

Hypertension management for older people with diabetes in Nanchang, China: from evidence-base to outcomes

by

Qiang Tu

B. Med, M.P.H

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DECLARATION

I certify that this thesis does not incorporate without acknowledgment any material previously submitted for a degree or diploma in any university; and that to the best of my knowledge and belief it does not contain any material previously published or written by another person except where due reference is made in the text.

Signed.....

Date.....

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Summary

Background

Hypertension is the most common health condition that affects up to 82% of people living with diabetes. The prevalence of hypertension increases with aging. China possesses the largest number of older people living with multimorbidity of hypertension and diabetes in the world. However, the primary care system is largely underdeveloped to respond to the health care needs of this population. Hospital-centred care services are widely used in managing hypertension for this population resulting in fragmental care and lack of follow-up support in the community.

Aims

The overall aim of the project was to develop and evaluate an evidence-based hypertension management program for older people with diabetes in Nanchang, China. The specific aims were:

Aim 1: to gain health professionals' consensus on the applicability of an evidence-based hypertension management program for older people with diabetes who were ready to be discharged from hospital and required follow-up support in the community; and

Aim 2: to test a hypothesis that the evidence-based hypertension management program can improve blood pressure control in people aged 60 and over with diabetes as compared to usual care.

Methods

This project included Study 1 and Study 2 to address each of the aims. In study 1, a modified Delphi study with an expert panel in Nanchang, China was conducted. In Study 2, a 6-month cluster randomised controlled trial was undertaken to test the hypothesis stated in the Aim 2.

Results

In Study 1, 70 health professionals from four hospitals and six Community Health Centers participated in the Delphi study. The participants were multidisciplinary experts with experience in the study area. The questionnaire used in round one of the Delphi study described an evidence-based hypertension management program identified in a literature

review. Participants achieved consensus on the program within two rounds.

In study 2, a cluster randomized controlled trial involving ten wards from four hospitals were randomly allocated to either intervention group (N=5) or usual care group (N=5). A total of 270 older people (135 in each group) were recruited into the trial. The mean age of participants was 70.9 (SD=5.8) years and the average duration of diabetes and hypertension diagnosis was 9.4 (SD=6.0) and 9.3 (SD=6.8) years respectively. On the completion of the trial, the intervention group demonstrated a statistically significant decrease of a mean systolic blood pressure of 10.7 mmHg (95%CI: -14.2 to -7.1, P<0.001) and a mean diastolic blood pressure of 4.1 mmHg (95% CI: -6.2 to -2.2, P<0.001), compared to the usual care group. Findings also demonstrated significant improvements of HbA1c, LDL, hypertension knowledge, diabetes knowledge, treatment adherence, quality of life, reduced adverse events and hospital readmission in the intervention group compared to the usual care group. There was no significant difference on HDL between the two groups.

Conclusion

An evidence-based hypertension management program built on collaboration of hospital and Community Health Centers and targeted individualized care needs improved hypertension control for older people with diabetes. Findings have implications for policy, resource and care services development.

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Abbreviations

BP	Blood pressure
RCT	Randomized Controlled Trial
GP	General practitioner
HbA1C	Glycosylated hemoglobin
HDL	High density lipoprotein
LDL	Low density lipoprotein
ML-MC	Multillevel- and Multicomponent
URBMI	Urban Resident Basic Medical Insurance
UWBMI	Urban Worker Basic Medical Insurance

Glossary

Terms	Definition
Care coordination	The deliberate organisation of patient care services between two or more providers to
	achieve agreed upon care outcomes.
Geriatric syndromes	Clinical conditions in older people (e.g., cognitive impairments, falls, incontinence, malnutrition and pressure ulcers) that have a multifactorial aetiology and negative effects on health, well-being and the level of functioning. The terms 'geriatric conditions' and 'geriatric syndromes' are used
HbA1c	interchangeably within this thesis. Haemoglobin A1c is a minor component of
HDATC	haemoglobin ATC is a minor component of haemoglobin to which glucose binds. It reflects the average glucose level of an individual in the past three months. According to the American Diabetes Association (ADA), one of treatment goals for older people with diabetes and hypertension is to achieve an HbA1c level less than 8.0% (American Diabetes Association, 2018).
HDL cholesterol	High density lipoprotein (HDL) cholesterol, is commonly referred to as 'good' cholesterol. Higher HDL cholesterol levels are associated with lower risks of coronary artery disease and stroke. Under the ADA standards, one of the treatment goals for

older people with diabetes and hypertension is to achieve a HDL cholesterol level higher than 45 mg/dL (American Diabetes Association, 2004; Basak et al., 2013).

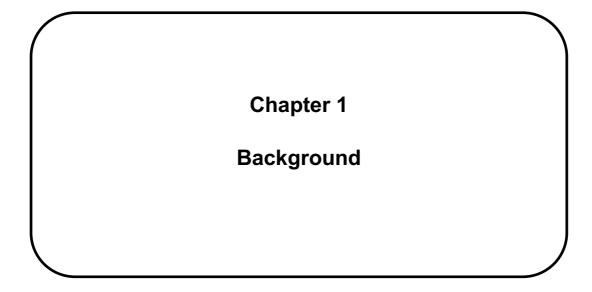
HypertensionAccording to the Oxford textbook of
medicine, hypertension usually refers to
essential hypertension (the most common
type of hypertension). It has no clear
aetiology and treatments to lower blood
pressure produce significant clinical
benefits (Williams, 2010). A blood pressure
level equal to or higher than 140/90 mmHg
is generally considered an indicator of
hypertension (Williams, 2010).

Hypertension-related quality of An individual's quality of life as measured life across four broad domains: physical function. psychological health. social function and а domain specific to hypertension that considers the related symptoms and side effects (Wan et al., 2012).

Integrated care The patient-centred care services delivered by multidisciplinary teams whereby primary care facilities and other high levels of health facilities (e.g., secondary and tertiary hospitals) collaborate to share their expertise and resources to strengthen the primary care approach adopted to manage the hypertension of individuals with diabetes (World Health Organisation,

	2016).
	,
Isolated systolic hypertension	An increase in systolic blood pressure
	(higher than 140 mmHg) and a diastolic
	blood pressure within normal range (less
	than 90 mmHg) (Bavishi et al., 2016).
LDL cholesterol	Low-density lipoprotein (LDL) cholesterol is
	commonly referred to as 'bad' cholesterol.
	Under the ADA standards, one of the
	treatment goals for older people with
	diabetes and hypertension is to achieve a
	LDL cholesterol less than 100 mg/dL
	(American Diabetes Association, 2018;
	Eldor & Raz, 2009).
Multimorbidity	The simultaneous presence of two or more
Wattinoibiaity	long-term medical conditions (Wallace et
	al., 2015).
	al., 2013).
Multimorbidity of hypertension	The simultaneous presence of hypertension
and diabetes	and diabetes.
Treatment adherence	The extent to which an individual's
	behaviours (e.g., taking medications and
	adopting lifestyle changes) coincides with
	the recommendations of healthcare
	providers (Price, 2016). It is measured
	across two broad domains: medication
	adherence and health lifestyle adherence
	(Ma et al., 2012).
Type 2 Diabetes	According to the Oxford textbook of
	medicine, type 2 diabetes is the most
	medicine, type z diabetes is the most

	a state of chronic hyperglycaemia, resulting			
	from a combination of insulin resistance and			
	β-cell failure (Dayan & Williams, 2010). It can cause long-term damage to specific tissues such as the retinas, kidneys, nerves			
	and arteries. The peak incidence of type 2			
	diabetes occurs among older people age			
	60 to 65 years (Dayan & Williams, 2010).			
Uncontrolled hypertension	According to the Eight Joint National			
	Committee (JNC 8) Criteria (Adeniyi et al.,			
	2016), uncontrolled hypertension is			
	identified by an average systolic blood			
	pressure higher than 140 mmHg or an			
	average diastolic blood pressure higher			
	than 90 mmHg			
Uncontrolled diabetes	An individual with diabetes has a random			
Uncontrolled diabetes	blood glucose level higher than 11.0 mmol/L			
	č č			
	or a HbA1c level of more than 7.0%. If left			
	untreated, uncontrolled diabetes can lead to			
	cardiovascular disease, kidney disease,			
	eye disease and stroke (Xu et al., 2009).			



Chapter 1 Background

1.1 Introduction

Globally, hypertension is the most common health condition that affects most of the adult population who live with type 2 diabetes. Hypertension is more prevalent in older people with diabetes, as advanced ageing is a risk factor for hypertension. Hypertension is also more difficult to control in older people with diabetes than it is for people in other age groups. Older people with the multimorbidity of hypertension and type 2 diabetes usually have other ageing-associated health conditions and are the main users of healthcare services. It is predicted that the number of populations living with multimorbidity of hypertension management for community-dwelling older people with type 2 diabetes requires a primary care approach to supporting self-care at home. China has many older populations throughout the world, many of whom live with the multimorbidity of hypertension and type 2 diabetes. However, the primary care system is largely underdeveloped to respond to the increasing burden of this multimorbidity in older people. Hospital-centred care for this population is widely used and is associated with fragmented healthcare services, high costs and poor care outcomes. Studies on hypertension management programs that address these problems are greatly needed to provide evidence to inform practice.

This chapter introduces hypertension among people with type 2 diabetes as a public health issue in China and in the global context. As type 1 diabetes and gestational diabetes are not included in the study, the word 'diabetes' refers to type 2 diabetes in the thesis. This chapter begins with an overview of hypertension among people with diabetes, including an outline of the burden of hypertension and diabetes in China and the global context. The second section introduces the challenges and opportunities to improve hypertension management for older people with diabetes in a socio-political context in China. The third section outlines the hypertension management program developed, implemented and evaluated in the present study. The aims, objectives and significance of the study and the thesis structure are also described in this chapter.

1.2 An overview of hypertension among people with diabetes

1.2.1 Hypertension

Hypertension is a complex chronic condition. It is defined as persistent elevation of blood pressure that exceeds normal blood pressure (or \geq 140/90 mmHg) (Williams, 2010). Blood pressure reflects the level of the cardiac output and peripheral resistance in the circulation of the human body

(Williams, 2010). Blood pressure is recorded as two measurements: systolic blood pressure and diastolic blood pressure. Hypertension is classified into two categories: essential hypertension and secondary hypertension. Essential hypertension has unknown causes and affects up to 95 per cent of people with hypertension (Bolívar, 2013). Secondary hypertension is less common; it is caused by underlying medical problems—for example, kidney disease, sleep apnoea and coarctation of the aorta (Puar et al., 2016; Rimoldi et al., 2014). There are two subtypes of hypertension: isolated systolic hypertension (ISH) (SBP > 140 mmHg and DBP < 90 mmHg) and isolated diastolic hypertension (IDH) (SBP < 140 mmHg and DBP > 90 mmHg) (Williams, 2010). Older people are at a high risk of developing hypertension because their arteries become less elastic with age (Lionakis et al., 2012; Williams, 2010).

1.2.2 Uncontrolled hypertension

Uncontrolled hypertension is defined as an average systolic blood pressure (SBP) equal to or higher than 140 mmHg (or \ge 140 mmHg), or an average diastolic blood pressure (DBP) equal to or higher than 90 mmHg (or \ge 90 mmHg), as proposed by Eighth Joint National Committee (JNC 8) criteria (James et al., 2014). Criteria of hypertension control vary with the age and severity of the disease. Uncontrolled hypertension can be classified into four grades according to level of blood pressure (National Heart Foundation of Australia, 2016) (see Table 1.1). The American Heart Association has recommended a target blood pressure less of than 140/90 mmHg for older people with diabetes and hypertension (Solini & Grossman, 2016). This criterion will be used throughout the thesis. Uncontrolled hypertension is associated with an increased risk of myocardial infarction, stroke, other complications and mortality (James et al., 2014).

Category	Systolic Blood Pressure		Diastolic Blood Pressure	
	(mmHg)		(mmHg)	
Stage 1 (mild) hypertension	140–159	and/or	90–99	
Stage 2 (moderate)	160–179	and/or	100–109	
hypertension				
Stage 3 (severe)	≥ 180	and/or	≥ 110	
hypertension				
Isolated systolic	> 140	and	< 90	
hypertension				

Table 1.1 Classification of hypertension

Source; National Heart Foundation of Australia (2016)

1.2.3 Diabetes

There are three main types of diabetes: type 1, type 2, and gestational diabetes. The thesis concentrates on type 2 diabetes. Type 2 diabetes is the most common form of this disease, accounting for 85–90 per cent of diabetes cases in the world (Dayan & Williams, 2010). Type 2 diabetes is a chronic metabolic disorder that is caused by a combination of the human body's inability to respond properly to the insulin produced by the β -cells of pancreas (insulin resistance) and β -cell failure (Dayan & Williams, 2010). The causes of type 2 diabetes are unknown. Risk factors associated with type 2 diabetes include lifestyle factors—for example, a lack of physical activities, an unhealthy diet, overweight or obesity (Diabetes Australia, 2018). Type 2 diabetes leads to an increase of blood glucose in the body. Diabetes is characterised by fasting blood glucose level of \geq 7.0 mmol/L, HbA1c \geq 6.5% and a blood glucose level of \geq 11.1 mmol/L two hours after a 75 g glucose load (American Diabetes, 2009). Cases of type 2 diabetes peak among older people aged 60–65 years (Dayan & Williams, 2010).

1.2.4 Uncontrolled diabetes

Uncontrolled diabetes is defined as a random blood glucose level higher than 11.0 mmol/L in people with diabetes (Xu et al., 2009). Uncontrolled diabetes can lead to serious medical complications including cardiovascular diseases, kidney diseases, vision loss and nerve damage (Chawla et al., 2016). High blood pressure is one of the risk factors for uncontrolled diabetes. Uncontrolled diabetes not only affects quality of life, it also places additional burdens on health systems (Siaw & Lee, 2018).

1.2.5 Multimorbidity

Multimorbidity refers to the simultaneous presence of two or more long-term medical conditions (King et al., 2018; Wallace et al., 2015). Multimorbidity is more common in older people, as almost all hospitalised older people are affected by multimorbidity and/or geriatric conditions (Clerencia-Sierra et al., 2015). Geriatric conditions are described as clinical conditions in older people, such as cognitive impairment, malnutrition, falls, incontinence, and pressure ulcers that have a multifactorial etiology and negative effects on health, wellbeing and level of functioning (Cigolle et al., 2007; Inouye et al., 2007). Multimorbidity is associated with increased complexity of care, increased healthcare utilisation, and decreased quality of life (Wallace et al., 2015).

1.2.6 Multimorbidity of hypertension and diabetes

Hypertension is the most common health condition affecting people living with diabetes (up to 82 per cent) (Iglay et al., 2016). Older people with hypertension and diabetes usually have other chronic conditions and geriatric conditions (Cigolle et al., 2007; Iglay et al., 2016; Inouye et al., 2007). The clinical care of older people is complicated by concomitant geriatric syndromes (Clerencia-Sierra et

al., 2015). Older people with the multimorbidity of hypertension, diabetes and other chronic conditions usually have complex care needs and require a coordinated continuum of care services across several care providers.

1.2.7 Burden of multimorbidity of hypertension and diabetes

Hypertension and diabetes are two major non-communicable diseases that have significant burdens on health systems in high-income countries, and low- and middle-income countries (Mohan et al., 2013; World Health Organisation, 2013; World Health Organisation, 2014). According to World Health Statistics, one in three adults worldwide suffer from hypertension and one in 10 has raised blood glucose (World Health Organisation, 2012). By 2050, the number of adults with hypertension is expected to reach 1.56 billion. Further, the number of populations living with diabetes worldwide is anticipated to rise from 120 million in 2000 to 360 million in 2030, representing a large increase in populations living with the multimorbidity of diabetes and hypertension (Mohan et al., 2013; World Health Organisation, 2014).

China has the largest number of people living with type 2 diabetes in the world (Chen et al., 2012). It is estimated that 33.3 per cent of adults with diabetes (over 100 million) around the world live in China (World Health Organisation, 2014). According to International Diabetes Federation (IDF) and the Chinese Centre for Disease Control and Prevention (CCDC), the prevalence of diabetes among Chinese adults has increased 17-fold over the past 30 years, from 0.67 per cent in 1980 to 11.6 per cent in 2010 (International Diabetes Federation, 2016; Shen et al., 2016; Xu et al., 2013; Yu et al., 2014). Unlike the gradual increase in Western countries, the incidence of diabetes in China increased substantially in a very short period (Li et al., 2012; Shen et al., 2016). This trend has challenged the Chinese healthcare system to respond to the disease burden in a timely and appropriate manner (Weng & Bi, 2010).

Hypertension is the most common health condition in people living with diabetes (Cheung & Li, 2012; de Boer et al., 2017). Globally, the frequency of hypertension in individuals with diabetes is twice as high as in the general population because there is a common metabolic pathway between diabetes and hypertension in etiology and disease mechanisms (Grossman & Grossman, 2017; Tashko & Gabbay, 2010). In China, the challenge for the healthcare system arising from this increase in patients with the multimorbidity of hypertension and diabetes is more serious. This is because the prevalence rate of hypertension among people with diabetes is 3.16 times as high as it is for patients without diabetes (Yu, 2010). Managing hypertension among people with diabetes is essential to reduce diabetes-associated serious complications such as renal failure and cardiovascular events (Emdin et al., 2015).

It was estimated in a study that more than 75 per cent of people with diabetes have been diagnosed

with high blood pressure levels \geq 130/80 mmHg (Bakris & Sowers, 2008). Moreover, it is reported in the Framingham cohort study that 40–80 per cent of people with diabetes have the added complication of hypertension (high blood pressure levels of \geq 140/90 mmHg), which is the strongest risk factor for cardiovascular events and death (Chen et al., 2010). In China, the hypertension prevalence rate among people with type 2 diabetes ranges from 49.9–76.5 per cent (Colosia et al., 2013). Mortality is almost 7.2-fold higher in people with the multimorbidity of hypertension and diabetes than it is for non-affected populations (Bakris & Sowers, 2014).

The multimorbidity of hypertension and diabetes has a significant impact on life expectancy and health system costs in China (Liu et al., 2014). Uncontrolled diabetes not only affects individuals' quality of life, it also increases the care burdens of health systems (Camargos et al., 2018; Vanstone et al., 2015). It is estimated that China must provide \$26 billion USD annually for to cover the medical costs of diabetes and its complications; this is predicted to reach \$47.2 billion USD in 2030 (Wang et al., 2009). The disability-adjusted life year (DALY) is widely used to describe the burden of chronic diseases on health systems and is measured as the sum of years of life lost due to premature death and years of life lost due to disability (Wang et al., 2016; World Health Organisation, 2015). In China, the burden of disease attributable to diabetes is 5.36 DALYs per 1,000 population; 37.94 million person-years DALYs were the result of hypertension (Liu et al., 2014). Studies on hypertension management for people with diabetes are greatly needed to provide evidence to inform practice to address the disease burden in China.

1.2.8 Uncontrolled hypertension in people with diabetes

Hypertension is usually poorly controlled in individuals with diabetes (Chen et al., 2010). Similarly, people with uncontrolled hypertension are more likely to have poorly controlled blood glucose (El-Shafie & Rizvi, 2010). Despite the known benefits of reducing blood pressure, 75 per cent of populations with the multimorbidity of hypertension and diabetes in the world still have uncontrolled blood pressure (Duggirala et al., 2005; Yue et al., 2007). A systematic review based on 24 original studies conducted in different countries investigated hypertension management among a sample of 49,420 people living with the multimorbidity of hypertension and diabetes between 1990 and 2004 (McLean et al., 2006). The study found that 87 per cent of people received antihypertensive treatment. However, only 12 per cent met the blood pressure goal of 130/85 mmHg (McLean et al., 2006). Moreover, only 4–10 per cent of people with diabetes met the goals for simultaneous control of hypertension, diabetes and associated complications, as established by the American Diabetes Association (Stults & Jones, 2006). According to a national epidemiological survey, blood pressure control in people with diabetes in China was far from ideal, with only 31 per cent of treated patients adequately controlled (Gao, 2008).

Hypertension is a leading risk factor of cardiovascular complications in individuals with diabetes, as up to 75 per cent of cardiovascular disease in diabetes can be attributed to uncontrolled blood pressure (Arya, 2003; Chen et al., 2010; Gilbert et al., 2011; Sowers et al., 2001). People with the multimorbidity of hypertension and diabetes are at a significantly higher risk of cardiovascular events and mortality than those without hypertension. A Framingham study found that the risk of mortality (7 per cent) and cardiovascular events (9 per cent) were attributed to diabetes, but this risk could increase to 44 per cent and 41 per cent respectively in the presence of the multimorbidity of hypertension and diabetes (Chew et al., 2012). This multimorbidity can lead to pathophysiological changes at the macrocirculation and microcirculation levels that contribute to cardiovascular complications (Chew et al., 2012). This is of great concern, as the main physiopathologic basis of hypertension, arteriosclerosis can cause or worsen the microvascular complications (nephropathy, retinopathy and neuropathy) and macrovascular complications (peripheral vascular disease, ischemic heart disease, and cerebrovascular disease) among diabetic patients, and eventually aggravate the development of diabetes (Cade, 2008; Pan, 2010). Sarcopenia and frailty are two geriatric syndromes that are commonly found in older people who have multimorbidity of hypertension and diabetes. The impact of multimorbidity on the burden to older individuals is considerable (Pefoyo et al., 2015). As one consequence of multimorbidity, polypharmacy increases the medication burden and healthcare costs (Picco et al., 2016). Therefore, it is imperative to implement deprescribing strategies where possible and safe (Reeve et al., 2017).

