酒对血压的影响 Impacts of excessive alcohol intake
		3 饮酒量的判断 Judgment of alcohol intake
		4 其它 Other
	服用药物 Medicine administration	1 服药的剂量、次数、时间的指导 Guidance of dosages, frequency and time of medicines intake
		2 药物保管 Storage of medicine
		3 其它 Other
	药物作用和副作用 Medication action/side effects	1 按照医嘱服用药物的重要性 Importance of medication administration according to prescriptions
		2 抗高血压药物的作用 Effects of anti-hypertensive drugs

		3 抗高血压药物的副作用 Side effects of anti-hypertensive drugs
		4 规律监测血压和定期体检的重要性 Importance of regular blood pressure monitoring and physical examination
		5 其它 Other
	症状/体征-生理性 Signs/symptoms-physical	1 需要及时报告的症状和体征：如并发症，药物副作用及实验室检查结果 Signs and symptoms should be reported such as complications, side-effects of drugs and the results of tests
		2 其它 Other
	实验室结果 Laboratory findings	1 血液、尿液检查报告结果的解释 Interpretation of the results of blood and urine tests
		2 其它 other
	医疗/牙科保健 Medical/dental care	1 按时复诊，定期接受检查的重要性 Importance of regular visiting and physical examination
		2 其它 Other
	其它 Other	
治疗和程序 Treatments and procedures	心脏护理 Cardiac care	1 血压监测：在固定体位，固定时间，使用正确测量方式测量血压每天 1 次（高血压自我管理手册） Daily monitoring blood pressure in guided position, time and method according to the booklet of hypertension self-management
		2 其它 Other
	运动 Exercises	1 无运动禁忌者：每周中等强度的有氧运动 3-5 次，每次持续运动 20min-60min For cases without health problems or symptoms contraindication to exercise, moderate intensity of aerobic exercise with 3 to 5 times per week and each time continues to 20 - 60 min is suggested
		2 有心脏疾病或有其它不适宜运动的疾病和症状者：每日 6000 步身体活动量，每周 2 万步的身体活动量。 For cases combined with heart diseases or other diseases and symptoms which is not suitable for exercises, daily physical activities reached 6000 steps per day and 20000 steps of physical activities per week is suggested

		3 其它 Other
	医疗/牙科保健 Medical/dental care	1 治疗方案：各种的常规治疗 Algorithm for treatment
		2 其它 Other
	服用药物 Medication administration	1 药物的服用：剂量、次数、时间 Medication administration including dosage, frequency and time
		2 其它 Other
	药物设置 Medication set-up	1 使用药盒分类所服用的药物 Classification of medication by using drug box
		2 其它 Other
	其它 Other	
case management 个案管理	耐用医疗物品 Durable medical equipment	1 协调血压计的订购或者借用 Coordination of devices of blood pressure monitoring
		2 其它 Other
	医疗/牙科保健 Medical/dental care	1 转介 Referral
		2 其它 Other
	其它 Other	

Appendix 5

健康行为协议（NO.）

Health Behaviour Contract（NO.）

个案管理护士和个案就以下内容进行协商后制定完成

The following contents should be finalised by the case management nurse and the case after negotiation

类别 Category	**内 容 Content**	**达成一致处打√ Agreement**	**执行处√ Implementation**
血压监测 Blood pressure monitoring	每天至少测量 次 Monitoring at least____times a day		
	每次都记录测量结果 Recording each result of monitoring		
饮食 Dietary	使用盐勺控制钠盐的摄入 Using a spoon to restrict the salt intake		
	少吃或者不吃高钠的食物 Reducing intake of high-sodium foods		
	多吃高镁、高钾、高钙食物 Taking high-magnesium, high-potassium and high-calcium foods		
身体活动 Physical activity	运动方式： Exercise type:		
	每周 次，每次不少于 min ____times per week, at least____min each time		
	运动强度： Exercise intensity		
	身体活动： Physical activity		
戒烟和限酒 Quitting smoking and moderating	不吸烟或者戒烟 No smoking or quitting smoking		
	减少吸烟数量，每 天 支		

alcohol intake	Cutting down smoking		
	每天　　酒不多于　　ml No more than____ml alcohol intake every day		
药物 Anti-hypertensive drug	药物 1： Anti-hypertensive drug		
	每次　片，每日　次 服用时间： __tablets per time, ___times per day taking time		
	药物 2: Anti-hypertensive drug		
	每次　片，每日　次 服药时间： __tablets per time,____times per day taking time		
	及时补充药物 Refilling drugs in time		
	使用药盒分类保管药物 Using a store box for drugs classification		
其它 Other			
日期 Date			