Maintaining blood pressure within a normal range in people with the multimorbidity of hypertension and diabetes is associated with a decreased risk of complications (Parati et al., 2011). In the hypertension optimal treatment study, people with the multimorbidity of hypertension and diabetes were randomly assigned to a DBP target of 80 mmHg. This group achieved a 51 per cent decrease in total cardiovascular events, compared to those assigned to a DBP target of 90 mmHg (Hansson et al., 1998). In the United Kingdom (UK) prospective diabetes study, researchers conducted a randomised controlled trial among 5,000 patients from 23 hospitals in a 20-year follow-up to test the impact of intensive blood pressure control on complication reduction (Lagani et al., 2013). This study indicated that each 10 mmHg decrease in SBP was associated with a 24 per cent reduction in risk of diabetes-related endpoints, a 37 per cent reduction in macrovascular events and a 44 per cent reduction in stroke. However, a reduction from 7.9 to 7.0 per cent in HbA1c can only achieve a decrease of 12 per cent in diabetes-related complications, 25 per cent in microvascular events and 16 per cent in myocardial infarction (Qi & Li, 2009). In fact, this study discovered that compared with proper control of blood glucose, well-controlled blood pressure could bring more beneficial outcomes in reducing the risk of developing complications and more positive long-term health impacts in terms of quality of life and lifespan (Markku, 1999; Weber, 2014). Therefore, effective blood pressure control is an essential goal for people with hypertension and diabetes because lowering blood pressure can significantly prevent and retard the progression of macrovascular and microvascular complications of diabetes (Arya, 2003; Hata et al., 2013).

1.2.9 Major factors contributing to uncontrolled hypertension among people with diabetes

Although numerous trials have demonstrated the benefits of lowering blood pressure in people with hypertension and diabetes, hypertension control among people with diabetes is still suboptimal due to multiple factors, including unmodifiable and modifiable factors (see Table 1.2). The pathogenesis of uncontrolled hypertension in people with diabetes is complex, involving strong interactions between a range of environmental and biological factors and genetic predisposition (Gilbert et al., 2011). Major unmodifiable and modifiable factors contributing to uncontrolled hypertension among people with diabetes are summarised in Table 1.2 and discussed in the following sections.

Unmodifiable factors	Modifiable factors					
Advanced ageing	Patient factors:					
Ethnicity	 behavioural factors—physical inactivity, unhealthy diet (high-fat, high-sodium diet), 					
Family history	tobacco use, harmful use of alcoholcognitive factors—low health literacy (non-					
Sex (female)	adherence to therapy and follow-up visits)mental factors—depression or stress					
Disease factors	Clinician factors:					
	 clinical inertia (lack of treatment intensification) 					
	lack of a team carelack of professional support					
	Health system factors:					
	universal coverage					
	 primary care system 					

Table 1.2 Risk factors contributing to the uncontrolled hypertension among people with diabetes

1.2.9.1 Unmodifiable factors

1.2.9.1.1 Advanced ageing

The prevalence of hypertension increases significantly with ageing, as reduced arterial compliance and stiffening of the blood vessels leads to a considerable increase in blood pressure (Pinto, 2007; Steppan et al., 2011). Accordingly, the risk of cardiovascular and cerebrovascular events in older people with hypertension increases more significantly than it does in younger people. This population usually has one or more ageing-associated functional decline or health condition. Further, these patients are major users of services across healthcare settings (Martín Lesende et al., 2018). Older people with diabetes have a steady tendency towards unsatisfactory blood pressure control (Duggirala et al., 2005; Hyman & Pavlik, 2001). It has been found that advanced age is a strong predictor for uncontrolled hypertension among people with diabetes (Chew et al., 2012). Cross-sectional studies conducted in China and in other countries have confirmed that older people with diabetes are more likely to have uncontrolled blood pressure than people younger than 60 years (Chew et al., 2012; Yang et al., 2014). Compared with people with diabetes whose blood pressure is controlled, those with uncontrolled blood pressure are significantly older (Duggirala et al., 2005). Therefore, this patient population requires additional attention in hypertension management.

1.2.9.1.2 Gender, ethnicity and family history

Gender, ethnicity and a family history of hypertension or diabetes are important determinants of uncontrolled hypertension in people with diabetes. Research indicates that Swedish females with diabetes were more likely to have uncontrolled hypertension than their male counterparts (Leosdottir et al., 2011). According to the Mayo clinic in the United States (US), being female is one predictor of uncontrolled blood pressure (Duggirala et al., 2005). People with a family history of hypertension or diabetes are more prone to uncontrolled blood pressure due to the hereditary nature of hypertension (Babiker et al., 2013; Esposti et al., 2004; Ranasinghe et al., 2015). Racial disparities were found in hypertension control. In a retrospective analysis of 16,881 people with uncontrolled hypertension, Black people were 1.63 times more likely to have uncontrolled blood pressure than white people (Umscheid et al., 2010). Country-specific disease surveillance data separated by ethnical groups, social groups and gender have value to inform prevention and control strategies that are relevant to groups and gender.

1.2.9.1.3 Disease factors

Hypertension is more difficult to control in people with diabetes. Resistant hypertension is defined as uncontrolled blood pressure despite the simultaneous use of more than three categories of antihypertensive agents (Judd & Calhoun, 2014). This kind of hypertension is more common among older people with the multimorbidity of hypertension and diabetes (Ciobanu et al., 2015; Mohammad et al., 2017; Solini et al., 2014). In the international nifedipine GITS study with a goal in hypertension treatment, people with the multimorbidity of hypertension and diabetes required more combinations of multiple antihypertensive drugs. They also had elevated blood pressure after antihypertensive treatment and were more likely to develop drug tolerance than hypertensive patients without diabetes (Grossman et al., 2011; Mancia et al., 2003).

1.2.9.2 Modifiable factors

1.2.9.2.1 Patient factors

Non-adherence to therapy and follow-up visits are two important patient factors that contribute to uncontrolled hypertension in people with diabetes. In a study by Lindholm (2002), 70 per cent of primary care physicians agreed that non-adherence to therapy and irregular medication were responsible for hypertension management failure. Medication possession ratio (MPR) is commonly used to measure the level of adherence to therapy (McKenzie et al., 2012). A systematic review based on 53 original studies between 2000 and 2005 evaluated the level of adherence to antihypertensive treatment. The findings show that MPR of one year was only 67 per cent, indicating that patients did not follow their treatment 33 per cent of the time over one year (Cramer et al., 2008). Although the review was conducted for patients with hypertension, adherence to treatment is expected to be even worse in people with the multimorbidity of hypertension and diabetes. Limited knowledge of blood pressure management and cardiovascular disease risk, healthcare costs and anxiety of adverse drug reactions leads to non-adherence to medications and follow-up visits (Mann et al., 2009; Zidek et al., 2009). In a survey of 2008 patients with diagnosed diabetes, 68 per cent were unaware that cardiovascular disease was a serious comorbidity of diabetes and less than half realised they were at risk of cardiovascular diseases (Merz et al., 2002). Moreover, only five per cent of respondents were aware that lowering blood pressure could reduce cardiovascular disease risk (Merz et al., 2002). Improving communications between healthcare providers and patients is regarded as an effective approach to increase adherence to treatment (Lili & Jonathan, 2018).

Patients who have diet high in sodium are associated with poorer blood pressure control; a salty diet increased the risk of uncontrolled hypertension by 1.73 times (Khosravi et al., 2014). People with diabetes who smoke tobacco are associated with uncontrolled hypertension because smoking is associated with insulin resistance, vasoconstriction, endothelial dysfunction and dyslipidemia (Rosendorff, 2013). Smokers are also more likely to be sedentary and have unhealthy diets, which can directly increase blood pressure (Rosendorff, 2013). Further, it was found that smoking was a risk factor for diabetes and hypertension-related mortality via the progression of cardiovascular diseases (Fagard, 2009; Khosravi et al., 2014). A low level of physical activity can lead to the development of blood vessel stiffness, which increases the risk of high blood pressure and reduces the effectiveness of insulin, which accelerates the progression of diabetes (Anwer et al., 2011).

Depression is also a modifiable risk factor for people with diabetes at risk of uncontrolled hypertension (Almas et al., 2014; Krousel-Wood & Frohlich, 2010; Rubio-Guerra et al., 2013). Depression lowers patients' motivation to self-manage hypertension and impedes their self-care ability (Crosson et al., 2010). A meta-analysis was conducted to explore the association between depressive symptoms and diabetes management (Gonzalez et al., 2008). The study revealed that people with depression were associated with isolation, non-help-seeking behaviours and at greater

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risk of non-compliance with medications and follow-up visits. This leads to uncontrolled hypertension (Crosson et al., 2010; Groot et al., 2001). Therefore, it is important for healthcare providers to enable patients to be optimistic about their ability to manage their conditions and advise patients to seek treatment for their depression.

1.2.9.2.2 Clinician factors

Clinical inertia is a key factor that contributes to uncontrolled hypertension among people with diabetes (Aujoulat et al., 2014). Clinical inertia is defined as the failure of healthcare professionals to intensify therapy for people who do not meet therapeutic goals (Aujoulat et al., 2015). A prospective cohort study was conducted to evaluate clinical inertia related to hypertension treatment in 598 people with diabetes at a medical centre in the US (Stults & Jones, 2006). Only 30 per cent of people with the multimorbidity of hypertension and diabetes whose SBP was above the treatment goal had their antihypertensive regimen increased in the following years. This was attributed to doctors paying greater attention to blood glucose control than to blood pressure control, or a closer focus on blood glucose control at the expense of hypertension when treating patients with both diabetes and hypertension (Elasy, 2008; Grant et al., 2004; Peng et al., 2012; Putnam et al., 2011). In Spain, a large cross-sectional study of 35,424 people with elevated blood pressure from 428 health centres revealed that 37 per cent of cases had clinical inertia for hypertension treatment (Gil-Guillén et al., 2010). Clinical inertia was significantly increased by the coexistence of diabetes in these patients (Gil-Guillén et al., 2010). Failure to adjust drug doses and types in a timely manner was a primary reason that patients were unable to reach their target blood pressure in the follow-up visits (Lili & Jonathan, 2018; Peng et al., 2012; Salisbury & Fahey, 2006). Clinical inertia is also attributed to a lack of competencies in managing non-communicable diseases among health professionals. Developing competent workforces, revising job descriptions and regulating performance are key approaches to ensure treatment goals are achieved (Milman et al., 2018; World Health Organisation, 2014).

Insufficient access to a multidisciplinary team is reported as a barrier to effective hypertension management for people with diabetes. Due to the complexity of coping with multimorbidity of hypertension and diabetes and competing care demands of patients, multidisciplinary team is widely recommended by international guidelines (Jardim et al., 2018). A multidisciplinary team can promote comprehensive and coordinated care through communication about care plans and clear instructions about who is responsible for managing diabetes care (Crosson et al., 2010). A care approach involving a multidisciplinary team including nurses, pharmacists, medical assistants, nutritionists and dieticians could effectively provide individualised treatment in hypertension management to patients with the comorbidities of hypertension and diabetes (Choe et al., 2008). Considering the differences in health resources among different countries, using a multidisciplinary team approach to standardize

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hypertension care should be carefully designed (Choe et al., 2008).

1.2.9.2.3 Health system factors

Healthcare systems play a major role in the public health response to the increasing burden of chronic disease and its complications in terms of prevention, early detection and proactive management (Selby, 2010; Victorian Government Department of Human Services, 2008). Improving universal health coverage is one way to provide affordable health services for all members of society and to ensure citizens can access the health care they need without suffering financial hardship (World Health Organisation, 2015). Building an efficient and well-established health system, including a primary care approach to chronic condition management, is necessary to improve universal health coverage in a country (World Health Organisation, 2015). It is reported that considerable out-of-pocket payments for health care and a lack of financial protection drive 100 million people in the world into poverty each year (Chuma & Maina, 2012). Universal health coverage and equitable access to non-communicable diseases care services are often presented as idealistic goals that remain unattainable for many low- and middle-income countries where the non-communicable diseases burden has a disproportionate impact (Sen, 2015; World Health Organisation, 2015). Unaffordable healthcare is viewed as a major reason for diabetes patients' failure to attend diabetes clinics and seek medical treatment (Jerant et al., 2005; Nam et al., 2011).

In China, the distribution of healthcare services is extremely unequal (Zhang et al., 2017). Those who live in rural areas fear falling ill because most do not have enough money for medical treatment due to high healthcare services fees. Patients suffer financial catastrophe once they accept medical treatment (Fan, 2011; Wang et al., 2014). Moreover, health service benefits are limited; most outpatient visits and some inpatient admissions are not fully insured (Chisholm & Evans, 2010). Therefore, universal health coverage must be improved through policy interventions to enable people to use all types of health services—health promotion, disease prevention, treatment and rehabilitation—without suffering financial hardship.

A well-established primary care system, robust care coordination across care settings and clear collaboration among different groups of health professionals are required to adequately manage blood pressure conditions and prevent complications in affected populations (Huang et al., 2016; Maimaris et al., 2013; Rich et al., 2012). However, primary healthcare systems in low- and middle-income countries are largely underdeveloped (Asante et al., 2016). China is one of these low- to middle-income countries and is taking action to improve the primary care approach and optimise hypertension management for community-dwelling older people with diabetes (Wang et al., 2015).

Based on the analyses above, developing hypertension management programs for people with diabetes should prioritise modifiable factors. Therefore, analysis of the presence of these risk factors

is warranted to identify hypertension management programs that address these modifiable risk factors in the project.

1.3 Study context

1.3.1 Overview of the Chinese health system and its responses to non-communicable diseases

Like other low-and middle-income countries, healthcare organisations in China are structured at three levels—primary, secondary and tertiary—according to their functions and delivery of health services in the system (Wu et al., 2017; Xiao, 2010) (see Table 1.3). Secondary and tertiary healthcare organisations provide specialised care targeting acute and short-term illness. Primary healthcare organisations aim to provide essential primary care services, including rehabilitation services, preventive care, health promotion, health education, management of chronic conditions, vaccinations and family planning services (Wei et al., 2015).

Categories of healthcare organisations	Functions	
Primary healthcare organisations (i.e.,	Rehabilitation care, preventive care,	
community health centres)	health promotion, health education,	
	management of chronic conditions,	
	vaccinations and family planning	
	services	
Secondary healthcare organisations (i.e., secondary hospitals)	Specialised care	
, , ,		
Tertiary healthcare organisations (i.e., tertiary hospitals)	Specialised care	

Table 1.3 Healthcare system in China

Source: Xiao (2010)

Two healthcare systems enable people to access health care in the world: the gatekeeper system and the direct access system (non-gatekeeper system) (González, 2010). The gatekeeper system is widely applied in high- income countries, while direct access is used in low- and middle- income countries such as China (Dyckerhoff & Wang, 2010). In a gatekeeper system, all patients who have free medical care or social medical insurance must accept consultation and diagnosis from primary healthcare providers as the first contact of care. They are then referred to secondary or tertiary hospitals for more specialised care if required. In contrast, China uses the direct access model with an open access and free referral system that allows patients to access all three levels of health care without referral appointments (Li et al., 2017).

China still faces enormous challenges to improve universal health coverage for citizens in the context of the increased burden of chronic diseases attributed to the ageing population (Shan et al., 2017). Due to the urbanisation of China, the rapidly increasing migration of people from rural to urban areas has led to an increased care burden on urban healthcare organisations and high demand for easy access to high-quality primary care services in the community (Gong et al., 2012; Liu et al., 2017). Simultaneously, the migration of healthcare professionals from rural to urban areas has triggered the loss of health human resources in rural areas, further exacerbating the existing unequal distribution of healthcare resources between urban and rural areas (Mou et al., 2013). The poor distribution of health human resources contributes to health system's lack of capacity to deliver equitable health care for the population in need (Anand et al., 2008; World Health Organisation, 2016). Maintaining stabilised health workforces in rural areas and primary care settings is the most important factor for the successful implementation of universal health coverage and sustainable health care (Lehmann & Dieleman, 2008; World Health Organisation, 2016). Compared with highincome countries, the quantity and quality of the health workforce in China is still poor and the workforce is unequally distributed between rural and urban areas (World Health Organisation, 2013; Wu et al., 2016). As indicated in Table 1.4, the ratio of health professionals to patient populations in China is much lower than in high-income countries such as Australia.

Health personnel (10,000 population)	China	Australia	
Doctors	14.6	32.7	
Nursing and midwifery personnel	15.1	106.5	
Pharmaceutical personnel	2.6	10.2	

Source: World Health Organisation (2014)

It is widely recognised that non-communicable diseases can be effectively prevented and managed through well-established primary care systems (Checkley et al., 2014; Kane et al., 2017). However, currently the primary health system in China is not structured to efficiently address the growing care burden of non-communicable diseases (Tang et al., 2013; Wu et al., 2017). Although community

health centres in China have been established, they still function as mini acute-care hospitals with limited services in chronic disease management due to a shortage of general practitioners (GPs), nurses and limited resources (Yang et al., 2008; Yang et al., 2015). Well-qualified health professionals in China are less likely to work in primary health settings. This further compromises the quality of care at the community level (Wu et al., 2017). Although China has recently recognised the crucial role of primary health providers in preventing and managing chronic diseases, the quantity and expertise of health professionals working in primary care facilities are still far from optimal. Doctors employed in primary care settings in China usually have lower qualifications than those in tertiary and secondary hospitals (Wu et al., 2017). Incentives for medical graduates to work in primary care settings are low and few choose primary care practice as their career pathway (Zhang et al., 2016). A cross-sectional study conducted in 190 community health centres from 10 provinces in China found only 7.3 health professionals (3.2 doctors and 2.3 registered nurses) were available for every 10,000 people (Chen et al., 2014). In addition, around 88 per cent of health professionals working in community health centres did not have undergraduate qualifications or postgraduate training (Tao et al., 2017). Therefore, most people in China choose urban hospitals, usually tertiary hospitals, as their first medical treatment option (Liu et al., 2018; Wu et al., 2017). In 2011, urban hospitals accommodated 94.78 million inpatients while urban community health centres served only 2.65 million patients (State Council of China, 2015). Overcrowding at urban hospitals and underutilisation of community health centres pose a great challenge for the Chinese government, which must achieve a primary care approach to chronic disease prevention and management as recommended by the World Health Organisation (Liu et al., 2018; World Health Organisation, 2016). Therefore, it is imperative to allocate human resources properly between hospitals and community health centres to achieve health equity for all citizens.

1.3.2 Fragmented care in healthcare systems in China

Consultation with specialists in hospitals in China does not require referrals. Unlike health systems in high-income countries, health professionals at community health centres do not have the exclusive power of referral for patients to access secondary and tertiary healthcare organisations. Despite recent reforms in urban primary health care, community health centres still experience difficulties attracting the best medical graduates due to lower salaries, lack of prestige and limited career opportunities (Zhang et al., 2016). Patient confidence in the performance of primary care facilities is low and they usually seek specialised treatments directly from secondary and tertiary hospitals, even for minor conditions (Yue et al., 2007). This situation has led to the inappropriate use of hospitals. Notably, older people with chronic conditions are the main users of hospital services (Kong, 2012; Lopez et al., 2006; Wang et al., 2015; Wang et al., 2006). This care-seeking pattern is unsustainable to meet the complex care needs of populations living with multimorbidities who require a primary care approach to encouraging self-care in the community. Hospital-centred care in chronic disease

management is associated with fragmented and uncoordinated care services, which conflicts with the integrated and people-centred healthcare services recommended by the World Health Organisation (Hu et al., 2016; Wong et al., 2017; World Health Organisation, 2016). Overcrowding in hospitals and underutilisation of primary care services undermine the efficiency of the health system and contribute to unaffordable healthcare expenditures (Liu et al., 2018). In recent health reforms, the Chinese government has repeatedly emphasised the key role of community health centres in preventing and managing chronic conditions and providing rehabilitation care (Wang et al., 2015). Although the government has made a great effort to improve infrastructure and resources for primary care facilities, including manpower and medical equipment, no restriction has been made in patient freedom to select ideal healthcare organisations and professionals for their treatment (Li et al., 2011; Yu et al., 2017). However, in the health reforms, community health centres are expected to be the first contact for people seeking health care. They are also to serve as gatekeepers to care services provided by secondary and tertiary healthcare organisations (Li et al., 2011; Yu et al., 2017).

The Chinese healthcare system is facing considerable challenges in responding to the growth of chronic diseases, including hypertension and diabetes, that are related to the ageing of the population (Bilgel et al., 2017). Hospital-centred care leads to highly fragmented health care delivery in China due to the lack of collaboration and communication between different levels of health organisations and the duplication of health services (Qian et al., 2017; Wang et al., 2016). Building integrated and coordinated health services that focus on primary care is critical to improve health care equity and quality and reduce health expenditures (Wang et al., 2016). World Health Organisation (2016) strongly states that people with chronic diseases require continuous and seamless care from health professionals across different levels of health care. Among the limited referrals across different healthcare organisations, the rate of downward referral from hospital to community centre is much lower than that of upward referral from community centre to hospital (Yu et al., 2017). A survey found that upward and downward referrals in China account for 96.3 and 3.7 per cent of total referrals respectively, which further implies the underuse of community health resources in China (Yu et al., 2017). Therefore, building downward referrals is more urgent than upward referrals in China. However, considering the lower qualifications and lack of GPs in primary care settings, two-way referral should be considered to allow the sharing of expertise and resources of different healthcare organisations in managing hypertension for people with diabetes.

1.3.3 Challenges in managing hypertension among people with diabetes in China

1.3.3.1 The community context

Most GPs employed at community health centres do not attend standard training of chronic conditions management and lack of knowledge of medication adjustment (Lili & Jonathan, 2018; Wang et al., 2013). Peng et al. (2012) conducted a qualitative study in the Jiangsu province of China

to investigate primary physicians' proficiency level for blood pressure management of people with diabetes. Only 37 per cent of primary physicians indicated sufficient blood pressure management knowledge. Based on this, most people with diabetes in China do not trust the quality of primary care services and opt for tertiary healthcare organisations for treatment (Eggleston, 2012). A survey in China found that 91 per cent of patients expressed low trust in primary care providers due to the latter's lower medical educational attainment compared with hospital specialists (Wu et al., 2017). The proportion of registered doctors in primary care settings who have studied medicine for more than three years was only 76.6 per cent in 2013. However, 90 per cent of hospital specialists had studied medicine for more than three years, with more specialists completing postgraduate education and training (Wu et al., 2017). These phenomena have resulted in patients with chronic conditions using tertiary resources, rather than those who require acute care (Yu et al., 2017).

Considering patients' distrust of primary care facilities, it is difficult to encourage people to use community care services as their first point of contact. However, hospital-initiated collaboration with community health centres is considered a promising way to encourage patients to use primary care and improve the competency of primary care providers. A cross-sectional survey in China applied the Chinese primary care assessment tool to compare the quality of primary care services between the three levels of healthcare organisations among 864 patients (Hu et al., 2016). The study demonstrated that community health centres provided a higher quality of primary care than secondary and tertiary hospitals did in terms of comprehensiveness of services, first-contact access, and ongoing care (Hu et al., 2016). The study indicated the need to develop services in community health centres to support patients, especially older people with diabetes and hypertension who are discharged from hospitals but require follow-up support to reduce readmission rates (Wang et al., 2014). Studies that explore opportunities and challenges in integrating hospital and community care services in practice in the healthcare system.

In response to the increased burden of chronic disease and the demand for community care services for older people, the Chinese government launched its 'Healthy China 2030' plan in 2016 (Tan et al., 2018). This plan aims to restructure the primary care system with a main focus on achieving accessible and affordable basic health care for all citizens by 2030 (Li et al., 2016; Li et al., 2017; Tan et al., 2018). This reform is also reinforced by two government-sponsored medical insurance schemes: (1) basic medical insurance for urban employees and residents, and (2) the new rural cooperative medical scheme for rural citizens (Fu et al., 2018). These schemes cover nine essential public health services provided by community health centres, including health management for people with hypertension and/or diabetes, and health management for people aged 60 or over (Tian et al., 2015). Despite these efforts, use of community health centres is low and the challenges remain. It is reported that only 20.79 per cent of patients in China consulted community health

centres for health care, which is far from the 90 per cent rate recommended by the World Health Organisation (Yang et al., 2014). Both inpatient and outpatient departments in secondary and tertiary hospitals are overloaded, treating people with hypertension and/or diabetes, especially older people with multimorbidity (Feng et al., 2016; Wu & Lam, 2016; Yang et al., 2014). Although the importance of primary health care in preventing and managing chronic disease was emphasised in recent health forms, a detailed implementation plan with clearly defined roles for health professionals in managing hypertension for people with diabetes is still lacking. Further, consensus of this plan among health professionals in China is also lacking.

There has been an increased number of intervention studies conducted in China in recent years to improve usage rates of community health centres. Among these, an integrated care delivery model is viewed as the most desirable method to address the factors underlying the underutilisation of primary care services (Lin et al., 2015; Miao et al., 2016; Qian et al., 2017; Shi et al., 2015). In this model, community health centres are mandated in the insurance scheme as the first point of contact in the health system for people with hypertension and diabetes. A vertical referral system has been tested in a pilot study to allow community health centres to share expertise and resources with secondary and tertiary hospitals in managing these conditions and other geriatric conditions for older people (Lin et al., 2014). However, methods to adapt this model in different local contexts have not yet been explored.

People-centred, non-pharmacological interventions underscore behavioural changes in controlling hypertension and diabetes, and reduce the risk of complications associated with these conditions (World Health Organisation, 2013). These interventions value people as change agents in determining and managing their own chronic conditions (Michie et al., 2011). An optimal primary care system should be structured and resourced to enable the population to build knowledge, self-care skills, and have the motivation to change behaviours to adopt healthy lifestyles (Lin et al., 2014; Peiris et al., 2015). A pilot study in China reported positive outcomes for lifestyle interventions delivered by community health centres to reduce blood pressure and blood glucose for middle-aged and older adults (Lin et al., 2014). Although the study showed significant improvement for the intervention group, it relied on project funding to recruit community workers to deliver education and training activities for participants.

1.3.3.2 The hospital context

It has been argued in the literature that patient-centred and integrated care delivered by a multidisciplinary care team is an effective approach to manage non-communicable diseases, prevent complications, improve patient satisfaction through optimise resource allocation and enhance access to primary care services (Shi, 2012; Wen & Schulman, 2014; World Health Organisation, 2013; Yip & Hsiao, 2014; Zhao et al., 2017). Moreover, preventing disease and

associated complications is an important component in acute care hospitals. This is usually undertaken by nurses through patient education during the hospitalisation and discharge planning (Johnson & Chang, 2014). In China, multidisciplinary team-based hypertension management for people with diabetes has not been established in hospital settings (Wong et al., 2017). Hypertension management for people with diabetes mainly focuses on medication treatment (Wang et al., 2018). Doctors usually play a leading role in hypertension management for people with diabetes. The importance of other health professionals, including nurses, dietitians and pharmacists, is often overlooked (Mash et al., 2015).

The World Health Organisation has recommended that patients be referred from hospitals to primary care centres, where 80 per cent of diseases can be treated or managed (Yu et al., 2017). However, a survey has found that only 20.8 per cent of doctors in hospitals are willing to implement downward referrals (Yu et al., 2017). The lack of policies and resources to enable communication, task sharing and collaboration in chronic disease management might contribute to this situation. A survey investigating healthcare referral services in China found that 56 per cent of hospital doctors never had any work-related communications with GPs (Zhou & Nunes, 2016). It is strongly suggested that studies need to explore chronic disease management in a healthcare system, ways to improve communication among health professionals within the system and a consensus on how to improve downward referrals (Lin et al., 2015).

It is evident that quality of care for hospitalised people with chronic conditions is suboptimal. An investigation of current status of diabetes management in secondary hospital revealed that only 6.9 per cent of patients are given diet instruction and 0.7 per cent are given education on healthy lifestyles as part of their discharge (Chui et al., 2010). Studies on discharge planning to improve patients' knowledge about diabetes and hypertension management and self-care capabilities are needed to improve quality of care for patients and reduce readmission rates.

1.3.4 Challenges in caring for older people with diabetes and hypertension

The World Health Organisation (2015) defines older people in low- and middle-income countries as those 60 years and older. Over the past two decades, the population in China has been ageing rapidly because of the 'one-child' policy and the improvement in life expectancy (Gustafson & Baofeng, 2014). In 2007, there were around 100 million Chinese citizens aged 65 and older. This is predicted to reach to more than 300 million by 2050 (United Nations, 2007) (see Figure 1.1). Between 2007 and 2050, the proportion of people aged 65 and over will rise from 7.9 per cent to 23 per cent (United Nations, 2007) (see Figure 1.2). The growing elderly population in China will inevitably increase ageing-associated disease burden on an already overburdened healthcare system and demand for a sustainable healthcare system with a primary care approach to chronic disease

management and an integrated care model to emphasise continuum of care across healthcare facilities and settings (McPake & Mahal, 2017; World Health Organisation, 2016). A rapidly ageing population and the increased prevalence of older people with a multimorbidity demands the provision of community-based and people-centred primary care services (Lin et al., 2015). Hospital-centred and fragmented healthcare services are viewed as incapable of meeting the care needs of older people with multimorbidity (Qian et al., 2017).

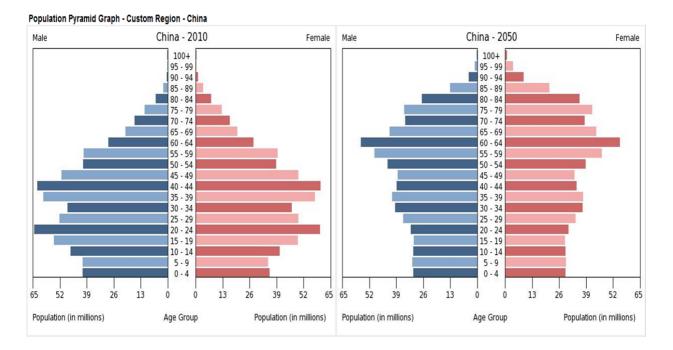
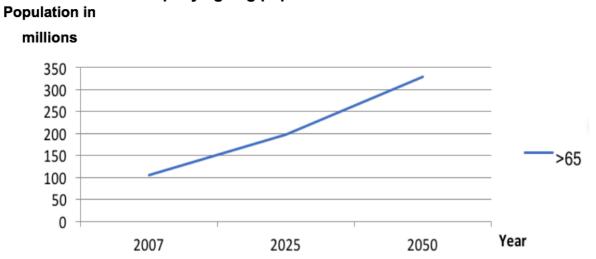


Figure 1.1 Ageing population in 2010 and 2050

Source: World Population Data (United Nations, 2007)



Rapidly ageing population in China

Figure 1.2 Rapidly ageing population from 2007 to 2050

Source: United Nations (2007)

The hypertension in diabetes study concluded that 40 per cent of people who have diabetes at the age of 45 years also suffer from hypertension (Wallace, 1999). However, the prevalence rate of hypertension reaches 60 per cent for people who have diabetes at the age of 75 (Wallace, 1999). There is a positive association between older age and poorer blood pressure control in people with diabetes. People with the multimorbidity of diabetes and hypertension are less likely to have their blood pressure controlled (Schmieder & Ruilope, 2008). According to the analysis of Framingham study data, advanced age was the strongest determinant for lack of blood pressure control (Calhoun et al., 2008). It is reported that less than 25 per cent of patients aged over 75 years have controlled blood pressure (Calhoun et al., 2008).

It is predicted that the prevalence of the multimorbidity of hypertension and diabetes will increase in China because the incidence of both hypertension and diabetes increases with age and China's population has been ageing rapidly (Hu & Jia, 2018; Peng et al., 2017). In a large survey of 4,371 hospitalised patients in China, people with diabetes aged 60 years or older comprised a significant proportion of the patient population in the hospital (Zhao et al., 2011) (See Figure 1.3). Disease burden in China is associated with the ageing population (Zhao et al., 2011). By 2030, the older population is predicted to account for two-thirds of the total burden of non-communicable disease in China (Chatterji et al., 2008).

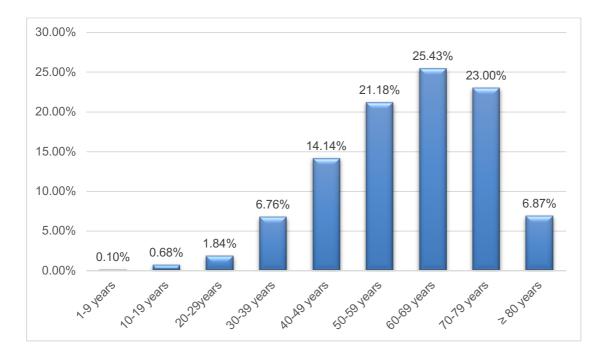


Figure 1.3 Association between prevalence rates of hospitalised people with diabetes and age in China

Source: (Zhao et al., 2011)

Low income, educational background, health literacy and medication compliance are the most influential barriers for older people with diabetes to obtain a high quality of health care, treatment satisfaction and health outcomes (Alberti et al., 2007; Goudswaard et al., 2004; Lam et al., 2004; Saatci et al., 2010). Low health literacy is found to be more prevalent among older populations, even in higher-income countries. According to the assessment of adult literacy in US, almost half of the population living in the US has marginal or suboptimal functional health-related literacy, and the proportion significantly increased with age (Kutner et al., 2005). Patients with poor literacy are less likely to follow instructions and adhere to the recommendations provided by health professionals. Low literacy is a major barrier to obtaining adequate medical care because people with low literacy are unable to understand directions for self-care, appointment slips, health education material and medicine labels (Bilgel et al., 2017; Lee et al., 2017; Masoompour et al., 2017). Further, patients with low health literacy have more hospitalisations and consume higher medical expenditures (Howard et al., 2005). People with low literacy are also more likely to come from low socioeconomic backgrounds. Low health literacy is more prevalent in low- and middle-income countries, including China, where resources for public health education are inadequate (Alwan et al., 2011; Nielson-Bohlman et al., 2004). According to the Chinese residents' health literacy monitoring report in 2013, less than 10 per cent of people in China possess adequate levels of health literacy, with people aged over 65 years reporting the lowest levels (National Health and Family Planning Commission of the People's Republic of China, 2014). In addition, China is experiencing a dramatic shift to a more western diet and lifestyle, namely, a high salt, high fat, high calorie diet. This typical lifestyle will lead to the challenge in managing multimorbidity of hypertension and diabetes.

Poor compliance with medication is the other significant barrier for older people to receive adequate treatment for hypertension. A study analysed 100 hospitalised older people with diabetes and hypertension from 2012–2013 to measure their compliance with medication (Cao, 2014). The results showed that the medication compliance rate was only 21.9 per cent among older people with disease duration of under 10 years and 33.8 per cent among those with a disease duration of over 10 years (Cao, 2014). Factors contributing to poor medication compliance identified in the study are summarised in Table 1.5. Analysing these factors revealed the lack of knowledge about disease and treatment among patients and the urgent need to improve health education for patients to improve medication compliance. The findings also indicated the cost of medication was a factor in non-compliance with medication. Improving universal health coverage should be considered as a scientific strategy to improve medication adherence.

Percentage
24.3%
21.4%
18.6%
14.3%
11.4%
7.1%
2.9%

 Table 1.5 Reasons for poor medication adherence in elderly people with diabetes and hypertension

Source: Cao (2014)

The prevalence of hypertension increases significantly with ageing, as the stiffening of blood vessels and reduced arterial compliance leads to a large increase in blood pressure (Steppan et al., 2011). Accordingly, the risk of cardiovascular and cerebrovascular events in older people with hypertension increases more significantly than it does in younger people. This population usually has one or more ageing-associated functional decline or health condition and are major users of healthcare services across multiple settings (McPake & Mahal, 2017). Therefore, a well-established primary care system, robust care coordination across care settings and clear collaboration among different groups of health professionals are required to achieve an ideal blood pressure levels and to prevent complications among this population (Rich et al., 2012).

A body of evidence shows that up to 50 per cent of community-dwelling older people had one or more geriatric conditions, such as cognitive impairment, falls, incontinence, malnutrition and pressure ulcers (Cigolle et al., 2007; Inouye et al., 2007). These conditions compound the complexity

of other illness such as hypertension and diabetes, and contribute to adverse outcomes (Inouye et al., 2000). Community-dwelling older people who are susceptible to or have those conditions require primary care services to manage these conditions and prevent complications. Considering the lifelong treatment of diabetes and hypertension, this group of patients—who are frequent users of health services—needs support from primary care settings to address their care needs (Cheng et al., 2014; Liu et al., 2017). These challenges will need to be addressed in the current study by implementing an evidence-based intervention program.

1.3.5 Impact of health reform on healthcare delivery in China

Following an outline of health reform plan launched in 2009, China developed a health reform policy entitled 'Deepening Health Reform In China: Building High-Quality and Value-Based Service Delivery' in 2016 to proceed with the ongoing reforms (World Bank, 2016). The policy has developed a concrete implementation plan for health sectors in China to build a more integrated healthcare delivery system. It emphasises the establishment of collaboration between hospitals and community health centres to downward allocation of hospital-based resources towards primary care settings such as community centres (Wang et al., 2018; World Bank, 2016). Local government is implementing the national health reform and local health sectors are changing their regulations and restructuring their health services to respond the health reform (Barber et al., 2014; Jiang et al., 2017). The reform has redefined the roles of hospitals and community health centres within a vertically integrated network (Li & Fu, 2017; World Bank, 2016). As a focus of health reform, hospitals are required by the government to reduce patients' length of stay and develop referral systems with community services to enable timely referral from hospital to community health centres for follow-up care. In addition, the development of multidisciplinary teams with clearly defined roles and responsibilities is also highlighted in the health reform to promote individualised care plans for patients (World Bank, 2016). The health reform has also developed insurance benefit packages and established tiered reimbursement systems to shift patients seeking care to primary care settings and improve access to primary care (Barber et al., 2014; Li & Fu, 2017). People are encouraged to obtain optimal care at the appropriate level of the health system and can receive a higher reimbursement for health care and medicines in primary care settings, such as community health centres, than they can for hospital expenses (Barber et al., 2014). This study was undertaken during reforms in the local health system in Nanchang, China. The hypertension management program developed, implemented and evaluated in the study targeted the needs of government and healthcare providers.

1.4 Introduction to the hypertension management program

The hypertension management program was specifically developed for older people with the multimorbidity of hypertension and diabetes who were ready to be discharged from hospital to home

and required community-based care. The development of the hypertension management program was based on a comprehensive literature review and was underpinned by the chronic care model (Improving Chronic Illness Care, 2006) and the practice questions—evidence-translation (PET) model (Dang & Dearholt, 2017) (see Chapter 2). The research team conducted consultations with an expert panel in the study context through a two-round Delphi study to reach consensus of the program (see Chapter 3). The intervention components in the program emphasised integrated care between hospitals and community health centres and collaboration in care services delivered by health professionals within and between hospitals and community health centres in the program. The interventions comprised two stages. Stage 1 was implemented in the hospital prior to discharge and Stage 2 was implemented in community health centres in a six-month follow-up after discharge. In Stage 1, individualised health education and medication treatment plans were provided to the hospitalised patient by specialists and in-charge nurses. In Stage 2, patients were referred to community nurses to enhance patients' self-care ability, treatment adherence, lifestyle modifications and health knowledge. The program is illustrated in Figure 1.4 and explained in Chapter 4.

Figure 1.4 Development and implementation process of the hypertension management program

Comprehensive literature review

to identify effective interventions and conceptual frameworks

Delphi study

to develop a culturaly adapted intervention program in the study setting

Translation to practice

to implement and evaluate the program using a cluster randomised controlled trial

1.5 Aims of the study

This PhD project has two related aims:

- 1. Aim 1: to gain health professionals' consensus on the applicability of an evidence-based hypertension management program for older people with diabetes who were ready to be discharged from hospital and required follow-up support in primary care in Nanchang, China
- 2. Aim 2: to test a hypothesis that a hypertension management program built on collaboration between hospitals and community health centres in Nanchang, China, can improve blood pressure control in people aged 60 years and over with diabetes compared to usual care.

A Delphi study was applied to address Aim 1 of the project. The specific objectives of the Delphi study were to: (1) determine the consensus from a multidisciplinary expert panel on the applicability of the proposed hypertension management program; and (2) provide the expert panel with opportunities to revise the hypertension management program.

A cluster randomised controlled trial (RCT) was utilised to address Aim 2 of the project. Hospital wards and community health centres in Nanchang were invited to the trial. The intervention includes individualised self-care education prior to discharge and six-months' follow-up in community health centres. The primary outcome was change in SBP at six months post-discharge. Secondary outcomes were changes in self-care knowledge, treatment adherence, HbA1c and lipid levels, quality of life, incidence of adverse events and incidence of unplanned hospital readmission at six-months' follow-up.

1.6 Significance of the study

Currently, secondary and tertiary hospitals in China are designed for acute care, while community health centres are designed to prevent and manage chronic diseases/conditions. However, community health centres are underdeveloped in China. Medical resources are unevenly distributed between acute care hospitals and community centres. Therefore, patients with chronic diseases usually choose tertiary and secondary hospitals when seeking treatment. Consequently, tertiary and secondary hospitals are overwhelmed with a vast number of patients. This situation is worsened by a lack of collaboration and communication between hospitals and community health centres. The demand for managing hypertension in primary care settings through comprehensive strategies is largely overlooked. Establishing collaboration between hospital and community health centres is of paramount importance for alleviating this imbalance.

In 2015, the Chinese government issued an 'Outline for the Planning of the National Medical and Health Service System (2015-2020)', which emphasised building collaboration between hospitals and community health centres to improve prevention and management of chronic disease in primary care settings, reduce hospital care burden and national medical cost burden. This project supports the implementation of the national plan in chronic disease management in primary care settings. It

is anticipated that the implementation of the proposed program will also improve collaboration among health professionals. The ultimate goal of the program is to promote optimal care services for community-dwelling older people with diabetes and hypertension. In addition, improved selfmanagement skills of community-dwelling patients will reduce unplanned hospital admission due to uncontrolled hypertension and other geriatric conditions, thereby reducing the national healthcare cost. This study is novel, as it is the first in China to generate and test an evidence-based and comprehensive hypertension management program for older people with diabetes. In addition, this study is innovative as it is built on hospital-initiated collaboration with community health centres in chronic disease management. If the intervention program significantly improves blood pressure control among community-dwelling older people with diabetes, the program can have immediate application to hypertension management in the healthcare system in Nanchang, China.

1.7 Thesis structure

The thesis is presented in eight chapters. Chapter 1 reveals that the multimorbidity of hypertension and diabetes has become a prominent public health issue in China and the global context. Uncontrolled hypertension and associated complications among older people with the multimorbidity of hypertension and diabetes are the main reasons for hospital admission in China. Moreover, people aged 60 years and over comprise a large proportion of this hospital population. It has also identified that primary care system in China is underdeveloped and unable to support older people with multimorbidity of hypertension and diabetes to manage their conditions at home to avoid preventable complications. There is little research on collaboration between hospitals and community health centres in implementing discharge planning for this patient population. Therefore, it is highly likely that the readmission rate for this population may remain unchanged or even higher without appropriate intervention. The significance of the study to build a comprehensive health system with collaboration between hospitals and community health centres has been discussed.

Chapter 2 provides a literature review of RCTs and systematic reviews in hypertension management programs for people with diabetes in the global context. It reviews the essential intervention components in hypertension management for people with diabetes and identifies the strategies to implement these interventions. Conceptual frameworks are critically analysed and identified in the planned RCT study. This literature review informs the intervention design in the planned RCT. As the interventions identified in the literature review are from high-income countries with developed health systems and highly trained health professionals, it is important to investigate the applicability of the planned interventions to the Chinese context.