个案管理护士签名：

Case Management Nurse Signature:

个案签名：

Case Signature:

Appendix 6

转介记录单

Referral Record

如个案符合转介要求，由个案管理护士填妥转介单的内容交给协调员安排转介

If the case meets the criteria of referral, case management nurse should fill the referral form and contact the coordinator to arrange referral

转介单 Referral form			
个案姓名 Name of the case		个案联络电话 Phone number of the case	
转介原因 Reasons for referral			
转介目的 Referral	□药物治疗 Pharmacological treatment □检查 Medical check □其它 Other		
转介对象 Referral target	□社区医生 General Practitioner □其他机构的医生 Doctors of other institution		
转介日期 Date of referral	年 月 日 date month year		
个案护士姓名 Name of case management nurse		个案护士联络电话 Phone number of case management nurse	

以下内容请转介受理人填妥后交给协调员安排随访

Referral assignee should fill the referral acceptant form and contact the coordinator to arrange the follow up

转介受理单 Referral acceptant form			
受理人姓名 Name of referral assignee		受理人联络电话 Phone number of referral assignee	
受理的情况 Process of treatment	□提供服务 Providing service 处理情况 Process of treatment		
	□无法提供服务 Cannot provide service 原因 Reasons		

Appendix 7

护士为主导的高血压管理项目培训课程概要及时间安排

Schedule of the training program for the nurse-led hypertension management programme

单元 **Unit**	**课程概要** **Outline**	**时间** **Time**	**地点** **Address**	**讲者** **Lecturer**	**课时** **Credit Hours**
第一单元 Unit 1	1. 项目概述 Outline of the program 2. 项目理论框架 The conceptual framework of the program 3. 高血压的基本知识（一）：流行病学 The basic knowledge of hypertension Part 1: Epidemiology 4. 高血压的基本知识（二）：非药物干预 The basic knowledge of hypertension Part 2: Non-pharmacological treatment 5. 高血压的基本知识（三）：药物干预 The basic knowledge of hypertension Part 3: Pharmacological treatment	2012.06.22 (周五 Friday) 8:40am-12:30pm	广州 Guangzhou	黄金月 Wong Kam Yuet, Frances 胡丽霞 Wu Lai Har, Candy 赵 琼 Zhao Qiong	4
第二单元 Unit 2	1. 高血压患者的依从性 Hypertensive patient adherence 2. 高血压患者的健康教育 Health education on hypertensive patients 3. 动机式访谈及其应用 Motivational interview and its application	2012.06.22 (周五 Friday) 2:00pm-6:00pm	广州 Guangzhou	朱雪娇 Zhu Xuejiao 王少玲 Wang Shaoling	4

第三单元 Unit 3	1. 自我赋能及其应用 Self-empowerment and its application 2. 自我管理 及其应用 Self-management and its application	2012.06.23 (周六 Saturday) 8:30am-12:30pm	广州 Guangzhou	简静儿 Jian Jinger, Eva	4
第四单元 Unit 4	1. 参观医院 Hospital visit 2. 家访见习 Home visit 3. 专科护士座谈 Focus group of advanced nursing practitioners	2012.07.06 (周五 Friday) 8:30am-5:00pm	香港 Hong Kong	九龙医院社区护士 The community nurses of Kowloon Hospital	8
第五单元 Unit 5	奥马哈系统及其应用 Omaha System and its application	2012.07.07 (周六 Saturday) 8:30am-12:30pm	香港 Hong Kong	王少玲 Wang Shaoling 朱雪娇 Zhu Xuejiao	4
第六单元 Unit 6	1. 常见高血压合并症的个案管理及成效 Case management and its effect on comorbidities of hypertension 2. 奥马哈系统在常见高血压合并症的个案管理中的应用 The application of the Omaha System to case management for comorbidities of hypertension	2012.07.07 (周六 Saturday) 1:30pm-5:30pm	香港 Hong Kong	杨笑明 Yang Xiaoming, Sue 吴绮雯 Wu Qiwen, Alina 谭美玲 Tan Meiling, Bonnie 王少玲 Wang Shaoling	4
第七单元 Unit 7	1. 家访方案及其应用 Protocol of home visit and its application 2. 电话干预方案及其应用 Protocol of the telephone follow-up and its application 3. 个案练习 Case practice	2012.07.12 (周四 Thursday) 5:30pm-9:30pm 2012.07.13 (周五 Friday) 8:30am-12:00pm	广州 Guangzhou	黄金月 Wong Kam Yuet, Frances 胡丽霞 Wu Lai Har, Candy 杨笑明 Yang Xiaoming, Sue 王少玲 Wang Shaoling 朱雪娇 Zhu Xuejiao	8
课时合计 TOTAL					36