Chapter 3 describes the process of developing the intervention program through a Delphi study. The rational of using a Delphi study is discussed and the findings and discussions of the Delphi study

are reported. A hypertension management program for older people with diabetes that is applicable to the Chinese context is identified through the Delphi study.

Chapter 4 provides a detailed description of the research design and methods for the hypertension management program for community-dwelling people with diabetes. This includes a rationale for cluster randomisation, process of randomisation, eligibility of participants, data collection and analysis method, sample size and ethical issues.

Chapter 5 reports the study findings. First, social demographics and clinical characteristics at baseline are presented and compared between the intervention and usual care groups. Second, findings from the cluster RCT are analysed and presented. Finally, the results from the inductive content analysis of the open-ended questions for the intervention group on the completion of the trial are presented.

Chapter 6 discusses the impact of the intervention program on study outcomes and relations to similar studies reported in the literature. Strengths and limitations of the study are discussed. In addition, participants' satisfaction with the program and issues identified in the program are analysed.

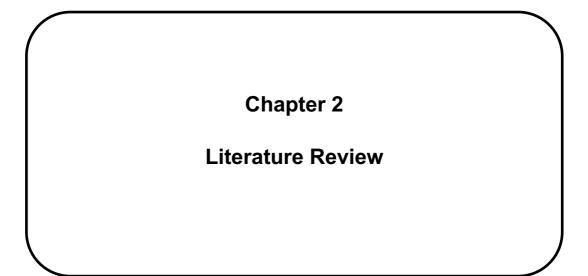
Chapter 7 extends the discussion to a multilevel and multicomponent (ML-MC) intervention design, explaining the positive impact on the present study outcomes. It emphasises the importance of designing multilevel and multicomponent interventions in a healthcare system to enable a primary care approach to support older people to manage hypertension, diabetes and other comorbidities.

Chapter 8 summaries the Delphi study and the cluster RCT and identifies implications for policy and resource development, healthcare service development, professional development and future research.

1.8 Summary

This chapter presents an overview of hypertension and diabetes in both the Chinese and global context. China has the largest number of people living with the multimorbidity of hypertension and diabetes in the world. The ageing population aggravates the complexity of hypertension and diabetes management. Primary care system in China is still underdeveloped and underutilised to reduce the care burdens of hospitals in the care of older people with both hypertension and diabetes. Merely relying on a hospital-centred care cannot address the complex care needs of older people with this multimorbidity. Integrated care with a focus on primary care services in community health centres to strengthen the care of older people with multimorbidity of hypertension and diabetes. This proposed

hypertension management program is built on the collaboration between hospitals and community health centres and supports health reforms in China. The significance of the study, aims and objectives of the study, and structure of this thesis were also presented.



Chapter 2 Literature Review

2.1 Introduction

The preliminary literature review in Chapter 1 reveals that the multimorbidity of hypertension and diabetes in the adult population has become a public health issue in the Chinese social context. However, the primary care system in China is underdeveloped and unable to support this population to perform self-care at home and avoid preventable complications. People with the multimorbidity of hypertension and diabetes usually seek treatment at secondary and tertiary hospitals. Among this population, people aged 60 years and over usually have other chronic disease or/and geriatric conditions and account for a significant proportion of hospital patients. Hospital-centred care without a primary care approach to support self-care for this population is associated with unmet care needs, high costs and poor care outcomes. There is little research on collaboration between hospitals and community health centres in implementing discharge planning for this patient population. Therefore, it is highly likely that readmission rates for this population may remain unchanged or even higher without appropriate interventions. This chapter presents a literature review of the studies on effective management of hypertension among people with diabetes to inform a study to improve hypertension management for community-dwelling older people with diabetes. This chapter also discusses the conceptual frameworks applied to the study.

2.2 Literature review aims

The aim of this literature review is to identify characteristics in effective intervention studies designed to improve hypertension management for people with diabetes in community care settings or prior to discharge from hospital. Under this aim, the specific objectives are to identify:

- essential intervention components included in the reviewed studies
- strategies used to implement the interventions.

2.3 Literature search methods

2.3.1 Search strategies

Five online databases including PubMed, Web of Science, Scopus, Science Direct and Cochrane Library were searched to identify relevant studies for the literature review. These databases were selected because they contain peer-reviewed studies involving healthcare interventions. The Cochrane database was selected because it collects evidence-based practice guidelines and high-quality RCTs. Two major Chinese databases, Wanfang Database and China National Knowledge

Infrastructure, were also searched to reduce publication bias. The population, intervention, comparison, outcome and study design (PICOS) framework was applied to frame search terms and keywords to achieve the objectives set out in the review. A set of terms and keywords relevant to the research topic was identified through (1) searching the keywords that appeared in preliminary readings, (2) discussions with supervisors, (3) and a consultation with a librarian. The terms and keywords—based on the PICOS framework—are outlined in Table 2.1.

Search terms and keywords in English								
PICOS	Terms and keywords							
Population	People with diabetes discharged from hospital for ongoing hypertension management at home; population living with multimorbidity of hypertension and diabetes in the community setting							
Intervention	Continuum of care; chronic disease management; discharge planning; follow-up; hypertension management; integrated care; medication adjustment; medication management; patient education; self-care							
Comparison	Usual care or conventional care							
Outcomes	Primary outcome measure: SBP Secondary outcome measures: DBP, HbA1c, fasting blood glucose, HDL, LDL, medication adherence, health knowledge, quality of life							
Study designs	RCT, systematic review and meta-analysis							
	Search terms and key words in Chinese							
PICOS	Terms and keywords							
Population	需要居家高血压管理的糖尿病出院病人;糖尿病并发高血压的社区病人;							
Intervention	连续性照护; 慢性病管理;出院计划;教育; 随访;高血压管理; 整合护理; 药物 调整; 药物管理; 自我照护;							
Comparison	常规治疗和护理							
Outcomes	主要结果: 收缩压							

 Table 2.1 Search terms and keywords based on the PICOS framework

次要结果:舒张压;糖化血红蛋白;空腹血糖;高密度脂蛋白;低密度脂 蛋白;药物依从性;健康知识;生活质量;

Study designs 随机对照试验;系统性回顾和荟萃分析

Note: the search terms and key words in Chinese are the same as described in English.

A Boolean search was conducted by combining the five sets of terms/keywords listed under the PICOS framework. Examples of the combination of Boolean operators and phrase searching are presented in Appendix 1.

2.3.2 Inclusion and exclusion criteria

Criteria for considering studies for this review were developed based on the PICOS framework and other factors. Studies were included if they met the selection criteria as outlined in Table 2.2. Studies were excluded if they did not meet the selection criteria.

PICOS	 Inclusion criteria Adults (18 years of age or older) with multimorbidity of hypertension and diabetes living in the community Adult patients with multimorbidity of hypertension and diabetes in the discharge period from hospital to home In the absence of multimorbidity of hypertension and diabetes, studies reporting discharge planning that included people with diabetes will be included to inform a planned RCT to test a hypertension management program as described in Chapter 1 						
Population							
Intervention	 Intervention should include at least one of the following components: Hospital to home discharge planning Health professional-led hypertension management in the community settings Self-care for multimorbidity of hypertension and diabetes 						
Comparison	Usual care or conventional care provided in the study						
Outcomes	At least one of the following outcomes should be included: Primary outcomes • SBP Secondary outcomes						

Table 2.2 Inclusion criteria based on the PICOS framework

	• DBP				
	HbA1c				
	 fasting blood glucose 				
	• HDL				
	• LDL				
	medication adherence				
	health knowledge				
	quality of life				
	discharge planning				
Study designs	RCTs or systematic reviews and meta-analyses				
Time frame	Published in 2008 or later; relevant studies published before 2008				
	identified via manual search				
Language	English or Chinese				

2.3.3 Selection of studies

Abstracts of potential articles identified in the database search were screened for eligibility. Reference lists of key articles were manually checked to identify potentially relevant studies to be included in the literature review. All citations and accompanying abstracts retrieved from the online database were downloaded and converted to a reference manager (Endnote). Duplicate references were identified and removed prior to the screening process. The PhD candidate screened the titles and abstracts of studies according to the predetermined inclusion and exclusion criteria. Full texts of selected studies were retrieved and critically analysed. The study selection process was discussed in regular meetings with the supervisory team.

2.3.4 Data abstraction

A narrative analysis was applied to synthesise the main findings from the literature review. Relevant information from each study was collected, summarised and classified in a table to facilitate analysis and comparison. A predefined data abstraction table was used to present the main characteristics of the included studies, such as sample size, number of groups, theoretical framework that guided the intervention development, key components of the intervention, duration of intervention, healthcare professionals who implemented the interventions, results and limitations. The PhD candidate extracted data from the included studies and discussed the process and outcomes with supervisors in regular meetings. Disagreements and uncertainty in data abstraction were resolved through discussion.

2.3.5 Critical appraisal

The CONSORT statement guideline was used as a checklist to identify RCT articles that might not meet the quality of report and trustworthiness of the study (Moher et al., 2010). Of the 25 items included in the CONSORT statement, some (3b, 6b, 7b, 8b, 11b, 12b, 14b, 18, 19, 23, and 24) were not applicable to this literature review. The summary of critical appraisal using the CONSORT statement guideline is presented in Appendix 2: CONSORT 2010 checklist of information to include when reporting a randomised trial.

To assess the risk of bias in the included studies, the Cochrane's 'Risk of bias tool for randomized controlled trials' was applied to the critical appraisal. Seven main domains are included in the tool: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting and other generic sources of bias. For studies included in the literature review, the seven areas were assessed in terms of high, low or unclear risk of bias.

The Cochrane's 'Tool to assess risk of bias in systematic reviews' (ROBIS) was applied to evaluate the risk of bias for systematic review. The evaluation process comprised three phases: assessment of relevance, identification of concerns with the review process and judgement of risk of bias (Whiting et al., 2016). Each domain in the ROBIS tool was individually assessed by describing the methods used. Fulfilment of each specific criteria within that domain was determined by answering 'yes', 'probably yes', 'probably no', 'no' or 'no information'. After considering the fulfilment of each criterion, a rating of 'high risk of bias', 'low risk of bias', or 'unclear risk of bias' was determined and assigned to the overall domain.

2.3.6 Synthesis

Content analysis was applied to examine the intervention components, process and outcomes of all reviewed studies. Findings from the analysis were grouped based on similarities and differences. Findings were presented narratively to address the objectives set out for the present literature review.

2.4 Findings

2.4.1 Search outcomes

A total 11,075 records were located from database searches and manual retrieval. After duplicate removal, 3,329 articles were withdrawn and 7,746 articles remained for screening through browsing the title and abstract of each article. Of those for screening, 281 articles were evaluated for eligibility and 30 articles were finally included in this literature review. The 30 studies included four systematic

review and meta-analysis, 23 RCTs published in English and three RCTs published in Chinese. The selection process is presented in Figure 2.1.

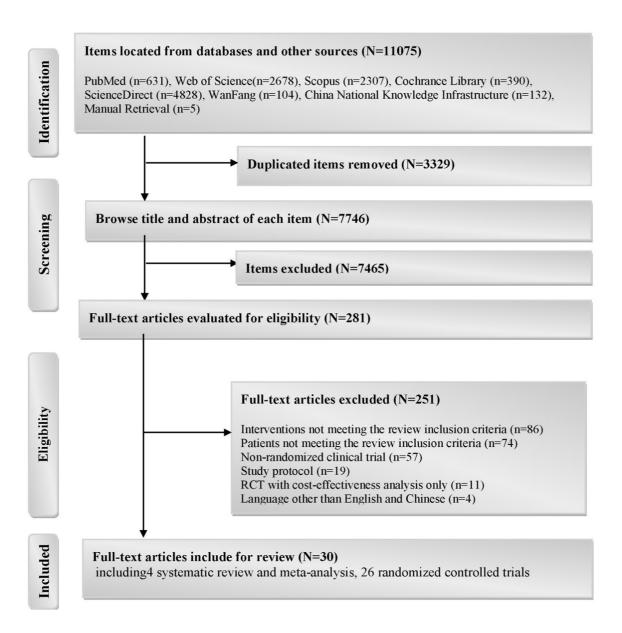


Figure 2.1 Selection process

2.4.2 Findings from the critical appraisal

Of the 26 RCT articles, only three reported all 25 items stated in the CONSORT (see Appendix 2). The 22 RCT articles that did not meet all required items mainly were ineligible due to blinding and allocation concealment. Further analyses revealed that most selected RCTs (19 articles) reported sample size calculation and power analysis. Seven RCTs did not mention power analysis (Davies et al., 2008; Dobrosielski et al., 2012; Gabbay et al., 2013; MacMahon et al., 2009; Scain et al., 2009; Xia et al., 2014; Yu, 2014). Most selected RCT articles reported the rationale for selecting statistical methods to compare outcomes from the intervention group and the usual care group. Most statistical

methods applied included multivariate linear regression model or ANOVA to calculate the blood pressure changes over time points. However, one RCT study did not justify the selection of the statistical methods and the different outcomes between the intervention group and the usual care group (MacMahon et al., 2009).

The risk of bias for each reviewed RCT study was carefully assessed and results were summarised in Appendix 3: Summary of risk of bias for studies included in the review based on the Cochrane's "Risk of Bias Tool for Randomized Controlled Trials. Only one of the 26 RCT studies showed a low risk of bias, 10 studies showed uncertain risk and 10 studies indicated a high risk of bias. Most of the reviewed RCTs (19 studies) clearly described the methods of randomisation including random sequence generation and allocation concealment. Six studies did not explicitly explain the process or methods of randomisation including random sequence generation and allocation concealment (Dobrosielski et al., 2012; Gabbay et al., 2013; Hotu et al., 2010; Paula et al., 2015; Xia et al., 2014; Yu, 2014). Therefore, the selection of participants in the intervention or usual care group might have been associated with subjective bias. Most included studies did not report the blinding of participants, healthcare providers and outcome assessors. The nature of the health professionals' participation in hypertension management interventions made it difficult to maintain the blinding design among patients and their health care providers. Only seven of the 26 studies reported a blinding design for outcome assessments to minimise bias (Edelman et al., 2015; Edelman et al., 2010; Hotu et al., 2010; Ishani et al., 2011; McLean et al., 2008; Willard-Grace et al., 2015; Wong et al., 2005). How bias was controlled and minimised using a blinding design for outcome assessments in other studies was unknown. Only five studies reported participant dropouts and associated attrition bias. Most of the selected studies did not report attrition rate details. Intention-to-treat analysis was implemented in most of the studies reviewed. All predetermined outcome measures were analysed and reported.

The bias risk for each systematic review study was assessed. Overall, three of the four systematic reviews were judged as having an overall low risk; one of the four systematic reviews was judged to have an overall high risk of bias after an assessment of all domains using the ROBIS quality evaluation tool. The summary of the bias assessment is presented in Appendix 4.

2.4.3 Characteristics of reviewed RCT studies

Main characteristics of reviewed RCT articles are detailed in the literature review summary table (see Appendix 5). The 26 RCT studies were published between 2005 and 2018; the countries in which the studies were conducted differed. Most of the reviewed studies were conducted in high-income countries. Ten of the studies included were carried out in the US, two in the UK, three in Canada, three in China, two in Hong Kong, one in New Zealand, one in the Netherlands, one in Ireland, one in Germany and one in Brazil.

Interventions aimed at hypertension management for people with diabetes were conducted by different types of health professionals. The most common interventions were led by multidisciplinary team (13 studies) (Allen et al., 2011; Bellary et al., 2008; Crowley et al., 2013; Edelman et al., 2010; Gabbay et al., 2013; Heisler et al., 2012; Hotu et al., 2010; Ishani et al., 2011; McLean et al., 2008; Mons et al., 2013; Paula et al., 2015; Simpson et al., 2011; Wakefield et al., 2011) or nurses (five studies) (Dobrosielski et al., 2012; Edelman et al., 2015; Houweling et al., 2011; MacMahon et al., 2009; Scain et al., 2009). Intervention duration varied across studies. The longest intervention was 24 months (Bellary et al., 2008; Gabbay et al., 2013) and the shortest was four weeks (Paula et al., 2015; Scain et al., 2009). The frequently reported intervention durations were 24 months (two studies), 14 months (two studies), 12 months (12 studies), six months (three studies) and four weeks (two studies).

In 12 of the 26 reviewed studies, the intervention was developed and implemented independently by a single provider. These providers were either nurses (ten studies) (Dobrosielski et al., 2012; Edelman et al., 2015; Houweling et al., 2011; MacMahon et al., 2009; Scain et al., 2009; Wong et al., 2014; Wong et al., 2005; Xia et al., 2014; Xiao et al., 2009; Yu, 2014), trained healthcare professional educators (one study) (Davies et al., 2008), physicians (one study) (Dasgupta et al., 2017) and medical assistants (one study) (Willard-Grace et al., 2015). The remaining 13 studies were implemented by a multidisciplinary team. Among these 13 studies, nurses worked collaboratively with a multidisciplinary team (Allen et al., 2011; Bellary et al., 2008; Crowley et al., 2013; Edelman et al., 2010; Gabbay et al., 2013; Heisler et al., 2012; Hotu et al., 2010; Ishani et al., 2011; McLean et al., 2008; Mons et al., 2013; Paula et al., 2015; Simpson et al., 2011; Wakefield et al., 2011). These multidisciplinary teams consisted of different combinations of the following professionals: nurses (nurse practitioner, practice nurse, diabetes specialist nurse, nurse case manager and nurse educator), primary care providers, pharmacists, dietitians, physicians and community health workers.

2.4.4 Essential components in the RCTs

Intervention components were grouped based on similarities. These components were classified into eight categories as presented in Sections 2.4.4.1–2.4.4.8. Most studies applied three or more intervention components. Four studies applied two intervention components (Dasgupta et al., 2017; Dobrosielski et al., 2012; Paula et al., 2015; Scain et al., 2009). Only one study applied medication review and adjustment as a single intervention (Houweling et al., 2011). None of these reviewed studies used implementation science strategies such as engagement with key stakeholders and consumers to design and implement the interventions. The overview of intervention components reported in the reviewed studies is presented in Table 2.3. The detailed intervention items are summarised in Appendix 6.

Studies	Intervention components								Effective in blood
	Lifestyle modifica tion	Close monitoring/ surveillance of conditions (i.e., regular follow-up visits)	Treatment adherence (medication and behaviour)	Medication review, adjustment and intensification	Health education on diseases	Timely referrals for further treatment (BP assessment/discussi on with primary physician)	Partnership with patients in goal setting and action plans	Motivation in self- care	pressure control
Allen et al. 2011	1	1	✓ ✓	1	1	1	✓	1	Effective
Ballary et al. 2008	1	1		1	1	1			Non- effective
Crowley et al. 2013	1		✓	1	1	1		1	Non- effective
Dasgupta et al. 2017	1						✓		Non- effective
Davies et al. 2008	1				1		✓		Non- effective
Dobrosielski et al. 2012	1	1							Non- effective
Edelman et al. 2015	1	1	✓ ✓						Non- effective
Edelman et al. 2010	1	1		1	1		✓		Effective
Gabbay et al. 2013	1	1	✓	1		1		1	Non- effective
Heisler et al. 2012		1	✓				✓	1	Non- effective
Hotu et al. 2010	1		✓	1	1				Effective
Houweling et al. 2011				1					Non- effective
Ishani et al. 2011	1	1		1			✓		Effective
MacMahon et al. 2009	1	1		1			✓		Effective
McLean et al. 2008	1	<i>✓</i>		1	1				Effective
Mons et al. 2013	1	1	✓			✓		1	Effective

Table 2.3 Overview of intervention components reported in the reviewed studies

Studies	Intervention components								Effective in blood
	Lifestyle modifica tion	Close monitoring/ surveillance of conditions (i.e., regular follow-up visits)	Treatment adherence (medication and behaviour)	Medication review, adjustment and intensification	Health education on diseases	Timely referrals for further treatment (BP assessment/discussi on with primary physician)	Partnership with patients in goal setting and action plans	Motivation in self- care	control
Paula et al. 2015	~		✓						Effective
Scain et al. 2009	\checkmark				1				Non- effective
Simpson et al. 2011		1	1	\checkmark		1			Effective
Wakefield et al. 2011	1	1	✓		1	1			Effective
Willard-Grace et al. 2015	1	✓ ✓	<i>√</i>		1	✓ ✓	1	1	Effective
Wong et al.2005	<i>✓</i>	1		1		1			Not measured
Wong et al. 2014		1		✓ ✓			✓		Not measured
Xia et al. 2014	✓ ✓	1	✓		1				Effective
Xiao et al. 2009	1	1	1	✓	1				Effective
Yu et al. 2014	✓		✓		1				Effective
Percentage	22/26 (84.6%)	18/26 (69.2%)	14/26 (53.8%)	14/26 (53.8%)	13/26 (50%)	9/26 (34.6%)	9/26 (34.6%)	6/26 (23.0%)	
Variables targeted	Patient factor	Healthcare system factor	Patient factor	Organisational/ health professional factors	Organisation al/health professional factors	Healthcare system factors	Organisational/ Health professional factors	Organisati onal/Healt h profession al factors	

2.4.4.1 Lifestyle modifications

The effectiveness of lifestyle modifications for hypertension control was reported in a meta-analysis conducted to evaluate the impact of multifaceted lifestyle change on caloric intake and physical activity among diabetic patients with cardiovascular comorbidities (Chen et al., 2015). A total of 22 studies were included in the meta-analysis. The meta-analyses identified that interventions contributed to statistically significant control in both SBP and DBP in the intervention group (SBP: – 0.16, P = 0.016, DBP: –0.27, P < 0.001). Findings provided strong evidence that lifestyle modifications were significantly associated with better control of cardiovascular disease-associated risk factors such as SBP and DBP among diabetic patients (Chen et al., 2015).

The other meta-analysis of RCTs that assessed the impact of supervised exercise on blood pressure control among patients with diabetes revealed similar outcomes-supervised exercises by nurses was effective in improving blood pressure control among patients with diabetes (Dobrosielski et al., 2012). More importantly, this study indicated that supervised exercise could provide greater reductions in SBP for older patients than in younger patients. Additionally, longer durations of physical activity were more effective in reducing blood pressure than shorter period of exercises. It was found that regular physical exercise spanning 40 weeks could reduce SBP by 4.42 mmHg compared with shorter durations of physical exercise (Hayashino et al., 2012). Developing individualised action plans for behavioural change and establishing behavioural change goals were keys to improving hypertension control for people with diabetes. Among the literature involving effective lifestyle behavioural change, most studies developed personalised action plans for lifestyle management according to patients' unique needs. Patients' personalised action plans were developed in collaboration with a nurse case manager (Dobrosielski et al., 2012), diabetes specialist nurses (MacMahon et al., 2009), a pharmacist and primary care internist (Edelman et al., 2010), a nurse and pharmacist (Heisler et al., 2012) and a nurse practitioner and community health worker (Allen et al., 2011).

Lifestyle modifications were the most frequently reported interventions in the RCTs reviewed (22 studies of 26 applied lifestyle modifications, see Table 2.3). Lifestyle interventions in these studies aimed to remove modifiable risk factors or unhealthy lifestyles and establish and sustain healthy lifestyles using self-management of behaviour changes outlined in diabetes education sources (Dizaji et al., 2014; Mou, 2010). In these 22 studies, effective lifestyle interventions mainly focused on increased physical activity, reduced caloric intake, low-sodium diets, smoking cessation, reduced alcohol intake and weight reduction. Twelve of the 22 studies included a component of health behavioural change for participants in the intervention group. The results revealed a significant improvement of blood pressure control compared to the usual care group (Allen et al., 2011; Edelman et al., 2010; Hotu et al., 2010; Ishani et al., 2011; MacMahon et al., 2009; McLean et al., 2008; Mons et al., 2013; Paula et al., 2015; Simpson et al., 2011; Wakefield et al., 2011; Xia et al.,

2014; Xiao et al., 2009; Yu, 2014).

The impact of physical exercise on lowering blood pressure in people with diabetes was reported in an RCT conducted by Balducci et al. (2010). The intervention was a combination of twice weekly supervised aerobic and resistance training plus structured exercise counselling. It was found that supervised exercise significantly reduced both SBP (-4.2 mmHg, P = 0.002) and DBP (-1.7 mmHg, P = 0.03) in the intervention group compared to the usual care group. For older diabetic patients with poorly controlled hypertension, vigorous intensity training that might lead to injury needed to be avoided. Moreover, it was reported that participating in high-intensity resistance training could increase blood pressure and posed a potential risk of increased vascular hardness (Hordern et al., 2012; Miyachi et al., 2004). Therefore, these training exercises should be avoided. It was suggested that regular moderate-intensity physical activity was sufficient to improve blood pressure control (Dobrosielski et al., 2012).

2.4.4.2 Close monitoring and surveillance of conditions

Close monitoring and surveillance of conditions were described in one systematic review (Wu et al., 2010). In this study, telephone follow-up was applied to monitor self-care for patients with multimorbidity of hypertension and diabetes (Wu et al., 2010). The subgroup analysis of this systematic review demonstrated that the follow-up support was more effective if it was interactive and frequent, based on patient needs. A follow-up visit was helped translate complex self-care advice into self-care behaviours through close symptoms monitoring, medication management, continuous blood pressure review and health lifestyle maintenance (Wu et al., 2010).

Close monitoring and surveillance of conditions was described in 18 of the 26 RCT studies reviewed (see Table 2.6). This strategy was viewed as imperative for patients admitted to hospitals for uncontrolled diabetes and was incorporated into discharge planning by Wong and colleagues (2005). In this study, nurse-led follow-up in community settings after hospital discharge significantly improved patients' adherence to self-monitor blood glucose and implement lifestyle changes, and reduced HbA1c compared to the usual care group (Wong et al., 2005). In an RCT study that included older people with diabetes, nurse-led post-discharge support incorporated home visits or regular telephone contact to monitor patients' health conditions (Wong et al., 2014). The study showed significant reduction of hospital readmission rates compared to the usual care group. In an RCT conducted by Xiao and colleagues (2009) in China, nurses in the intervention group provided telephone follow-up to monitor patients' adherence to medication and blood pressure control. They also advised patients on healthy diet, exercises and sleep health in daily life. The patients were also informed of the importance of seeking timely treatment from specialists if their blood pressure was uncontrolled. The findings indicated that patients in the intervention group achieved statistically

significant better control of blood pressure, blood glucose and blood lipid compared to the usual care groups.

Nurse-led telephone-based counselling was applied in discharge planning for patients to improve self-care and reduce hospital readmission in the study by Mons and colleagues (2013). The intervention in the study included a monthly 10-minute telephone-based counselling session conducted by practice nurses over a year. The intervention was found to be effective in controlling hypertension (SBP reduction of 5.27 mmHg, P = 0.007) compared to the usual care group (Mons et al., 2013). The telephone-based counselling included a series of questions focused on patients' medication adherence, health lifestyle maintenance, and physical and mental conditions. During the counselling session, nurses were able to motivate patients to maintain their health behaviours, identify barriers to complying with diabetes treatment and enable early detection of diabetes-associated complications. As maintaining normal levels of blood pressure for patients after discharge depends on self-management at home, nurse-led telephone-based counselling follow-up is necessary to sustain self-care and overcome barriers in self-management after discharge.

The systematic review and meta-analysis by Wu and colleagues (2010) revealed the effectiveness of telephone support in improving hypertension control and other associated health conditions for patients with the multimorbidity of diabetics and hypertension. This intervention strategy is suitable for application in the Chinese context considering that most Chinese families have access to the telemedicine. The increasing prevalence of diabetes in China and the geographic spread of the population also support the application of this intervention. A telephone follow-up could address transportation barriers and allow more patients to be reached (Carter et al., 2012). Moreover, telephone follow-up was able to provide medication adjustment for patients without clinic visits, as time was an issue for doctors in busy practice environments in China (Wu et al., 2010). Telephone intervention was also carried out by nurses in reviewed studies to motivate patients to engage in healthy lifestyles, medication adherence, self-monitoring of blood pressure and blood glucose, and to reinforce knowledge in managing diabetics and hypertension (Wong et al., 2005). The most mentioned frequency of telephone contact with patients was once every one to two weeks (Fatma et al., 2010; Wong et al., 2005).

In a nurse-led RCT, intervention nurses conducted telephone intervention every two months for two years to support participants to change behaviour and maintain healthy lifestyles (Edelman et al., 2015). However, the study did not lead to any improvements in blood pressure control for people with diabetes (Edelman et al., 2015). The two-month interval might not be regular enough to enable patients to change behaviours. In contrast, an RCT that delivered telephone contact with patients once a month and emphasised dietary adherence as an adjunct to pharmacotherapy achieved significant blood pressure improvements (SBP difference: 6.2 mmHg; DBP differences: 3.1 Hg)

(Himmelfarb et al., 2016). It was found that shorter intervals between patients and health professional encounters were associated with a faster reduction in blood pressure and earlier blood pressure normalisation in people with diabetes (Punnoose, 2011; Turchin et al., 2010). Therefore, the frequency of intervention needs to be considered when planning behavioural change for patients.

2.4.4.3 Treatment adherence

Treatment adherence was described in 14 of the 26 studies reviewed (see Table 2.3). Treatment adherence includes adherence to pharmacological and non-pharmacological treatment. Ten of the 14 studies identified that interventions to improve medication adherence were effective in reducing blood pressure among diabetic patients (Allen et al., 2011; Hotu et al., 2010; Mons et al., 2013; Paula et al., 2015; Simpson et al., 2011; Wakefield et al., 2011; Willard-Grace et al., 2015; Xia et al., 2014; Xiao et al., 2009; Yu, 2014). In a prospective, multisite cluster randomised pragmatic trial entitled 'Adherence and intensification of medications', pharmacists were employed to assess patients' adherence to each prescribed medication, identify barriers to adherence medication and assist patients to overcome these barriers. The barriers that contributed to the lack of medication adherence included side effects and forgetfulness. Progress on prior action plans was also assessed in each encounter with pharmacists. However, the findings showed that both the intervention and usual care group had the same level of SBP reduction, and there was no significance difference in blood pressure between groups (Heisler et al., 2012). In the intervention arm, only 53 per cent of subjects had a pharmacist encounter. The limited interaction between patients and the pharmacist might have contributed to the result.

2.4.4.4 Medication review, adjustment and intensification

Medication review, adjustment and intensification was described in 14 of the 26 reviewed studies (see Table 2.3) (Allen et al., 2011; Bellary et al., 2008; Crowley et al., 2013; Edelman et al., 2010; Gabbay et al., 2013; Hotu et al., 2010; Houweling et al., 2011; Ishani et al., 2011; MacMahon et al., 2009; McLean et al., 2008; Simpson et al., 2011; Wong et al., 2014; Wong et al., 2005; Xiao et al., 2009). Nine RCT studies and one Systematic review found that nurse prescribing had a positive impact on controlling hypertension and improving quality of life among diabetic patients (Allen et al., 2011; Clark et al., 2011; Edelman et al., 2010; Hotu et al., 2010; Houweling et al., 2011; Ishani et al., 2011; Clark et al., 2009; McLean et al., 2008; Simpson et al., 2010; Houweling et al., 2011; Ishani et al., 2011; MacMahon et al., 2009; McLean et al., 2008; Simpson et al., 2011; Xiao et al., 2009). In an RCT conducted by (Houweling et al., 2011), practice nurses in GP clinics received training in accordance with a detailed treatment and management guideline aimed at optimising blood pressure profile regulation among patients with diabetes. The practice nurses were authorised to prescribe 14 different medications and adjust dosages for a further 30 medications. The results indicated that patients treated by a practice nurse achieved significant blood pressure reduction compared to patients in the usual care group. Similar findings were reported in another RCT that applied nurse-led case management (Ishani et al., 2011). Interventions led by nurses included the review of

antihypertensive medications and adjustments to the medications according to established protocols and a treatment algorithm. The interventions were associated with improved control of multiple cardiovascular risk factors for diabetic patients at one year post-intervention (Ishani et al., 2011). Further, the intervention targeted improved control of cardiovascular risk factors that might damage blood vessels in diabetes treatment.

2.4.4.5 Health education on diseases

Health education was described in 13 of the 26 studies reviewed (see Table 2.3) (Allen et al., 2011; Bellary et al., 2008; Crowley et al., 2013; Davies et al., 2008; Edelman et al., 2010; Hotu et al., 2010; McLean et al., 2008; Scain et al., 2009; Wakefield et al., 2011; Willard-Grace et al., 2015; Xia et al., 2014; Xiao et al., 2009; Yu, 2014). Among these studies, a tailored educational session delivered by a nurse educator in an RCT showed a significant reduction in blood pressure compared to in the usual care group (mean differences between groups: -7.3 mmHg, P = 0.011) (Edelman et al., 2010). Topics included in this education intervention were relevant to diabetes and hypertension selfmanagement. Participants in the intervention group were encouraged to select topics according to their learning needs. The positive outcomes reported in the studies were attributed to the tailored education.

Another effective approach to enhance health education was to provide patient-centred health education materials—for example, hypertension education brochure and informative films (McLean et al., 2008). In an RCT involving 227 diabetic patients from 14 community pharmacies in Canada, a nurse-pharmacist team provided the patients with a hypertension education brochure and cardiovascular risk reduction counselling (McLean et al., 2008). The goal of the education intervention was to help patients understand symptoms of diabetes, causality between blood pressure and diabetes, and the health consequences of hypertension. Patients in the intervention group had a greater reduction of SBP at six months (5.6 mmHg) compared with those in the usual care groups. Health education was also incorporated to nurse-led discharge planning and post-discharge support for patients admitted to hospitals due to uncontrolled diabetes (Wong et al., 2005). In the nurse-led post-discharge support to reduce readmission, health education was incorporated in home visits and telephone support (Wong et al., 2014).

2.4.4.6 Timely referrals for further treatment

Timely referrals for further treatment were described in nine of the 26 studies reviewed (see Table 2.3) (Allen et al., 2011; Bellary et al., 2008; Crowley et al., 2013; Gabbay et al., 2013; Mons et al., 2013; Simpson et al., 2011; Wakefield et al., 2011; Willard-Grace et al., 2015; Wong et al., 2014). Hypertension and diabetes are complex chronic conditions that are associated with multiple complications, such as hypertension crises that need acute treatment and medication adjustment/intensification. Timely referrals for further treatments is an effective way to manage the

delay in treatment. In the eight reviewed studies that included referrals, a referral from GPs to specialists for blood pressure assessment and medication adjustment was applied as an intervention strategy. The successful implementation of timely referral was based on well-established communication between healthcare providers and the definition of clear roles and responsibilities among these health professionals. Referrals to certified diabetes nurse educators or dietitians were made when appropriate (Gabbay et al., 2013). Multidisciplinary collaboration to achieve timely referrals for further treatment was reported in most reviewed studies.

2.4.4.7 Partnership in goal setting and action plan

Nine of the 26 studies reviewed applied partnership-based goal setting and action plan development between patients and health professionals as intervention strategies to achieve hypertension control (see Table 2.3) (Allen et al., 2011; Dasgupta et al., 2017; Davies et al., 2008; Edelman et al., 2010; Heisler et al., 2012; Ishani et al., 2011; MacMahon et al., 2009; Willard-Grace et al., 2015; Wong et al., 2014). Dasgupta et al. (2017) evaluated a pedometer-based intervention that involved goal setting and the development of an action plan in physical activity. Patients developed a goal of walking steps in partnership with their physicians and were required to record the number of steps they had walked. Their action plan was regularly reviewed by their physician. However, this study did not demonstrate effective blood pressure control. This might due to the study design, which included only a single component on exercise. In the study by Edelman et al. (2010), patients' medical records including blood pressure and glucose readings were reviewed by a pharmacist and primary care internist during each session with patients. Each session lasted 90-120 minutes. Plans for medication use and lifestyle changes were individually developed through a partnership between patients and the pharmacist and primary care internist. This comprehensive review and action plan led to a significant reduction in SBP (7.3 mmHg) compared with patients in the usual care group (P = 0.011).

2.4.4.8 Motivation in self-care

Motivating patients in self-care was described in six of the 26 studies reviewed (see Table 2.3) (Allen et al., 2011; Crowley et al., 2013; Gabbay et al., 2013; Heisler et al., 2012; Mons et al., 2013; Willard-Grace et al., 2015). Among these six studies, health providers were provided training in motivational interviewing prior to the implementation of interventions. Health providers who delivered the intervention included nurses, pharmacists and medical assistants. Motivational interviewing was used as a patient-centred method to empower patients to build their intrinsic motivation and confidence in improving self-care behaviours. In Crowley et al. (2013) study, patients who received motivational interviewing were 4.4 times more likely to improve medication adherence than patients in the usual care group (P = 0.0008). Similarly, Mons et al. (2013) implemented a monthly telephone-based counselling session delivered by practice nurses over 12 months to encourage patients to self-manage their conditions. The study demonstrated that patients in the intervention group had a

significant reduction in SBP (7.6 mmHg) at 12 months compared with patients in the usual care group (P = 0.007).

2.4.5 Strategies used to implement the interventions

The analysis of intervention designs in reviewed RCTs revealed that team collaboration was applied as a strategy to implement the interventions. Intervention designs in reviewed RCTs also targeted collaboration across healthcare facilities. The detailed intervention implementation strategies and collaboration among health professionals and healthcare facilities are summarised in Appendix 6 and described in Section 2.4.5.1.

2.4.5.1 Team approach to implementing interventions

Of the 26 RCTs reviewed, 13 applied a team approach to deliver interventions (Allen et al., 2011; Bellary et al., 2008; Crowley et al., 2013; Edelman et al., 2010; Gabbay et al., 2013; Heisler et al., 2012; Hotu et al., 2010; Ishani et al., 2011; McLean et al., 2008; Mons et al., 2013; Paula et al., 2015; Simpson et al., 2011; Wakefield et al., 2011). Team members usually comprised physicians, nurses and pharmacists. Edelman and colleagues (2010) explored the effectiveness of group medical clinics (GMCs) in managing comorbidities of diabetes and hypertension. The team collaboration across disciplines complemented hypertension management and enabled individualised interventions in medication and lifestyle changes. The findings showed that mean SBP was 7.3 lower in the GMC group than it was in patients in the usual care group. The collaboration among diabetes nurse specialists and physicians to adjust medication was also reported by Wong and colleagues (2014).

Diabetes care involving the revision of professional roles demonstrated beneficial effects on blood pressure control (Houweling et al., 2011). Thirteen reviewed studies demonstrated that nurses play a leading role in effectively controlling hypertension among diabetic patients (Allen et al., 2011; Bellary et al., 2008; Crowley et al., 2013; Edelman et al., 2015; Edelman et al., 2010; Gabbay et al., 2013; Hotu et al., 2010; Houweling et al., 2011; Ishani et al., 2011; MacMahon et al., 2009; Mons et al., 2013; Scain et al., 2009; Wong et al., 2005). Moreover, a recent meta-analysis showed that nurse-led care was effective in managing hypertension among diabetic patients in interventions that targeted patient education, blood pressure measurement and self-management enhancement (Clark et al., 2010). A systematic review and meta-analysis analysed 11 studies of various nurse-led interventions, including the adoption of treatment algorithms, nurse-led clinics, nurse prescribing and nurse-led community monitoring (Clark et al., 2010). In comparison with usual doctor-led care, nurse-led interventions achieved greater reductions in blood pressure among diabetic patients (SBP weighted mean differences –5.8 mmHg; DBP weighted mean difference –4.2 mmHg) (Clark et al., 2010). In addition, nurse prescribing as a recent innovative intervention was identified as the only effective intervention to achieve SBP control (Clark et al., 2011). The positive outcome was attributed

to the application of an algorithm to increase adherence to protocols and guidelines (Clark et al., 2010).

Eleven reviewed studies revealed that nurses at an advanced practice level—diabetes nurse specialists, practice nurses, nurse case managers and nurse-practitioners—in high-income countries demonstrated adequate knowledge and skills to delivery effective medication treatment and proactively affect the care outcomes of diabetic patients with hypertension (Allen et al., 2011; Bellary et al., 2008; Crowley et al., 2013; Davies et al., 2008; Dobrosielski et al., 2012; Edelman et al., 2015; Gabbay et al., 2013; Houweling et al., 2011; Ishani et al., 2011; Mons et al., 2013; Wong et al., 2005). They played a leading role in the multidisciplinary team in managing hypertension for people with diabetes. However, nurse-practitioners and their roles in the multidisciplinary team were not reported in the reviewed studies from low- and middle-income countries.

Pharmacists played a crucial role in multidisciplinary teams. A systematic review and meta-analysis found that pharmacist interventions achieved significant reductions for SBP (-6.2 mmHg) and DBP (-4.5 mmHg) among people with diabetes when compared with usual care group (Santschi et al., 2012). The major intervention activities that pharmacists provided were medication management (adjustment of dosages, changes in medication and assessment of medication adherence), health education (information and counselling about medications, lifestyle and compliance), feedback to physicians (recommendations and discussions with doctors about medication changes or barriers of compliance, and the development of treatment plans), measurement of cardiovascular disease risk factors and patient-reminder systems. The other RCT, conducted in primary clinics in Canada, evaluated the effect of pharmacists in primary care teams on controlling blood pressure and reducing cardiovascular risk factors in patients with diabetes (Simpson et al., 2011). In the intervention group, pharmacists implemented medication assessment, physical examinations and guideline-concordant recommendations to improve medication management. It was found that 50 per cent of patients in the intervention group achieved a 10 per cent or more reduction in SBP compared to patients in the usual care group, of which only 28 per cent achieved a similar reduction (Simpson et al., 2011). The two groups showed a statistically significant difference.

Primary care physicians played an important role in providing care, as most patients with hypertension and diabetes were managed in primary care settings in high-income countries (Dasgupta et al., 2017; Davies et al., 2008; Edelman et al., 2010; Gabbay et al., 2013; Hotu et al., 2010; Mons et al., 2013; Scain et al., 2009). The most frequently reported physician-led interventions included:

- assessing blood pressure and cardiovascular risk factors (Dasgupta et al., 2017)
- developing plans for medication treatment and establishing goal attainment according to their

medical records and laboratory test results (Edelman et al., 2010; Gabbay et al., 2013; Mons et al., 2013)

• monitoring side effects of prescribed medication (Hotu et al., 2010).

Evidence from three studies showed that physicians working collaboratively with nurses or pharmacists produced improvements in clinical outcomes (Edelman et al., 2010; Hotu et al., 2010; Mons et al., 2013).

2.4.5.2 Collaboration across healthcare facilities

Most reviewed RCTs from high-income countries incorporated collaboration between primary care and tertiary care facilities to share healthcare resources and specialist knowledge in hypertension management for diabetes patients. Collaboration included referrals from GPs to specialists in tertiary care settings when there was a need to for diagnostic test or intensification therapy (Ishani et al., 2011; MacMahon et al., 2009; Wong et al., 2014; Wong et al., 2005). Patient referrals were also extended to diabetic nurse educators, dietitians or pharmacists when there was a need for specialised care (Davies et al., 2008; Edelman et al., 2010; Gabbay et al., 2013; McLean et al., 2008; Paula et al., 2015; Simpson et al., 2011; Wakefield et al., 2011). Three reviewed RCTs conducted in primary care settings in China did not mentioned collaboration across health facilities (Xia et al.; Xiao et al.; Yu, 2014). The underdeveloped primary care and the lack of collaboration between primary care and tertiary care facilities might have contributed to the absence of the collaboration in the studies. Reviewed RCTs revealed collaboration between acute care hospitals and primary care providers. For example, two studies reported nurse case managers in community care settings who implemented discharge plans to strengthen post-discharge support (Wong et al., 2014; Wong et al., 2005). The collaboration contributed to a significant reduction in hospital readmission rates (Wong et al., 2014), shorter hospital stays and improved self-monitoring of blood glucose, reduction of HbA1c and lifestyle changes (Wong et al., 2005).