Appendix 8

Self-care Behaviour Scale

1. During the past four weeks, did you take the anti-hypertensive drugs according to the prescription *(only applicable to the case received pharmacological treatment）*

   1.1 Dose □$_1$ No □$_2$ Yes

   1.2 Time □$_1$ No □$_2$ Yes

   1.3 Frequency □$_1$ No □$_2$ Yes

2. During the past four weeks，did you monitor your blood pressure every day?

   □$_1$ No

   □$_2$ Partly, _____times per week or_____times per month

   □$_3$ Yes

3. During the past four weeks, did you smoke?

   □$_1$ No

   □$_2$ Yes，_____per day

4. During the past four weeks, did you take alcohol?

   □$_1$ No

   □$_2$ Yes, _____ml per day

5. During the past four weeks, did you restrict salt intake?

   □$_1$ No

   □$_2$ Partly

   □$_3$ Yes (only applicable to the case whose salt consumption was less than 6g per day)

6. During the past four weeks, did you regularly engage physical activities?

   □$_1$ No

   □$_2$ Partly

   □$_3$ Yes (only applicable to the case who regularly engaged physical activities 3 times or more and lasted for at least 20 min each time)

自我管理行为

1. 在过去的一个月内，您服用药物（仅适用于服药者）

1.1 剂量和医嘱一致　　□1 无　　□2 有

1.2 时间和医嘱一致　　□1 无　　□2 有

1.3 次数和医嘱一致　　□1 无　　□2 有

2. 在过去的一个月内，您是否每日监测血压？

□1 无

□2 部分有，_____次/周或_____次/月

□3 有

3. 在过去的一个月内，您是否吸烟？

□1 无

□2 有，_____支/天

4. 在过去的一个月内，您是否饮酒？

□1 无

□2 有，_____酒，_____ml/天 __

5. 在过去的一个月内，您是否有限制食盐的摄入？

□1 无

□2 部分有

□3 有（仅适用与能确定每日额外摄入食盐＜6g 以下者）

6. 在过去的一个月内，您是否有进行规律运动？

□1 无

□2 部分有

□3 有（仅适用于每周运动 3 次以上，每次持续时间为 20min 以上或每次持续 10min*每天 3 次者）

Appendix 9

Short-form Chronic Disease Self-Efficacy Scale

For each of the following questions, please circle the number that corresponds to your confidence that you can do the tasks regularly at the present time.

1. How confident are you that you can do the different tasks and activities needed to manage your health condition so as to reduce you need to see a doctor?

Not at all confident 1 2 3 4 5 6 7 8 9 10 Totally confident

2. How confident are you that you can keep the emotional distress caused by your disease from interfering with the things you want to do?

Not at all confident 1 2 3 4 5 6 7 8 9 10 Totally confident

3. How confident are you that you can do things other than just taking medication to reduce how much your illness affects your everyday life?

Not at all confident 1 2 3 4 5 6 7 8 9 10 Totally confident

4. How confident are you that you can keep the fatigue caused by your disease from interfering with the things you want to do?

Not at all confident 1 2 3 4 5 6 7 8 9 10 Totally confident

5. How confident are you that you can keep the physical discomfort or pain of your disease from interfering with the things you want to do?

Not at all confident 1 2 3 4 5 6 7 8 9 10 Totally confident

6. How confident are you that you can keep any other symptoms or health problems you have from interfering with the things you want to do?

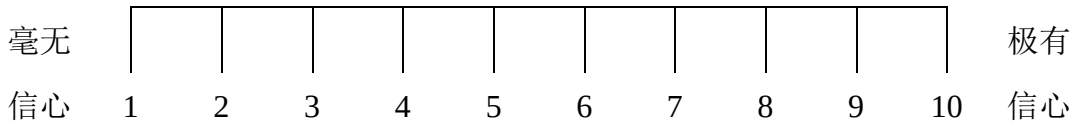
Not at all confident 1 2 3 4 5 6 7 8 9 10 Totally confident

自我效能量表

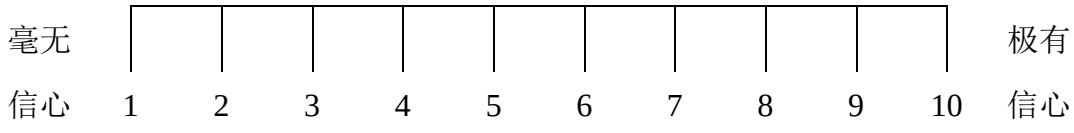
请在下面的问题中，请圈出一个和您在现在信心（相信自己一定能做到）相对应的数字。

疾病处理情况

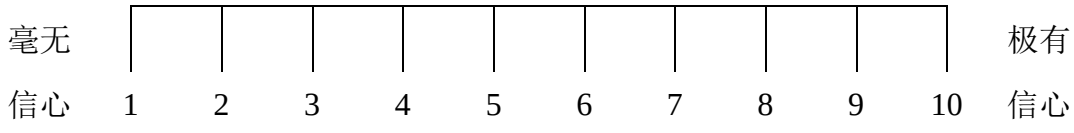
1. 你有多少信心可以做一些事情或者活动让你减少看医生的次数？



2. 这个病可能会导致一些情绪问题，你有多少信心可以减少它对你的影响？

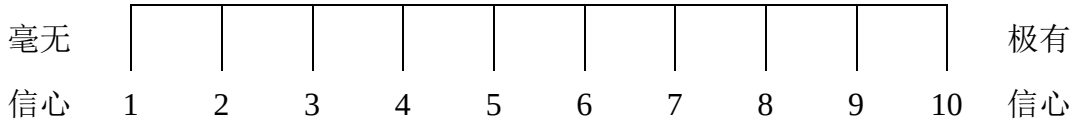


3. 除了吃药，你有多少信心可以去做一些事来减少疾病对你生活的影响？

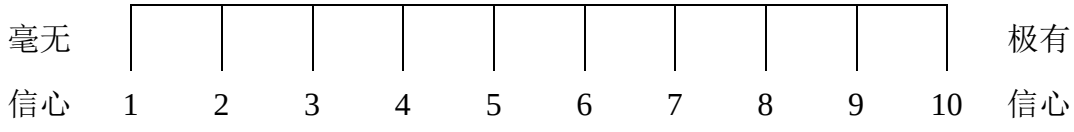


症状处理

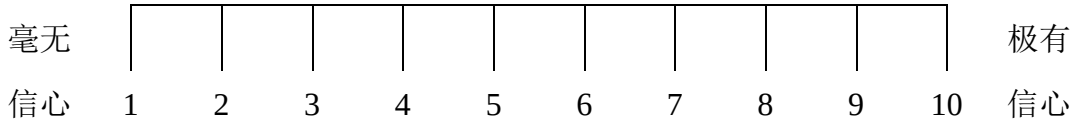
4. 就算这个病让你感到好累，你有多少信心可以做到自己想做的事情？



5. 就算这个病让身体不舒服或者痛，你有多少信心可以做到自己想做的事情？



6. 你有多少信心不让健康问题或者症状影响到你想做的事情？



Appendix 10

SF-36

The following questions are related to your view on your health condition, your feeling and your ability of physical activities. If you cannot confirm the answer, please choose one comes closest to yours. Please give your comments and suggestions after you answer the questions.

Please tick √ in the answer

1．In general, how would you rate your health?

Excellent	○
Very good	○
Good	○
Fair	○
Poor	○

2．Compared to one year ago, how would you rate your health in general now?

Much better now than one year ago	○
Somewhat better now than one year ago	○
About the same as one year ago	○
Somewhat worse now than one year ago	○
Much worse now than one year ago	○

Health and daily activities

3．The following items are about activities you might do during a typical day. Does your health now limit you in these activities? Is so, how much?

	Limited a lot	**limited a little**	**not limited at all**
（1）Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports:	○	○	○
（2）Moderate activities, such as moving a table, sweeping the floor, or stretching	○	○	○
（3）Carrying groceries, such as shopping	○	○	○
（4）Climbing several flights of stairs	○	○	○
（5）Climbing one flight of stairs	○	○	○
（6）Bending, kneeling, or stooping	○	○	○
（7）Walking about 1,500 metres	○	○	○
（8）Walking about 800 metres	○	○	○
（9）Walking about 100 metres	○	○	○
（10）Bathing or dressing yourself	○	○	○

4. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

Answer yes or no for each question

	Yes	**No**
（1）Cut down on the amount of time you spent on work or other activities	○	○
（2）Accomplished less than you would like	○	○
（3）Were limited in the kind of work or other activities	○	○
（4）Had difficulty performing the work or other activities (for example, it took extra effort)	○	○

5．During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems, such as depression or anxiety

Answer yes or no for each question

	Yes	**No**
（1）Cut down on the amount of time you spent on work or other activities	○	○
（2）Accomplished less than you would like	○	○
（3）Didn't do work or other activities as carefully as usual	○	○

6．During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours, or groups?