2.5 Discussions and implications

Most reviewed RCTs were designed to target multiple factors associated with self-management of hypertension for people with diabetics. Interventions were usually provided by a team comprising more than one discipline. Most importantly, a primary care approach to hypertension management was utilised in all intervention designs. To ensure this, collaboration efforts were made between healthcare facilities at different levels and care services were coordinated across these facilities. The implications of findings for a planned intervention study are discussed in the following sections.

2.5.1 Multicomponent interventions

The literature review revealed that most interventions included multicomponents. These components

were (1) lifestyle modification, (2) close monitoring and surveillance of conditions, (3) treatment adherence, (4) medication review, adjustment and intensification, (5) health education on diseases, (6) timely referrals for further treatment, (7) partnership in goal setting and action plans and (8) motivation in self-care. The findings were supported by a recent systematic review by Gorina et al. (2018) on primary health care for people with the multimorbidity of hypertension and diabetes. The study demonstrated that effective interventions in hypertension control for people with diabetes should target multiple rather than single components to address the multiple risks associated with hypertension (Gorina et al., 2018). The findings were also consistent with a scoping review that demonstrated that interventions with multiple components improved patient self-management outcomes (Yiu et al., 2018). However, multicomponent interventions aimed at hypertension management for diabetes patients were rarely reported in studies from low- and middle-income countries such as China. Therefore, it is necessary to address as many modifiable risk factors associated with hypertension control as possible in future studies in low- and middle-income countries.

The summary of intervention items and health professionals who delivered them (from the reviewed studies in Appendix 6) provided researchers with information to further analyse the application of these interventions in their study designs. Due to differences between the healthcare systems of developed and low- and middle-income countries, the applicability of these intervention items must be reviewed and approved by health professionals in a study context when designing an intervention study. For this reason, a Delphi study with health professionals in the Chinese context was conducted to gain consensus regarding intervention items. Their agreement on the intervention items informed an intervention protocol in the present study. The Delphi study is outlined in Chapter 3 and the intervention protocol is presented in Chapter 4.

2.5.2 Multidisciplinary team-based interventions

In high-income countries, patients with the multimorbidity of hypertension and diabetes were treated in primary care settings (Reynolds et al., 2018; Seitz et al., 2011). However, the lack of timely treatment and medication intensification and limited patient consultation times were reported as barriers to achieving treatment goals (Reach et al., 2017; Rushforth et al., 2016). It was strongly suggested that a single health provider could not address the complex care needs of patients— medical, educational and psychosocial aspects—therefore, multidisciplinary collaboration in intervention studies was required (World Health Organisation, 2016).

In studies involving a multidisciplinary team, the results showed a significant improvement in hypertension control (Allen et al., 2011; Edelman et al., 2010; Hotu et al., 2010; Ishani et al., 2011; McLean et al., 2008; Mons et al., 2013; Paula et al., 2015; Simpson et al., 2011; Wakefield et al.,

2011). The multidisciplinary team-based care generally included the patients' physicians, nurses, dietitians, pharmacists, community health workers, medical assistants and social workers. This team approach enabled greater synergy within the team and a valuable complement of specialities (Carter et al., 2009). Collaboration often involved a team working in patient education, assessing risk factors and care needs, motivating patients in self-monitoring their conditions and self-care, and prescribing and modifying treatments on a timely manner. A systematic review of 52 studies found the multidisciplinary team approach was effective in reducing SBP and DBP and achieving greater blood pressure control goals when compared with the usual care group, especially in cases in which nurses and pharmacists were in the team (Proia et al., 2014). Development of hypertension management programs should consider changes in healthcare organisational structure to support a multidisciplinary team approach to care services.

As important members of the healthcare workforce, nurses' contribution was recognised as essential to deliver effective care for people with the multimorbidity of hypertension and diabetes (Jiang et al., 2015). However, nurses who were prepared with advanced practice roles were scarce in most lowand middle-income countries, including China (Fang, 2007). The literature revealed that registered nurses in China were not authorised to prescribe or adjust medications for patients. Their roles mainly focused on implementing physicians' orders of medication treatment, providing patients with health education and administering medication (Jiang et al., 2015; Xu et al., 2018). Therefore, the effective interventions led by nurse-practitioners, nurse case managers, diabetes nurse specialists and nurse educators in high-income countries or regions might not be applicable to the Chinese healthcare context (Allen et al., 2011; Bellary et al., 2008; Dobrosielski et al., 2012; Gabbay et al., 2013; Ishani et al., 2011; MacMahon et al., 2009; Scain et al., 2009; Wong et al., 2014; Wong et al., 2005). Other options, for example, nurse-coordinated interventions supported by a multidisciplinary team, may be considered in the Chinese context. In the reviewed studies in China, pharmacists were rarely represented in the multidisciplinary team. This group of health professionals was not authorised to prescribe medications or modify dosages (Xu et al., 2018). Their roles in hospitals were mainly to dispense and deliver medications in accordance with doctor prescriptions and to explain medication instruction booklets to patients.

The significant differences between health professionals' roles and responsibilities in the healthcare systems of developed and low- and middle-income countries require researchers to reconsider task sharing in an intervention study delivered by a multidisciplinary team in low- and middle-income countries, including China. Approaching health professionals in a study context to gain their opinions on task sharing is imperative to a study protocol development.

2.5.3 Health professionals who delivered the intervention components

Health professionals who delivered intervention components in the reviewed articles were identified and summarised in Table 2.4. Overall, nurses played an essential role in delivering the eight intervention components. Studies demonstrated that nurses' roles in patient education significantly improved patients' health lifestyle behaviours and treatment adherence (Hacihasanoğlu & Gözüm, 2011). These components were regarded as key factors for long-term control of hypertension in community settings. The successful implementation of these intervention components by nurses was associated with their education preparation at the advanced practice level in high-income countries and regions (Himmelfarb et al., 2016; Wong et al., 2014; Wong et al., 2005). Considering that 64.5 per cent of nurses in China undertook only the diploma-level of nursing education (or the Associate Degree in Nursing in the US) (Wong et al., 2010), the way they share roles and responsibilities with other health professionals in the multidisciplinary team remains unknown.

In the reviewed studies, medication review, adjustment and intensification were mainly undertaken by the GP or pharmacist. Diabetes nurse specialists, nurse-practitioners and nurse case managers were also assigned to assist medication adjustment in collaboration with physicians (Allen et al., 2011; Bellary et al., 2008; Crowley et al., 2013; Houweling et al., 2011; MacMahon et al., 2009; McLean et al., 2008; Wong et al., 2005). However, nurses' role in medication adjustment was not reported in the reviewed studies in China. The roles for nurses and doctors in medication management were ambiguous and the shared responsibilities for nurses and doctors to implement these interventions were not clearly presented in reviewed studies in low- and middle-income countries. Currently, there are no guidelines in the Chinese primary care system that identify the clear roles of health professionals in implementing this intervention component. There is a gap in research to identify how to share roles and responsibilities in interventions in the Chinese context. Conducting a study to gain health professionals' consensus on their roles and responsibilities in a planned intervention study in the study context is necessary when developing a study protocol.

Table 2.4 Health	professionals who	delivered the eig	ht intervention com	ponents in the review	ed articles
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	Lifestyle modification	Close monitoring/ surveillance of conditions	Treatment adherence	Medication review, adjustment and intensification	Health education on diseases	Timely referrals for further treatment	Partnership in goal setting and action plan	Motivation in self-care
Nurse	16	13	9	5	8	5	5	3
Nurses in the multidisciplinary team	3	3	1	2	3	2		1
Pharmacists		1	1			1	1	1
Pharmacists plus primary care physicians			1	2			1	
GP or primary care physicians				5		1		
Other health professionals: dietitians, medical assistants, registered healthcare professionals	3	1	2		2		2	1
Total studies	22/26	18/26	14/26	14/26	13/26	9/26	926	6/26

2.5.4 Collaboration between primary care and hospitals

Most reviewed studies in the high-income countries or regions were conducted at primary care settings and provided patients with well-developed primary care services. These studies emphasised the horizontal programs that integrated care services provided by health professionals from various disciplines in the primary care system (Allen et al., 2011; Bellary et al., 2008; Crowley et al., 2013; Edelman et al., 2010; Gabbay et al., 2013; Heisler et al., 2012; Hotu et al., 2010; Ishani et al., 2011; McLean et al., 2008; Mons et al., 2013; Paula et al., 2015; Simpson et al., 2011; Wakefield et al., 2011). However, the primary care system in China remains underdeveloped. Care services described in intervention studies—such as community nurse-led telephone follow-up, home visits to strengthen self-care and medication adjustment for patients discharged from hospital-might not be feasible in the Chinese context. Therefore, a vertical program that integrates care services provided by different levels of health facilities (e.g., primary health care and tertiary hospitals) must be considered to address the lack of care services in primary care settings. A systematic review demonstrated that interventions designed to strengthen primary care services through collaboration with different levels of health facilities resulted in improved patient outcomes (Reynolds et al., 2018). Again, ways to share roles and responsibilities among health professionals involved in the vertical programs must be explored and incorporated in the study protocol in the planned RCT.

2.6 Identifying theoretical framework to inform study design

2.6.1 Outline of theoretical frameworks applied to the studies reviewed

In the 26 reviewed RCTs, only six clearly applied theoretical frameworks to the interventions. These frameworks (outlined in Table 2.5) mainly targeted individual and health provider factors (healthcare organisations and health professionals) in hypertension management. Of these six studies, only three were effective in hypertension control for people with diabetes (Allen et al., 2011; Hotu et al., 2010; Ishani et al., 2011). Theoretic frameworks applied to these three studies were (1) community-based model of care, (2) community-based participatory research and (3) the case management model. Based on World Health Organisation's (2016) definition of integrated care, these frameworks were viewed as similar to integrated care models, aimed at strengthening primary care services, patient engagement in self-care/prevention and collaborations across organisational (integration of different healthcare organisations), functional (integration of electronic patient record), service (integration of health professionals from multiple disciplines) and clinical (integration of shared guidelines and protocols) (World Health Organisation, 2016). These three frameworks mainly targeted service integration and emphasised collaboration between health professionals in primary care settings, relying on a well-developed primary care system in high-income countries. Considering

the deficiencies of services in primary care and the lack of communication and collaboration between healthcare organisations in the Chinese context, a conceptual framework that targets organisational integration at a health system level and addresses collaboration between health professionals should be applied in the planned RCT. Therefore, these three frameworks were not used in the design of the planned RCT. The other three studies—which only targeted individuals and did not produce positive outcomes—were also not considered in the planned RCT study.

Theoretical frameworks	Targeted factors	Studies	Effective or non- effective on blood pressure control
Community- based participatory research	Health providers and individual factors	Allen et al., 2011, US	Effective
Integrated, community-based model of care	Health providers and individual factors	Hotu et al., 2010, US	Effective
Case management model	Health provider factors	Ishani et al., 2011, US	Effective
Psychological theories of learning: Leventhal's common-sense theory, the dual process theory, and the social learning theory	Individual factors	Davies et al. 2008, UK	Non-effective
Health decision model	Individual factors	Edelman et al. 2015, US	Non-effective
Self- determination theory and social cognitive theory	Individual factors	Heisler et al. 2012, US	Non-effective

Table 2.5 Outline of theoretical frameworks applied to the RCTs reviewed

2.6.2 Chronic care model as the theoretical framework for the planned RCT

Integrated care models have been widely reported in chronic disease management. A systematic review including 167 studies confirmed that integrated care models could improve accessibility of health services, quality of care and patient satisfaction (Baxter et al., 2018). In this planned RCT, the definition of integrated care was informed by the recent World Health Organisation report (2016) on integrated care models. Integrated care was described as patient-centred care services delivered by multidisciplinary teams through collaboration between primary care facilities and higher levels of health facilities (such as secondary and tertiary hospitals) to share expertise and resources to strengthen the primary care approach to managing hypertension for people with diabetes (World Health Organisation, 2016). Integrated care was recognised in many high-income countries as an approach to address care fragmentation, facilitate care coordination and realize continuum of care for patients with chronic diseases (World Health Organisation, 2017). In addition, integrated care has proven effective in improving quality of care and satisfaction among patients with the multimorbidity of hypertension and diabetes (Yiu et al., 2018; Zhang et al., 2017).

The World Health Organisation report (2016) identified a number of integrated care models: the case management model, patient-centred medical home, chronic care model and collaborative care model. Among these models, the chronic care model, developed by researchers from the MacColl Institute for Healthcare Innovation in the US, was viewed as relevant to the planned RCT, as it explicitly explained six domains of healthcare systems (system factors) that shape individual factors (informed and activated patients) and healthcare provider factors (prepared, proactive practice team) (Improving Chronic Illness Care, 2006). It is widely recognised that effective hypertension control for people with diabetes and other chronic conditions is determined by the joint influence of the healthcare system, healthcare providers and individuals living with the condition (Mueller et al., 2015; Schmittdiel et al., 2017). Many unsuccessful interventions in hypertension management failed because of the target factors selected (Improving Chronic Illness Care, 2006). Applying the chronic care model enabled the researchers to carefully analyse factors from the three areas when developing a study protocol for the planned RCT. The chronic care model is illustrated in Figure 2.1 (Improving Chronic Illness Care, 2006). The six domains described in this model and their application to the planned RCT study are outlined in Table 2.6.



Figure 2.2 Chronic care model

Domains*	Description*	Application in the planned RCT
Community	Use community resources for patient care	Enable older people to use community health centres for follow-up support via referrals at discharge from hospital
Health system	Create a comprehensive health system to provide sustainable care	Establish collaboration between hospitals and community health centres in the program
Delivery system design	Clear delivery of care by professionals	Gain consensus on how to deliver the program in a healthcare system across hospitals and community health centres in a Delphi study

Self- management support	Available resources to provide support in improving patient self-management	Provide older people with self-management support through goal setting, action planning, health education and problem-solving in hospital discharge and during the follow-up period in community health centres
Decision support	Embed evidence-based interventions into routine practice	Develop evidence-based hypertension management program and integrate the program into routine practice in patient discharge planning and follow-up support in the intervention group
Clinical information system	Data sharing between health systems to facilitate efficient care	Share medical treatment and follow-up support between hospitals and community health centres

*Source: World Health Organization (2016, p. 11).

The application of the chronic care model to the planned RCT aimed at improving the capacity of the healthcare system in hypertension management for older people living with diabetes who were admitted to acute care hospitals for hypertension control or hypertension associated complications. These patients were ready to be discharged from hospital to home and required follow-up support to maintain hypertension control. The model addressed six domains to achieve integrated care for this patient population using a primary care approach. It emphasised interventions designed to improve efficiency and effectiveness. This was achieved in the present study by developing followup support in community health centres for the implementation of discharge planning from hospitals. The model facilitated collaboration among different levels of healthcare facilities and professionals from various disciplines. Those collaborations were considered in the collaboration between hospitals and community health centres and the collaboration between medical specialists, GPs, and nurses in the hospitals and community health centres. This evidence-based decision support as a domain in the model was addressed in the present study by developing the evidence-based hypertension management program. The model valued patients' active engagement in self-care and prevention of complications. This domain was built into the program through goal setting, self-care action planning and regular diary entries to record self-care. The model also emphasised proactive actions by health professional teams in supporting patients in self-care, monitoring their conditions and providing them with timely treatment or interventions in community health centre follow-up support.

Currently, there is an unequal distribution of healthcare resources between hospital and community settings in China (Zhang et al., 2017). Healthcare delivery in China still relies on fragmented and

hospital-centred care services that focus on acute care (Wang et al., 2016). There is no primary care approach to integrated care for patients living with chronic diseases. Healthcare services across the three levels of organisations (tertiary, secondary and primary care) in China is particularly fragmented (Qian et al., 2017). Effective collaboration among multiple healthcare providers is lacking and there is virtually no document sharing or communication between health providers across the different levels (Zhang et al., 2017). Therefore, a new model of health care, based on strengthening primary care and integrated healthcare services, is in strong demand. The integrated care model has demonstrated promise in improving patient-cantered hypertension management in high-income countries by addressing the fragmentation of care and promoting continuum of care across different levels of the system. For example, Canada, the UK and New Zealand have launched policy initiatives to strengthen the integration of health care across different levels of healthcare facilities (Mitchell et al., 2015). There is a need for urgent transition from fragmented care to integrated care in the healthcare system in China, considering the increased ageing population and the burden of chronic diseases. In 2016, the 'Deeping health reform in China' report was published by the World Health Organisation, World Bank and Chinese government (World Bank, 2016). The report proposed an integrated care model to guide the establishment of integrated healthcare delivery in China (Wang et al., 2018).

Switching to integrated care would provide comprehensive care to patients with chronic diseases in the community and reduce hospital admission. Therefore, this model of care would reduce health costs. However, empirical studies using the integrated care model are lacking in China. Recently, a cluster RCT was conducted in China to test integrated care across the three levels of health care (Zhang et al., 2017). Vertical integration (continuous care coordination across health systems) and horizontal integration (collaboration among health professionals from multiple disciplines) were implemented in the study. It was found that the integrated care model effectively reduced blood pressure, improved quality of life and hypertension-related hospitalisation (Zhang et al., 2017). However, the referral pathway presented in the study was from lower-level (i.e., community health centres) to higher-level organisations (i.e., secondary and tertiary hospitals). The effectiveness of the integrated care model in this reversed referral system in terms of from hospitals to community health centres remains unknown in China.

The current hospital-centred care model in China is opposed to the sustainable, patient-centred healthcare strategy proposed by the World Health Organisation (World Health Organisation, 2016; Xu et al., 2016). In the limited patient-health professional consultation times in hospitals, it is impossible for patients to consult with health professionals regarding behavioural change, such as lifestyle modification and medication adherence. Achieving behavioural change to manage chronic diseases is a long-term process that requires changes in behavioural intentions, motivations, attitudes and problem-solving skills. The establishment of hypertension management programs in

community health centres would enable patients to change their behaviours in self-care, prevention complications and improve patients' capability in self-care. This study, by applying the chronic care model based on the notion of integrated care, will provide research evidence to inform policy, resource and practice development in hypertension management for older people with diabetes.

2.6.3 The Practice questions-Evidence-Translation (PET) model applied to the implementation of hypertension management program

Evidence-based practice (EBP) is defined as 'a problem-solving approach to clinical decision making within a health-care organization. It integrates the best available scientific evidence with the best available experiential (patient and practitioner) evidence' (Dang & Dearholt, 2017, p. 4). A variety of EBP models have been developed and adopted to support the translation of research evidence into clinical practice (Polit & Beck, 2017). Among those, the PET model. developed by nurses from Johns Hopkins Hospital and School of Nursing, is most relevant to the proposed hypertension management program (Dang & Dearholt, 2017). The model includes five components:

- (1) identifying best available research evidence
- (2) incorporating health professionals' clinical expertise in the EBP
- (3) incorporating patient values when implementing the EBP
- (4) considering facilitators and barriers in the clinical context when implementing EBP
- (5) achieving best patient outcomes through rigorous evaluation of the EBP (Dang & Dearholt, 2017).

These five components are illustrated in Figure 2.3.



Figure 2.3 Components of EBP

Source: Dang and Dearholt (2017)

These components were considered in the present study when developing the hypertension management program. The practice questions were identified based on the PhD candidate's previous experience as a medical student in hospitals and community health centres. In this experience, older people with the multimorbidity of hypertension and diabetes mainly received medical treatment in acute care hospitals with little to no follow-up support from primary care providers in the community. The practice questions were further confirmed in literature review (see Chapter 1 and Table 2.7). The research evidence identified to address the problems was synthesised from a literature review reported in Chapter 2. Health professionals' expertise and experiences in the study area were considered through a two-round Delphi study (discussed in Chapter 3). The individualised discharge plan-codeveloped by patients and health professionals prior to discharge and follow-up support in community health centres in the hypertension management programconsidered patients' individual care needs and preferences. Factors affecting the translation of the proposed program into practice in the clinical context were considered in the analyses of implementation strategies in the literature review (see Chapter 2) and the Delphi study. The cluster RCT design (discussed in Chapter 4) enabled researchers in the present study to evaluate the impact of the program on hypertension control and other health outcomes (presented in Chapters 5 and 6). The application of the three interrelated PET processes in the present study is outlined in Table 2.7.

The PET model*	Description*	Application to the present study
Practice questions	To identify a practice area that needs to be improved	 Hospital-centred care services in managing hypertension for older people with diabetes Lack of follow-up support in the community after discharge Lack of collaboration between hospitals and community health centres
Evidence	To identify the best available research evidence, synthesise research evidence and non-research evidence (such as patients' and health professionals' experiences)	 A comprehensive literature review of RCT and systematic review and meta-analyses to identify effective intervention components and implementation strategies to address the practice question A Delphi study with an expert panel in the study context to reach consensus on the evidence-based program
Translation process	To implement the research evidence in the workplace and evaluate the outcome	 Partnership with the Department of Scientific Research Management at the Health and Family Planning Commission of Jiangxi Province, China to implement and evaluate the program Information for health professionals involved in the trial through workshops and written materials—'Guide to the implementation of hypertension management program for health professionals' and 'Intervention record—Community nurse and GP version. Information for participants in the intervention group through the 'Self-care booklet for older people with hypertension and type two diabetes' and the 'Intervention diary—Patient version'. Embedding the agreed program (intervention group Evaluating the outcomes of the program using cluster RCT

Table 2.7 The application of the Practice questions-Evidence-Translation process (PET)model

*Source: (Dang & Dearholt, 2017)

2.6.4 Facilitators and barriers to the implementation and evaluation of the evidencebased hypertension management program

The successful implementation of the evidence-based hypertension management program was

reliant on three facilitators. First, support was obtained from the local health authority, the Department of Scientific Research Management at Health and Family Planning Commission of Jiangxi Province, which was responsible for sponsoring the research project to implement the Chinese government's policy reform on chronic disease management through the primary care approach. In 2015, the Chinese government initiated healthcare reform—'Outline for the Planning of the National Medical and Health Service System (2015–2020)' that emphasised building collaboration between hospitals and community health centres to improve the prevention and management of chronic disease in primary care settings, reduce hospital care burdens and national medical costs (Wang et al., 2015). The evidence-based hypertension management program aligned with the reform. Thus, the proposed program gained approval and implementation support from the Department of Scientific Research Management at Health and Family Planning Commission of Jiangxi Province.

Second, hospitals and community health centres were required by the government to proactively support healthcare reform. This was to be achieved through: (1) reducing patients' length of stay in hospitals and developing referral systems with community health services to enable follow-up support for people with chronic conditions in primary care; and (2) developing collaboration between health professionals in hospitals and community health centres to support the primary care approach to chronic disease management (World Bank, 2016). The hospitals and community health centres accepted the invitation to the trial, as they considered this program a great opportunity to demonstrate their support and commitment of the reforms.

Barriers to the implementation of the program might include lack of time, experiences and resources to implement the intervention in a busy clinical setting, which was widely reported in the literature (McKee et al., 2017). To address these barriers, education was provided to health professionals through a two-day workshop. In addition, standardised protocols and diaries were provided to the health professionals during workshops to promote a deeper understanding of the program. The PhD candidate acted as a resource for any questions from health professionals involved in the program. The interventions were embedded in the routine care services to ensure minimal interference to normal workflow, based on feedback from the Delphi study prior to the trial.

2.7 Conceptual framework for the hypertension management program

The hypertension management program was built on the chronic care model and the Practice questions-Evidence-Translation (PET) model (Dang & Dearholt, 2017; Improving Chronic Illness Care, 2006). Improvement of health outcomes requires an integrated care system that is able to provide sustainable and evidence-based care (World Health Organisation, 2016). The chronic care model emphasises the integration of care services across different levels of healthcare facilities and

collaboration among health professionals and teams (Grover & Joshi, 2014; Stellefson et al., 2013). Integrated care is viewed as a cornerstone to improve patient outcomes in chronic disease management (Damery et al., 2016; Flanagan et al., 2017; Sampalli et al., 2012). The hypertension management program emphasised integrated care, as described in the chronic care model, through a two-way referral system: referring patients to services provided by community health centres upon discharge from hospital and referring patients from community health centres to specialists at hospitals for further treatment and diagnosis. The program also emphasised collaboration among health professionals within and between health facilities. In addition, the hypertension management program incorporated intervention components that targeted health system factors, patient–healthcare provider factors and individual patient factors in improving health outcomes (see Table 2.3).

The hypertension management program aimed to improve patient health outcomes through the implementation of up-to-date evidence. Essential components in effective RCT studies and in the systematic review and meta-analyses in hypertension control for people with diabetes were carefully analysed in a global context. Strategies applied to implement the interventions were also analysed. Clinicians' expertise in the study area was valued and incorporated into the program through a two-round Delphi study. In addition, patients' values and engagement in the program were considered through goal setting in self-care and individualised support in the six-month follow-up intervention in the community. The conceptual framework that incorporates the chronic care model and the Practice questions-Evidence-Translation (PET) model in the hypertension management program is illustrated in Figure 2.4.

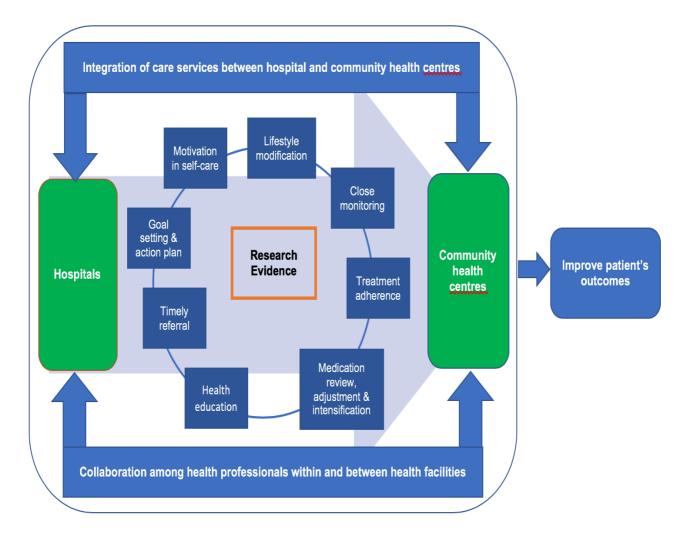


Figure 2.4 Conceptual framework of the hypertension management program

2.8 Summary

This chapter has identified eight essential components in effective RCTs and systematic review and meta-analyses studies reviewed:

- (1) lifestyle modification
- (2) close monitoring/surveillance of conditions
- (3) treatment adherence
- (4) medication review, adjustment and intensification
- (5) health education on diseases
- (6) timely referral for further treatment
- (7) partnership in goal setting and action plans
- (8) motivation in self-care.

Strategies to implement these components were also identified in the literature review. Most effective

intervention studies reviewed were undertaken in primary care settings and were implemented by a team that usually comprised physicians, nurses and pharmacists. Nurses played a leading role in the follow-up intervention after hospital discharge. As discussed in Chapter 1, applying those identified effective intervention items to a Chinese context might be challenging due to an underdeveloped primary care system. Therefore, a Delphi study is planned to gain health professionals' consensus on the applicability of the identified interventions and a team approach to deliver the intervention in a planned hypertension management program for older people with diabetes in Nanchang, China. Chapter 3 presents the methods and findings of a Delphi study.

Chapter 3

Methods and findings of Delphi study

Chapter 3 Methods and findings of Delphi study

3.1 Introduction

Chapter 2 identified essential components in effective RCTs and systematic review and metaanalyses studies reviewed. The detailed intervention items reported in the studies were carefully analysed and grouped in eight intervention categories. Health professional groups who delivered these intervention items were also analysed. Most intervention studies reviewed were undertaken in primary care settings. Studies in relation to follow-up after hospital discharge were conducted in collaboration between health professionals in hospital and primary care settings. Most effective intervention studies were implemented by a team that usually comprised physicians, nurses and pharmacists. Nurses played a leading role in the follow-up intervention after hospital discharge. As argued in Chapter 2, applying the identified effective intervention items to the Chinese context was challenging due to an underdeveloped primary care system. This chapter outlines the Delphi study conducted to gain health professionals' consensus on the applicability of the identified interventions and a team approach to deliver the intervention in a planned hypertension management program for older people with diabetes in Nanchang, China. This chapter is presented under these sections: (1) rational of the Delphi study, (2) Aim of the Delphi study, (3) Delphi study design and principles, (4) Delphi study questionnaire development, (5) Ethics consideration, (6) Methods of data collection and data analysis, (7) Findings and (8) Discussion.

3.2 Rationale of the Delphi study

Although research showed that interventions in primary care settings were effective in hypertension management for people with diabetes, the evidence was mainly from high-income countries with different healthcare systems and practice environments to China. A preliminary literature review on the healthcare system in China revealed a lack of health resources and mechanism to support the primary care approach to hypertension management. The differences in health contexts between China and high-income countries suggested that embedding an evidence-based intervention in a practice context needed to be carefully assessed by health professionals for its applicability. A Delphi study that engaged them in assessing and reaching consensus on the planned interventions was imperative. It was suggested that engaging health professionals in the design or revision of an evidence-based intervention program might also improve adherence and fidelity of the intervention in the study setting (Davidson et al., 2015). Consultation with intervention research (Ayala & Elder, 2011). Consultations with health professionals enabled them to participate in a process that shaped the intervention programs and made the intervention programs culturally appropriate for the

local health context (Nguyen et al., 2006).

An intervention delivered by a multidisciplinary team through collaboration of health professionals across care settings was viewed as a strategy to improve care outcomes for older people with hypertension, diabetes and other ageing-associated health conditions (Fortuna et al., 2015). This kind of intervention required a thoughtful design that included coordination, communication and task sharing among different groups of health professionals in a healthcare system. Barriers to implementing this kind of intervention included lack of consensus on the roles of health professionals and how to share tasks when working in a team across multiple settings. It was reported that health professionals seldom demonstrated proactive initiatives to communicate with each other for patients' conditions due to a lack of effective communication mechanisms in a busy clinical setting (O'Daniel & Rosenstein, 2008). Therefore, the Delphi study was necessary to investigate health professionals' opinions and consensus on collaboration between hospitals and community health centres and between health professionals from different disciplines in the planned hypertension management program. The Delphi study also provided participants with opportunities to suggest ways to coordinate the intervention across care settings and task sharing in a team (i.e., who would deliver the intervention in the planned intervention program).

A number of reviewed RCTs consulted with clinicians working in the local context prior to the intervention to gain from their expertise on hypertension management (Allen et al., 2011; Crowley et al., 2013; Liu et al., 2012). An RCT study involving 359 African Americans with diabetes examined the effectiveness of nurse telephone intervention (Crowley et al., 2013). The intervention program incorporated self-management education via monthly telephone calls and quarterly medication management facilitation. Before patients received the interventions, intervention materials were delivered to clinic directors to review and ensure the program was suitable for the patients, who were from a low-income and low-healthy literacy background (Crowley et al., 2013). Similarly, researchers in the COACH (Community Outreach and Cardiovascular Health) program applied a consultative process to design a community-based cardiovascular diseases management program delivered by nurse-practitioners or community health workers (Allen et al., 2011). A community-provider advisory committee was used in phase one of the study to guide study planning and design. The committee met quarterly to develop a culturally acceptable and relevant intervention program, advise on recruitment of study participants and select nurse-practitioners and community health workers. The committee consisted of six people with diabetes, two doctors, one community outreach worker and one nurse clinical service coordinator. After completion of the intervention program planning, phase 2 was reached: an RCT to implement and evaluate the planned program in the community (Allen et al., 2011).

In an RCT in China, a diabetes group program was conducted to evaluate its effectiveness on self-

care behaviours and quality of life for patients with diabetes in community settings (Liu et al., 2012). Prior to the intervention, a three-step consultative process with main stakeholders was conducted to develop the program. Step one was the identification of a cooperative healthcare clinic model through a literature review. Step two involved three focus group discussions with primary care providers, including GPs, nurses and doctors, to identify the content, frequency, and group size of the program. In step three, a workshop was conducted to finalise the design of the program, comprising the group visit model, the community diabetes control guidelines and the toolkit. The intervention topic identification, educational materials development and program implementation were completed through collaboration between public health experts, specialists, GPs and nurses (Liu et al., 2012).

The present Delphi study design considered the methods applied in the consultative process in these studies (described above) and the aim of the Delphi study. The consultative process involved health professionals from multiple disciplines to achieve consensus on the study protocol. Patients were not included in the consultative process, as the aim of the study was not suitable for this group of stakeholders. However, their participation in care plan development and implementation was considered in the study, as described in Chapter 4.

3.3 Aim of the Delphi study

The aim of the Delphi study was to gain health professionals' consensus on the applicability of an evidence-based hypertension management program for older people with diabetes who were ready to be discharged from hospital to home in Nanchang, China. Findings from the Delphi study informed an RCT study protocol (reported in Chapter 4).

The specific objectives of the Delphi study were to:

- determine the consensus from a multidisciplinary expert panel on the applicability of the proposed hypertension management program
- provide the expert panel with opportunities to revise the hypertension management program.

3.4 Delphi study design and principles

3.4.1 Delphi study design

There are three main research approaches to obtain consensus from experts on a specific topic: the Delphi study, the nominal group technique and the consensus conference (Keeny et al., 2011). Compared with the Delphi technique, a physical meeting is required for the nominal group technique

and the consensus conference. These two approaches were viewed as impractical in this study, as potential participants were busy with their daily work and difficult to meet with simultaneously. A Delphi study allows experts to express their opinions at their convenience without the need for a physical meeting. In addition, a Delphi study allows participants sufficient time to synthesise their views in a democratic way with less influence from those who usually play a dominant role in a group (Akins et al., 2005). Therefore, a Delphi study was chosen by the researcher as a suitable study design to address the aim and objectives of the study.

A Delphi study is widely used to collect opinions and obtain consensus on a specific topic from a group of experts through several rounds of questionnaires (Brady, 2015). Responses to each round of questionnaires are fed anonymously back to participants until consensus is reached (Carnes et al., 2010; Keeny et al., 2011). Round one of the classical Delphi study usually begins with a set of open-ended questions to allow experts to freely express their opinions. However, it is suggested that the use of open-ended questions in round one may lead to the researcher being overwhelmed (Keeny et al., 2011). A modified Delphi study evolved that begins with predetermined information developed through a synthesised literature review; participants then rank this information (Skulmoski et al., 2007). In addition, a modified Delphi study without a physical meeting ensures anonymity, which avoids domination from influential participants and provides each panel member with equal opportunity to express their opinions without feeling pressured (Carnes et al., 2010). It is particularly appropriate to use a modified Delphi study when a literature review has been undertaken to inform the development of the Delphi study questionnaire.

3.4.2 Defining consensus and acceptable consensus rate

A Delphi study is used to achieve consensus among experts who have different views and perspectives. Consensus in the Delphi study context is defined as a 'collective agreement' of expert panels on specific topics through the use of questionnaire rounds (Keeny et al., 2011). In some Delphi studies, achievement of consensus is regarded as a criterion for the termination of Delphi study while other Delphi studies run for a prespecified number of rounds (Diamond et al., 2014). The level of consensus is required to decide a priori, but there is no formal criterion for the measurement of consensus. A variety of measurements of consensus are used for Delphi studies, including percentage agreement, measure of central tendency and proportion of ratings within a range and decrease in variance (Diamond et al., 2014). Through a systematic review of 100 Delphi studies, percent agreement was identified as the most common definition for consensus, with 75 per cent considered the median threshold to define consensus (range: 50–97 per cent) (Diamond et al., 2014). Therefore, 75 per cent agreement was deemed as a reasonable consensus for this study.

3.4.3 Planned rounds

The number of rounds considered sufficient in Delphi studies vary depends on the research objectives. The number of rounds is determined by the time available and the broadness of the questions discussed in the initial round (Keeny et al., 2011). Normally, three to four rounds are required for a classical Delphi study. However, in modified Delphi studies, the initial round can begin with a predetermined list for participants to rank. Consequently, modified Delphi studies are usually shortened to two or three rounds, which is sufficient to reach consensus and achieve special research aims in most cases (Diamond et al., 2014). Through analysis of 100 Delphi studies from the databases Web of Science and Scopus, a systematic review found that 48 per cent of Delphi studies were completed in two rounds whereas 42 per cent Delphi studies were completed in three rounds. In addition, two rounds were able to retain a high response rate to the questionnaires in comparison with three rounds (Diamond et al., 2014; Keeny et al., 2011). Initially, the researchers estimated that two to three rounds would be required to achieve consensus with the expert panel in a modified Delphi.

3.4.4 Participants in Delphi study

Selection of an expert panel is often regarded as the most fundamental component of a Delphi study (Annear et al., 2015). Each individual in the expert panel should be an 'informed individual' who has knowledge about a specific topic or sufficient personal experience in the investigated area (Keeny et al., 2011). However, there is no clear criterion on what constitutes expert panels (Burns & Grove). The definition and selection of experts in a Delphi study may differ based on the study aims and topics discussed (Robinson et al., 2014). In most Delphi studies in the healthcare area, the experts are health professionals (Jorm, 2015). It is reported that heterogeneity within the expert panel plays a significant role in ensuring study quality (Pezaro & Clyne, 2015).

The objectives of this study were to gain health professionals' consensus on the applicability of an evidence-based hypertension management program for older people with diabetes who were ready to be discharged from hospital and required follow-up care in the community in Nanchang, China. Therefore, the expert panel members were from multiple disciplines within both hospital and primary care settings—medical specialists, nurses specialised in diabetic care, dietitians and pharmacists from hospitals, and GPs and nurses from community health centres in Nanchang, China. These participants had expertise and experience in hypertension management for older people with diabetes. The recruitment criteria were: (1) current employment in these positions in the hospitals and community health centres in Nanchang, China; (2) at least five years' experience in the current position (completed the five-year postgraduate program in China); and (3) current engagement in hypertension and diabetes management. In other words, the panels members must have possessed sufficient knowledge and experience to complete the questionnaire. This selection method reflects the heterogenic nature of participants.

The selection of participants in a Delphi study is based on their knowledge of the specific topic; therefore, random sampling is not applied (Harmsen et al., 2015). Most Delphi studies employ purposive and snowball sampling methods to recruit participants. For example, participants are recruited through literature searches and recommendations from other participants (Habibi et al., 2014; Naderifar et al., 2017). Purposive sampling enables researchers to identify suitable participants who can contribute expertly to the discussion in the Delphi study (Keeny et al., 2011). In the present study, purposive sampling was used to identify contacts within the study settings to refer the research project to specific experts in hospitals and community health centres who had expertise and experience in hypertension management for older people with diabetes.

3.4.5 Sample size in Delphi study

One of the most important considerations in a Delphi study is the size of the expert panel because the validity of the results depends on the expertise of panel members (Keeny et al., 2011). There are no formal recommendations or criteria in the literature around ideal sample sizes for Delphi studies (Jorm, 2015). The sample size is dependent on the objectives of the study, research design and range of expertise required (Keeny et al., 2011). It is suggested that a small sample size may be sufficient for a homogeneous group of panel members, while a larger sample size is required for a heterogeneous group of panel members (Keeny et al., 2011).

Participants in the Delphi study have the potential to withdraw or lose from the Delphi study due to fatigue and distractions over successive rounds of questionnaires (Keeny et al., 2011). The degree of consensus in the final results can be overestimated due to attrition bias (Slade et al., 2014). To reduce response bias and maintain the rigour of the Delphi study, it is suggested that at least a 70 per cent response rate should be achieved (Page et al., 2015). Attrition rate must be considered when calculating the sample size. Further, a large sample of 15–30 experts is required for a heterogeneous group in a Delphi study, while small sample of 10–15 experts is sufficient for a homogeneous group (Keeny et al., 2011). In the present study, a sample size of 30 was planned to reflect the heterogeneity of the panel members from multidisciplinary staff. Considering a potential attrition rate of 30–40 per cent over two rounds, it was estimated that a sample size of 60 panel members was required in the first round. To maintain the rigour of a Delphi study, a minimum 70 per cent response rate for each round as suggested by Sumsion (1998) was considered acceptable by the researcher for recruitment.

Attrition and participant fatigue is a common problem in Delphi studies (Page et al., 2015). Three strategies to prevent attrition bias and enhance response rate were implemented in the present study. The first strategy was to facilitate effective communication with participants. The participant information sheet clearly explained the Delphi process, including the number of rounds and the time required for each round of questionnaire. In addition, email communication with potential participants

and an online survey were used to enable participants to plan their time in their spare time that did not conflict with their work schedule to complete the questionnaires. All relevant information was presented in a concise and step-by-step manner. The second strategy was to limit the number of rounds to two to reduce the likelihood of panel fatigue. The third strategy was to provide punctual feedback for each round.

3.4.6 Providing feedback for participants

Multiple iterations followed by feedback are employed in Delphi studies to reach final consensus of experts. In each round of Delphi study, feedback provided to the experts usually includes a statement of the position of the whole group and the participant's own position. In other words, the feedback process informs participants of other participants' perspectives. Thus, feedback gives each participant a new opportunity to reassess and modify their previous responses in the later iterations (Balasubramanian & Agarwal, 2012). Feedback to the experts is widely provided in the form of numerical data summaries such as the mean as a measure for central tendency and the standard deviation as measure of dispersion and outlines of qualitative justifications (Gracht, 2008). In the present Delphi study, researchers provided participants with both a summary of content and numerical data summaries.

3.5 Delphi study questionnaire development

3.5.1 Overall of the Delphi study questionnaire development

The development of the questionnaire was informed by the chronic care model to address integrated care, foster collaboration between different levels of healthcare organisations and health professionals from different disciplines and improve self-care capabilities of people with chronic conditions. The questionnaire development was also informed by findings of "Intervention items and health professional groups who delivered the intervention items" in the literature review which were summarised in Appendix 6. The integrated care, beginning with hospital discharge (Stage 1) and continuing with follow-up support for patients in community health centres (Stage 2) was illustrated in the 'Flow diagram of the intervention protocol' (Figure 3.1 for the Delphi study participants. The collaboration between hospitals where the patient was discharge and community health centres where the patient resided was also demonstrated in the program through a two-way patient referral: (1) referral to GPs and community nurses to implement the discharge planning from the hospital and (2) referral from GPs to hospital specialists for further diagnosis and medication adjustment for the patient when needed. The collaboration between health professionals from a multidisciplinary team was also embedded to the program through detailed description of task sharing to implement the program. Figure 3.1 was attached to the Delphi study questionnaire for participants to facilitate an

understanding of the hypertension management program and gain their consensus on the proposed program.