Please tick √ in the answer

Not at all	○
Slightly	○
Moderately	○
Quite a bit	○
Extremely	○

7．How much bodily pain have you had during the past 4 weeks?

Please tick √ in the answer

None	○
Very mild	○
Mild	○
Moderate	○
Severe	○
Very severe	○

8．During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

Please tick √ in the answer

Not at all	○
A little bit	○
Moderately	○
Quite a bit	○

Extremely ○

Your feeling

9．These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling.

Please tick one √ in each row

How much of the time during the past 4 weeks	**All of the time**	**Most of the time**	**A good bit of the time**	**Some of the time**	**A little of the time**	**None of the time**
（1）Did you feel full of pep?	○	○	○	○	○	○
（2）Have you been a nervous person?	○	○	○	○	○	○
（3）Have you felt so down in the dumps that nothing could cheer you up?	○	○	○	○	○	○
（4）Have you felt peaceful?	○	○	○	○	○	○
（5）Did you have a lot of energy?	○	○	○	○	○	○
（6）Have you felt blue?	○	○	○	○	○	○
（7）Did you feel exhausted?	○	○	○	○	○	○
（8）Have you been a happy person?	○	○	○	○	○	○
（9）Did you feel tired?	○	○	○	○	○	○
（10）Have your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?	○	○	○	○	○	○

General health condition

10．Please choose the one answer that the status comes closest to yours in each following statements?

Please tick one √ in each row

	Definitely true	**Mostly true**	**Don't know**	**Mostly false**	**Definitely false**
（1）I seem to get sick a little easier than other people	○	○	○	○	○
（2）I am as healthy as anybody I know	○	○	○	○	○
（3）I think my health to get worse	○	○	○	○	○
（4）My health is excellent	○	○	○	○	○

Your comments or suggestions:

健康状况调查问卷 SF-36(中文版)

下面的问题是询问您对自己健康状况的看法、您的感觉如何及您进行日常活动的能力如何。如果您没有把握如何回答问题，尽量作一个最好的答案，并在 10 个问题之后的空白处写上
您的建议。

请打一个勾

1．总体来讲，您的健康状况是：

非常好	○
很好	○
好	○
一般	○
差	○

2．跟一年前相比，您觉得您现在的健康状况是：

比一年前好多了	○
比一年前好一些	○
和一年前差不多	○
比一年前差一些	○
比一年前差多了	○

健康和日常活动

3．以下这些问题都与日常活动有关。您的健康状况是否限制了这些活动？如果有限制，程度如何？

	有很多限制	有一点限制	根本没限制
（1）重体力活动（如跑步、举重物、激烈运动等）	○	○	○
（2）适度活动（如移桌子、扫地、做操等）	○	○	○
（3）手提日杂用品（如买菜、购物等）	○	○	○
（4）上几层楼梯	○	○	○
（5）上一层楼梯	○	○	○
（6）弯腰、曲膝、下蹲	○	○	○
（7）步行 1500 米左右的路程	○	○	○
（8）步行 800 米左右的路程	○	○	○
（9）步行约 100 米的路程	○	○	○
（10）自己洗澡、穿衣	○	○	○

4. 在过去四个星期里，您的工作和日常活动有没有因为身体健康的原因而出现以下这些问题？

每个问题都回答有或没有

	有	没有
（1）减少了工作或其他活动的时间	○	○
（2）本来想要做的事情只能完成一部分	○	○
（3）想要做的工作或活动的种类受到限制	○	○
（4）完成工作或其他活动有困难（比如，需要额外的努力）	○	○

5. 在过去四个星期里，您的工作和日常活动有没有因为情绪（如感到消沉或忧虑）而出现以下问题？

每个问题都回答有或没有

	有	没有
（1）减少了工作或其他活动的时间	○	○
（2）本来想要做的事情只能完成一部分	○	○
（3）做工作或其它活动不如平时仔细	○	○

6. 在过去的四个星期里，您的身体健康或情绪不好在多大程度上影响了您与家人、朋友、邻居或集体的正常社交活动？

请打一个勾

根本没有影响	○
很少有影响	○
有中度影响	○
有较大影响	○
有极大影响	○

7. 在过去四个星期里，您有身体上的疼痛吗？

请打一个勾

根本没有疼痛	○
有很轻微疼痛	○
有轻微疼痛	○
有中度疼痛	○
有严重疼痛	○
有很严重疼痛	○

8. 在过去四个星期里，身体上的疼痛影响您的正常工作吗（包括上班工作和家务活动）？

请打一个勾

根本没有影响	○
有一点影响	○
有中度影响	○
有较大影响	○
有极大影响	○

您的感觉

9．以下这些问题有关过去一个月里您的感觉如何以及您的情况如何。（对每一条问题，请钩出最接近您的感觉的那个答案）

请在每一行打一个勾

在过去一个月里持续的时间	所有的时间	大部分时间	比较多时间	一部分时间	小部分时间	没有此感觉
（1）您觉得生活充实吗？	○	○	○	○	○	○
（2）您是一个精神紧张的人吗？	○	○	○	○	○	○
（3）您感到垂头丧气，什么事都不能使您振作吗？	○	○	○	○	○	○
（4）您觉得平静吗？	○	○	○	○	○	○
（5）您精力充沛吗？	○	○	○	○	○	○
（6）您的情绪低落吗？	○	○	○	○	○	○
（7）您觉得筋疲力尽吗？	○	○	○	○	○	○
（8）您是个快乐的人吗？	○	○	○	○	○	○
（9）您感觉疲劳吗？	○	○	○	○	○	○
（10）您的健康限制了您的社交活动（如走亲访友）吗？	○	○	○	○	○	○

总的健康情况

10．请对下面的每一句话，选出最符合您情况的答案

每一横行只打一个勾

	绝对正确	大部分正确	不能肯定	大部分错误	绝对错误
（1）我好像比别人容易生病	○	○	○	○	○
（2）我跟我认识的人一样健康	○	○	○	○	○
（3）我认为我的健康状况在变坏	○	○	○	○	○
（4）我的健康状况非常好	○	○	○	○	○

您的批评或建议：

Appendix 11

Utilisation of Health Care Services

For the following questions, please choose the number that corresponds to your utilisation of health care service.

1. **During the past four weeks, did you self-prescribe any anti-hypertensive drug?**
   □$_1$ No
   □$_2$ Yes, number of times:
2. **During the past four weeks, did you visit the outpatient department due to hypertension?**
   □$_1$ No
   □$_2$ Yes, number of times:
   Number of times of visiting the community health centre:
3. **During the past four weeks, did you visit the emergency department due to hypertension?**
   □$_1$ No
   □$_2$ Yes, number of times:
   Did you seek help from the community health centre before visiting the emergency department?
   □$_1$ No
   □$_2$ Yes, number of times:
4. **During the past four weeks, did you hospitalise due to hypertension?**
   □$_1$ No
   □$_2$ Yes, number of nights:
   Did you seek help from the community health centre before hospitalising?
   □$_1$ No
   □$_2$ Yes, number of times:
5. **During the past four weeks, did healthcare providers visit you at home due to hypertension?**
   □$_1$ No
   □$_2$ Yes, number of times:
6. **During the past four weeks, did healthcare providers phone you due to hypertension?**
   □$_1$ No
   □$_2$ Yes, number of times:

社区卫生服务资源应用

1　在过去的 12 个星期，你是否有因高血压的问题自己买药（中药、西药）服用？

□$_1$ 无

□$_2$ 有，共___次

2　在过去的 12 个星期，你是否有因高血压的问题去看过门诊？

□$_1$ 无

□$_2$ 有，共___次，其中去社区卫生服务中心（站）的次数：___次

3　在过去的 12 个星期，你是否有因高血压的问题去看过急诊？

□$_1$ 无，请接着回答第 4 题

□$_2$ 有，共___次，请接着回答下面的问题

在去看急诊的过程中，你是否有寻求社区卫生服务中心（站）帮助？

□$_1$ 无

□$_2$ 有，共___次

4　在过去的 12 个星期，你是否有因高血压的问题去住院？

□$_1$ 无，请接着回答第 5 题

□$_2$ 有，共___晚，请接着回答下面的问题

在去住院的过程中，你是否有寻求社区卫生服务中心（站）帮助？

□$_1$ 无

□$_2$ 有，共___次

5　在过去的 12 个星期，是否有社区护士或医生关于高血压的问题来探访您？

□$_1$ 无

□$_2$ 有，共___次

6　在过去的 12 个星期，是否有社区护士或医生关于高血压的问题打电话给您？

□$_1$ 无

□$_2$ 有，共___次

Appendix 12

Patients' Satisfaction Scale

For each of the following questions, please choose the number that corresponds to your satisfaction of hypertensive care that you received from community healthcare providers

1. **The explanation of what is hypertension provided by community healthcare providers**
   □$_1$ Excellent □$_2$ Satisfactory □$_3$ Fair □$_4$ Needs improvement □$_5$ Very weak □$_6$ Not applicable
2. **The explanation of the treatment of hypertension provided by community healthcare providers**
   □$_1$ Excellent □$_2$ Satisfactory □$_3$ Fair □$_4$ Needs improvement □$_5$ Very weak □$_6$ Not applicable
3. **The suggestion of adhering to treatment of hypertension provided by community healthcare providers**
   □$_1$ Excellent □$_2$ Satisfactory □$_3$ Fair □$_4$ Needs improvement □$_5$ Very weak □$_6$ Not applicable
4. **The explanation of the importance of home blood pressure monitoring provided by community healthcare providers**
   □$_1$ Excellent □$_2$ Satisfactory □$_3$ Fair □$_4$ Needs improvement □$_5$ Very weak □$_6$ Not applicable
5. **The guidance of home blood pressure monitoring provided by community healthcare providers**
   □$_1$ Excellent □$_2$ Satisfactory □$_3$ Fair □$_4$ Needs improvement □$_5$ Very weak □$_6$ Not applicable
6. **The explanation of justifying the result of blood pressure monitoring provided by community healthcare providers**
   □$_1$ Excellent □$_2$ Satisfactory □$_3$ Fair □$_4$ Needs improvement □$_5$ Very weak □$_6$ Not applicable
7. **The effects of blood pressure control produced by community healthcare providers**
   □$_1$ Excellent □$_2$ Satisfactory □$_3$ Fair □$_4$ Needs improvement □$_5$ Very weak □$_6$ Not applicable
8. **The counselling of hypertension management provided by community healthcare providers**
   □$_1$ Excellent □$_2$ Satisfactory □$_3$ Fair □$_4$ Needs improvement □$_5$ Very weak □$_6$ Not applicable

满意度问卷

以下是关于您对社区医务人员提供的高血压有关服务的满意度问题

1. 社区医务人员能向你清楚讲解什么是高血压

□1 非常满意　□2 满意　□3 一般　□4 不满意　□5 非常不满意　□6 不适用

2. 社区医务人员能向你清楚讲解治疗高血压的方法

□1 非常满意　□2 满意　□3 一般　□4 不满意　□5 非常不满意　□6 不适用

3. 社区医务人员能向你提供实际的建议帮助你遵从高血压的治疗方法

□1 非常满意　□2 满意　□3 一般　□4 不满意　□5 非常不满意　□6 不适用

4. 社区医务人员能向你清楚说明家庭血压监测的重要性

□1 非常满意　□2 满意　□3 一般　□4 不满意　□5 非常不满意　□6 不适用

5. 社区医务人员能指导你家庭血压监测的方法

□1 非常满意　□2 满意　□3 一般　□4 不满意　□5 非常不满意　□6 不适用

6. 社区医务人员能指导你分析血压测量结果

□1 非常满意　□2 满意　□3 一般　□4 不满意　□5 非常不满意　□6 不适用

7. 社区医务人员能有效帮助你控制血压

□1 非常满意　□2 满意　□3 一般　□4 不满意　□5 非常不满意　□6 不适用

8. 社区医务人员能有效解答你日常生活中遇到的有关高血压的问题

□1 非常满意　□2 满意　□3 一般　□4 不满意　□5 非常不满意　□6 不适用

THE HONG KONG POLYTECHNIC UNIVERSITY
香港理工大學

To	WONG Kam Yuet (School of Nursing)		
From	KWONG Wai Yung, Chair, Departmental Research Committee		
Email	hsenid@	Date	11-Sep-2012

Application for Ethical Review for Teaching/Research Involving Human Subjects

I write to inform you that approval has been given to your application for human subjects ethics review of the following project for a period from 31-Aug-2012 to 31-Dec-2013:

Project Title: Effects of nurse-led hypertension management model in Mainland China:A randomized controlled trial

Department: School of Nursing

Principal Investigator: WONG Kam Yuet

Please note that you will be held responsible for the ethical approval granted for the project and the ethical conduct of the personnel involved in the project. In the case of the Co-PI, if any, has also obtained ethical approval for the project, the Co-PI will also assume the responsibility in respect of the ethical approval (in relation to the areas of expertise of respective Co-PI in accordance with the stipulations given by the approving authority).

You are responsible for informing the Departmental Research Committee in advance of any changes in the proposal or procedures which may affect the validity of this ethical approval.

You will receive separate email notification should you be required to obtain fresh approval.

KWONG Wai Yung

Chair

Departmental Research Committee

Appendix 14

Effects of Nurse-led Hypertension Management Model in Mainland China: A Randomised Controlled Trial

INFORMATION SHEET

You are invited to participate in a research study conducted by ZHU Xuejiao, a PhD student of the School of Nursing at The Hong Kong Polytechnic University, under the supervision of Professor WONG Kam Yuet and Dr. WU Lai Har. The project will be conducted in Huang-hua-gang-jie community health centre, Yue-xiu, Guangzhou, Guangdong. The project has been approved by the Human Subject Ethics Sub-committee (HSESC) of The Hong Kong Polytechnic University

The project aims to help you to improve the control of blood pressure and maintain better health condition at home. The study will involve completing a questionnaire, measuring blood pressure, body weight and height, and waist circumference, those will take you about half hour. All of you will have a health education booklet on blood pressure management and receive routine follow ups at outpatient clinic. Some of you will be allocated into for home visits and telephone follow-ups. The telephone calls will be recorded. There is no evident risk involved in the study since the intervention is not invasive but concerns the shaping of healthy lifestyle.

You have every right to withdraw from the study before or during the study without penalty of any kind. The duration of the study will take about 4 months. Your decision does not affect your health care service and other community service.

All data collected from you will remain confidential, and will be used solely for research and academic purposes. If you have any enquiry or suggestion about of this research study, please do not hesitate to contact ZHU Xuejiao, a Ph.D student of School of Nursing, Hong Kong Polytechnic University (Phone Number is 020-).

If you have any complaints about of this research study, please do not hesitate to contact Dr Virginia Cheng, Secretary of the Human Subjects Ethics Sub-Committee of The Hong Kong Polytechnic University in writing (c/o Research Office of the University) stating clearly the responsible person and department of this study.

Thank you for your cooperation and participating in this study!

School of Nursing, The Hong Kong Polytechnic University
Research group of the project of Effects of Nurse-led Hypertension Management Model in Mainland China

护士为主导的高血压管理模式在中国内地的效果：

一项随机对照试验

有关资料

今邀请您参与由香港理工大学护理学院博士研究生朱雪娇执行，由导师黄金月教授和胡丽霞博士的监督的研究计划。该研究在广东省广州市越秀区黄花岗街社区卫生服务中心开展。该研究已经通过香港理工大学人事伦理委员会的审核批准（审核编号：　　）。

本研究项目的是帮助您改善血压的控制状况，在家中维持较好的健康状态。该研究会涉及问卷调查和测量血压、身高、体重和腹围，完成这些需要半个小时左右。所有的参与者将有一本高血压管理的健康教育手册以及在门诊的常规随访。部分参加者会安排家庭访视和电话随访，电话将会被录音。由于本研究的干预涉及的是健康生活方式的形成而非侵入性的，因此无明显的风险。

您在参与本项目过程中（为期 4 个月）有权随时退出，并不接受惩罚。您的决定不会影响您接受正常的医疗护理及其它社会服务。

我们所收集的有关资料将会保密，并仅用于研究和学术交流。如果您需要查询该研究项目更多的内容或对该研究有意见和建议，请联系香港理工大学护理学院博士研究生朱雪娇(电话：020-　)。

如果您对该项目有任何不满，请联系香港理工大学人事伦理委员会秘书郑淑娟博士（地址：香港理工大学研究事务处 M502）。

感谢您的协助及参与！

香港理工大学护理学院

“护士为主导的高血压管理模式在中国内地的效果”研究项目小组

Appendix 15

CONSENT TO PARTICIPATE IN RESEARCH

Effects of Nurse-led Hypertension Management Model in Mainland China: A Randomised Controlled Trial

I _____ hereby consent to participate in the captioned research, which is will be conducted at the Huang-hua-gang-jie community health centre and conducted by the School of Nursing at the Hong Kong Polytechnic University.

I understand that information obtained from this research may be used in future research and published. However, my right to privacy will be retained, i.e. my personal details will not be revealed.

The procedure as set out in the attached information sheet has been fully explained. I understand that my participation in the project is voluntary.

I acknowledge that I have the right to question any part of the procedure and can withdraw at any time without penalty of any kind.

Name of participant

Signature of participant

Name of researcher

Signature of researcher

Date

参与研究同意书

本人 _____愿意参加香港理工大学护理学院在黄花岗街社区卫生服务中心开展的研究项目：护士为主导的高血压管理模式在中国内地的效果：一项随机对照试验。

本人明白该研究所获得的资料可能被用作日后的研究和学术交流，但本人的个人隐私权力将得到保留，即本人的个人资料不会被泄漏。

本人对所附加资料的内容已有清楚的了解，本人明白参与此项研究纯属自愿。

本人明白本人有权在研究过程中提出问题，并有权随时退除该研究项目，并不接受惩罚。

参与者姓名：

参与者签名：

研究员姓名：

研究员签名:

日　　期:　　年　　月　　日

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