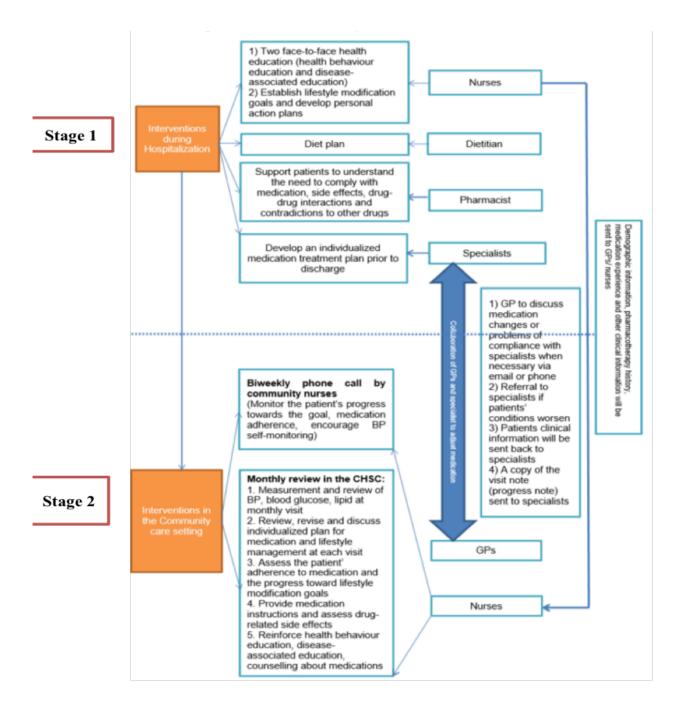


Figure 3.1 Flow diagram of the intervention protocol

The intervention items described in the first round of the Delphi study questionnaire were identified in the literature review (see Chapter 2) and summarised in Appendix 6. These intervention items reflected the eight essential intervention components discussed in Chapter 2. The proposed health professional group who would deliver the intervention items in the first round of the Delphi study questionnaire were informed by the findings of the literature review regarding the specific roles and responsibilities in the multidisciplinary team (see Table 2.4).

In the proposed hypertension management program, interventions would begin at hospital discharge (Stage 1) and continue in the community settings after discharge (Stage 2) (see Figure 3.2). Health professionals from both hospital and community health centres would work collaboratively to implement the interventions. In Stage 1, the hospital interventions would be managed by a multidisciplinary team consisting of medical specialists, nurses specialised in diabetic care, dietitians and pharmacists. The main intervention components in the discharge period included lifestyle modification, health education on diseases, partnership in goal setting and action plans, and referrals to community health centres.

The proposed intervention program required a nurse coordinator to bridge communication and collaboration between team members in hospitals and community health centres. The nurse coordinator, an in-charge ward nurse who oversaw patient discharges, provided GPs and community nurses with patients' intervention components that needed to be implemented in Stage 2. The main intervention components in Stage 2 in community health centres included lifestyle modification, close follow-ups to monitor conditions, improvement of treatment adherence, health education on diseases, motivation in self-care, medication review and adjustment, and arrangement of referral services when needed.

3.6 Questionnaire for Round 1

The modified Delphi study began with a questionnaire on the proposed intervention protocol as outlined above (see Figure 3.1) for potential participants to comment on and review. The questionnaire for Round 1 is presented in Appendix 7. The main sections in the questionnaire are explained in Sections 3.6.1–3.6.2.

3.6.1 Part A: Professional background

In this section of the questionnaire, participants were required to provide information on their demographic and professional background, including gender, age, profession, specialty in current profession, education level, years of experience in hypertension management for diabetic patients, and level of healthcare facility in which they were employed. Participants were also given a space to provide more details about their practice and professional background.

3.6.2 Part B: Content development of the intervention protocol

In this part of the questionnaire, a short introduction to the development of the proposed hypertension management program was provided and the program was illustrated in the 'Flow diagram of the

intervention protocol' for participants to view (Figure 3.1). Participants were encouraged to provide feedback on the applicability of the program. The interventions included in the program were described in a step-by-step manner in Figure 3.1. to enhance participants' understanding of and respond to these interventions. Part B was presented in a table with three main columns: (1) main interventions, (2) detailed items of main interventions, and (3) agreement and additional comments if unsure or disagree. A three-point Likert scale (agree, unsure, disagree) was used in the agreement columns.

In total, 24 items that represented effective interventions in the literature were presented in the Delphi study questionnaire (see Appendix 7). These items were organised in Stage 1 (nine items) and Stage 2 (15 Items). In Stage 1, nine items were presented and grouped in five areas: (1) health education by hospital nurse, (2) diet management by dietitian, (3) medication education by pharmacist, (4) development of medication treatment plan, and (5) collaboration and communication across groups and care settings. In Stage 2, 15 items were presented and grouped in six areas: (1) health education and lifestyle modification by community nurse, (2) improvement of treatment adherence by community nurse, (3) fortnightly telephone follow-ups to monitor conditions by community nurse, (4) goal setting and action plan by community nurse, (5) medication review and adjustment by specialists and GPs, and (6) follow-up visits in community health centres after discharge for older people.

Participants were asked whether they agreed with or were unsure about if the proposed interventions were embedded into care services in healthcare facilities in Nanchang, a capital city of Jiangxi Province in China. If they disagreed or were unsure, the following open-ended questions were asked:

- (1) What were their concerns or the barriers to implementing the intervention?
- (2) What were their recommendations to overcome these barriers?

Analysing participants' responses to these questions informed the modification of the intervention. The second round of the Delphi study with modified interventions was sent to participants to rate and comment upon further.

3.7 Ethical consideration

Ethics approval for the modified Delphi study was granted by the Flinders University Social and Behavioural Research Ethics (Approval no. 7109, see Appendix 9). Anonymity is a significant characteristic for Delphi studies, and was guaranteed in this study. Participants were informed that any information they provided would be treated in the strictest confidence. Participant identity was protected by not asking for names in the questionnaire and by not mentioning names of health care facilities in future publications. The researchers also informed potential participants that they may be identifiable due to the small population pool within hospitals and community health centres. There was no direct recruitment for this research study. All recruitment was conducted by email. The liaison person in each study site assisted the researchers by forwarding the Delphi study invitation to potential participants. The liaison person was unaware of whether potential participants had chosen to participate in the study. Participating in this study was entirely voluntary and participants were free to withdraw from the study at any time without any repercussions on their employment. No consent forms were obtained because completion and return of the questionnaire by email indicated participants' agreement to participate. All data will be stored on the Flinders University computer server under password protection.

3.8 Methods of data collection and data analysis

3.8.1 Data collection

After obtaining the permission of the directors of the participating healthcare facilities, the researcher sent a letter of introduction from the principal supervisor, a participant information sheet and the Round 1 questionnaire to the liaison contacts of each participating site. The contact forwarded the email attachment and text to potential participants to ensure informed consent. After the potential participants read the email, they could freely decide to participate or not (see Appendix 8). Returning the completed questionnaire to the researcher directly by email indicated their acceptation of invitation. In Round 2 of the Delphi study, the researcher sent the summary of first-round results and the revised questionnaire to participants who had returned the questionnaire. It allowed each participant to read the opinions of the group as whole, which may have influenced their responses in the second questionnaire. The participants returned the completed questionnaire to the researcher directly by email. The process of data collection was completely anonymous; participants expressed judgements freely by answering two rounds of questionnaires.

3.8.2 Data analyses

There are two purposes of data analysis in a Delphi study. First, the researcher needs to provide feedback for participants based on findings from data analysis between rounds. Second, the researcher needs to identify whether the consensus is reached based on predetermined criteria (Keeny et al., 2011). There were two types of data collected in the present Delphi study questionnaire: (1) quantitative data from participants' ratings for each item and (2) qualitative data from participants' responses to the two open-ended questions (see Appendix 7). The data analysis methods for each type of data are discussed Sections 3.6.2.1–3.6.2.2.

3.6.2.1 Quantitative data analysis

All statistical analyses in the study were performed using the Statistical Package for Social Science (version 22). Statistical descriptive analyses were primarily used to summarise the general perceptions of participants as listed in the Delphi questionnaires. The main descriptive statistics used in the present Delphi studies include the percentage in each category of the three choices, and measure of central tendencies using median and inter-quartile range. (Keeny et al., 2011).

Percentage was used to measure the level of consensus. The experts who answered 'agree' would be classified as granting consensus on the proposed interventions described in each item. A higher percentage indicated a larger proportion of participants who agreed that the intervention project was applicable to the study context in Nanchang, China. As mentioned above, this Delphi study set out a 75 per cent level of accumulative agreement as the criterion for achievement of consensus; this criterion was widely used in Delphi study (Keeny et al., 2011). If a statement was agreed upon by less than 75 per cent of participants, the statement was rejected or modified based on qualitative findings. The median represents the 50th percentile value of opinions, with a lower median indicating a greater degree of disagreement that most contents in the intervention project are applicable in the study context. Data were cross-checked by a PhD fellow outside the team.

3.6.2.2 Qualitative data analysis

Content analysis is the most common approach used in qualitative data analysis for Delphi studies to describe the attributes of participants' responses and enhance understanding of their qualitative statements (Keeny et al., 2011). To condense data and refine the questionnaire for Round 2, content analysis focuses on classifying participants' responses into categories of similar meanings through analysing explicit comments of participants as well as their inferred meanings (Keeny et al., 2011).

There are two forms of content analysis: inductive and deductive (Elo & Kyngäs, 2008). Deductive content analysis applies a preconstructed set of content categories that arise from prior literature to describe how frequently the pre-existing categories occur in the study under investigation (Elo & Kyngäs, 2008). Deductive content analysis is based on previous theory and knowledge, and is used when the researcher wishes to check the frequency of preconstructed categories in a new context (Vaismoradi et al., 2013). Overall, deductive content analysis originates from earlier theory; therefore, it moves from the general to the specific (see Figure 3.2).



Figure 3.2 Deductive content analysis

In contrast, inductive content analysis is used when knowledge about the phenomenon is lacking or fragmented. In this form of analysis, the researcher discovers patterns and themes that emerge from participants' responses (Elo & Kyngäs, 2008). Usually, inductive content analysis is recommended to describe a phenomenon that has not been extensively researched (Vaismoradi et al., 2013). In contrast to deductive content analysis, inductive content analysis moves from the specific to the general because it groups a set of specific statements to a general category (see Figure 3.3).



Figure 3.3 Inductive content analysis

Due to a lack of pre-existing knowledge, established theories and prior literature regarding the applicability of the proposed hypertension management program in China, an inductive analysis was chosen as the suitable method of qualitative data analysis for this study. It was required to identify major categories and subcategories. The process of inductive content analysis included three main steps (Elo & Kyngäs, 2008):

- Open coding—notes and headings are written in the text while reading and re-reading statements made by the panel members. These are then listed on the coding sheets to generate a category.
- Category generation—notes and headings with same or similar meanings are grouped together under higher-order categories.
- Abstraction—an overall description of the topic is formulated through generating categories.

As inductive content analysis generates categories from the raw data without a theory-based categorisation matrix, it is important to ensure credibility and trustworthiness of the analysis process (Elo et al., 2014; Watkins et al., 2013). Therefore, in this study, the qualitative data were coded and analysed by the PhD candidate. The entire analysis process and categorisation reflected the study rigour though review and cross-checking of statements, codes, group codes and categories by the supervisory team (Elo et al., 2014). Any divergent opinions during category generation were discussed in regular supervision meetings (Elo et al., 2014).

3.6.2.3 Providing participants with feedback

Providing participants with controlled feedback is one characteristic of a modified Delphi study (Keeny et al., 2011). The controlled feedback process distributes to each participant a summary of the prior iteration and presents participants' response from the previous round. Providing controlled feedback is particularly important to the development of the questionnaire for the following rounds because it allows participants to reassess and modify their initial responses when they consider the responses of other panel members (Hsu & Sandford, 2007).

On the completion of the first round, the PhD candidate analysed the data and revised the program based on participants' comments and suggestions that arose in Round 1. The items received agreement of at least 75 per cent; thus, consensus was achieved and no further modification was required. Researchers made some changes to the items that had not been agreed upon, which resulted in version 2 of the draft program. In Round 2, participants were given a new version of questionnaire with a summary of the findings from Round 1. The summary focused on the agreed and disagreed content and highlighted the changes made in version 2. The Round 2 questionnaire was structured similarly to Round 1 (i.e., in table format). Participants were invited to make further comments for the disagreed items in the Round 2 questionnaire. Upon completion of the Delphi study, a summary of findings was provided to participants. When all items gained consensus, the program was modified, and the final version of the program was achieved.

3.9 Findings

3.9.1 Participant characteristics

In Round 1, 70 eligible health professionals were invited to participate in the study (see Table 3.1). All participants completed the two rounds of questionnaire with a response rate of 100 per cent. They came from a variety of health backgrounds, including medical specialists in hospital (n = 19), specialised nurses in hospital (n = 12), dietitians (n = 8), pharmacists (n = 8), GPs in community health centres (n = 11) and nurses in community health centres (n = 12).

Table 3.1 Demographic	information of participants
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Categories	N (%) or Mean (\$		
Gender			
Male	21 (30)		
Female	49 (70)		
Age, mean (SD)	41.5 (8.2)		

Level of healthcare facilities

Community health centres	23 (32.8)
Secondary hospitals	22 (31.4)
Tertiary hospitals	25 (35.8)
Position	
Medical specialists employed in hospitals	19 (27.1)
Nurse specialists employed in hospitals	12 (17.1)
GP employed in community health centres	11 (15.7)
Senior nurses employed in community health centres	12 (17.1)
Dietitians employed in hospitals	8 (11.4)
Pharmacists employed in hospitals	8 (11.4)
Qualification	
Diploma	19 (27.1)
Bachelor	35 (50.0)
Master	12 (17.1)
PhD	4 (5.7)
Years of working experience, mean (SD)	18.7 (8.4)

3.9.2 Round 1 findings

Following Round 1 of the Delphi process, 18 of the 24 items met consensus, leaving six items to be rated again in Round 2 (see Table 3.2). Most participants perceived that the activities described in the 18 items could be embedded in practice in the local context. These items comprised health education provided by hospital in-charge nurses prior to discharge and by community nurses during follow-up in community health centres. Participants also agreed that medical specialists had a leading role in planning individualised treatment and adjustment for patients. GPs' role in monitoring treatment effects and collaborating with medical specialist to adjust treatment regimens was viewed as acceptable. Communication and collaboration through referral and information sharing between hospitals and community health centres achieved consensus.

The six items that were not considered applicable to the local health settings were mainly related to pharmacists' and dietitians' roles, due to lack of sufficient numbers and clear role descriptions of these allied health professionals in the local context (items 4 and 6). In addition, participants showed a low level of agreement on community nurses' engagement in motivational interviewing (item 16) and assessments of medication treatment and laboratory results for patients (items 17,18 and 20).

Table 3.2 First round of agreement among participants on the applicability of the proposed program in the Chinese healthcare context

Items	Agree ment	Disagreeme nt**	Unsure**
1. Patient will be provided with two face-to-face health education sessions (20 mins for each session) (health behaviour	87.1%	0	12.9%
and disease-associated education) by his/her in-charge nurse using a standardised guide and booklets provided by the researcher.			(4:4:0:0:0:1)
2. Patients (or his/her caregivers) will establish lifestyle modification goals and develop personal action plans, working with the in-charge nurse.	100%	0	0
3. A user-friendly 'Intervention diary—Patient version' will be provided to the patient by the in-charge nurse to document personal action plans, lifestyle modification goals, progress towards the goals and adherence to medication.	100%	0	0
4. Patients will be provided medication education by pharmacists, including: understanding the importance of complying with medication, how to identify and manage side effects, drug–drug interactions (including with traditional Chinese medicine [TCM]) and contraindications to other drugs or TCM.	54.3%	17.1% (5:1:1:2:2:1)	28.6% (7:4:0:4:3:2)
5 Prior to discharge, an individualised medication treatment plan will be developed for each patient by the specialist. These will be documented in the 'Intervention diary—Patient version' and the 'Intervention record—Community nurse and GP version' (Level 1).	100%	0	0
6. The dietitian will establish a diet plan for patients based on a dietary guideline (Dietary Approaches to Stop Hypertension (DASH) eating plan).	70%	5.7% (4:0:0:0:0:0)	24.3% (8:5:2:0:1:1)
7. When patients are discharged from hospital, they will be referred to the nearest community health centre.	75.7%	0	24.3% (5:4:1:0:4:3)
8. Discharge summary and pharmacotherapy history will be sent to the community nurse by the in-charge nurse on discharge.	87.1%	0	12.9% (1:4:0:0:1:3)
9. An 'Intervention record—Community nurse and GP version' will be sent to the community nurse and GP by the in- charge nurse to record required post-discharge interventions and outcomes.	95.7%	0	4.3% (0:0:0:0:2:1)
10. The community nurse will provide fortnightly telephone calls to monitor patients' progress towards setting goals, medication adherence and self- monitoring of blood pressure and blood glucose.	95.7%	0	4.3% (0:0:0:0:0:3)
11. The time and date for the telephone support will be documented in the 'Intervention diary—Patient version' by the patient and the 'Intervention record—Community nurse and GP version' by the community nurse.	100%	0	0
12. Patients will visit the community nurse and GPs in community health centres every month.	91.4%	0	8.6% (0:0:0:0:3:3)
13. The time and date for the monthly review by community nurse will be documented in the 'Intervention diary— Patient version' by the patient and the 'Intervention record—Community nurse and GP version' by the community nurse.	100%	0	0

Items	Agree ment	Disagreeme nt**	Unsure**
14. Based on the patient's needs, the community nurses will reinforce health education, improve prevention or	100%	0	0
treatment of existing geriatric conditions, or improve patient's self-management ability.			
15. The community nurse will review and assess patients' adherence to diet and lifestyle recommendations and current	90%	0	10%
medication therapy, and solve psychosocial barriers to self-care.			(0:1:0:0:1:5)
16. The community nurse will use motivational interviewing at monthly visits to help the patient adhere to	72.9%	0	27.1%
medication.			(6:3:1:0:5:4)
17. Problems of non-adherence to medication, possible medication side effects, blood pressure results and	65.7%	10%	24.3%
any other significant clinical events will be assessed by the community nurse and discussed with the patient.		(3:0:0:2:2)	(6:6:0:0:0:5)
18. At each visit, the community nurse will assess whether the patient's medication-related needs are being	60%	7.1%	32.9%
met and whether any medication therapy problems are present.		(0:1:0:1:1:2)	(8:5:0:1:3:6)
19. At each visit, the patient will be informed and reminded of the categories, dosage and frequency of medication to	100%	0	0
be taken prior to the next visit by the community nurse.			
20. Blood pressure, blood glucose, HbA1c, and a full lipid profile will be measured and assessed by the	72.9%	10%	17.1%
community nurse.		(1:0:0:0:4:2)	(5:2:0:0:0:5)
21. The GP will be given a treatment guideline that has been agreed upon by experts in China to review and revise	85.7%	0	14.3%
patients' individual treatment plans originally developed by the specialist. When necessary, the GP will discuss with the			(5:0:0:0:4:1)
specialist via email/telephone to adjust medication and therapeutic agents.			
22. All decisions made in medication changes will be documented in the 'Intervention diary—Patient version' and in the	100%	0	0
Intervention record—Community nurse and GP version'.			
23. Blood pressure, glucose readings and other clinical outcomes will be recorded and formatted as a monthly report	97.1%	0	2.9%
by the community nurse and then sent to specialist for review by email.			(0:0:0:0:0:2)
24. Urgent symptoms will be communicated to the specialist immediately for additional orders by GP via telephone.	78.5%	0	21.4%
			(6:1:0:0:4:4)

**The number of participants who expressed disagreement/uncertainty on the item (medical specialists in hospitals; nurse specialists in hospitals; dietitians in hospitals; pharmacists in hospitals; GPs in community health centres; senior nurses in community health centres).

In total, 97 recommendations were received in relation to the six non-consensus items. These recommendations were grouped based on similarities to identify categories that represented the collective recommendations for modifying the interventions (see Table 3.3). The six categories of suggestions for modifying these items were considered and incorporated into the second round of survey. Participants also suggested that having a coordinator was necessary to promote collaborative care services between hospitals and community health centres to ensure the implementation of the program. Two questions regarding this were added to the Round 2 survey: 'Is a coordinator required for transferring patients from hospital to community service centre?' and 'If yes, who will be the coordinator? Inpatient nurse, outpatient nurse, inpatient doctor or outpatient doctor?'.

Statements	Groups of statements	Categories
Pharmacist may not have enough medication knowledge	Pharmacists lack expertise to provide medication education to patients	
They may not familiar with the medication used for diabetes and hypertension treatment	. F	The need to re-think
Their main tasks are medication delivery in hospital pharmacies	Pharmacists mainly undertake medication delivery in pharmacy of hospital rather than wards.	 pharmacist-led medication education
Communication and care for patients in wards by pharmacists is minimal		
They do not participate in treatment for patients in wards		
There are not enough pharmacists working in wards		

Table 3.3 Example of	summary of	comments from	open-ended questions

3.9.3 Round 2 findings

All six modified items achieved consensus among all the participants (see Table 3.4). These items were accepted for inclusion in the hypertension management program for diabetic patients. Participants agreed that nurses were capable of replacing allied health professionals to deliver medication education and dietary education to patients prior to discharge. GPs were perceived as in an ideal position to assess the effectiveness of medication treatment and laboratory results for patients. There was 94.2 per cent agreement that a coordinator was required for providing patients

with referral to follow-up in community health centres. The patients' in-charge nurse from the hospital was considered by 80 per cent of participants as the ideal coordinator to refer patients from hospital to community health centres and communicate with community nurses.

Items	n	Agreement	Disagreement	Unsure
4. Patients will be provided medication education by specialised nurses. This includes understanding the importance of complying with medication; how to identify and manage side effects; drug–drug interactions (including with traditional Chinese medicine [TCM]) and contradictions to other drugs or TCM.	70	82.8%	11.4%	5.7%
6. The patient will be referred to a specialised nurse to discuss his/her diet plan and given a DASH eating plan to manage their diet.	70	94.2%	1.4%	4.2%
16. Community nurse will be provided education in relation to motivational interviewing skill. Then, the community nurse will use motivational interviewing at monthly visits to help patients adhere to medication.	70	90%	2.8%	7.1%
17. Problems of non-adherence to medication, possible medication side effects, blood pressure results and any other significant clinical events will be assessed by GP and discussed with patients.	70	94.2%	1.4%	4.2%
18. At each visit, the GP will assess whether the patient's drug-related needs are being met and whether any drug therapy problems are present.	70	97.1%	0	2.8%
20. Blood pressure, blood glucose, HbA1c and a full lipid profile will be measured by the community nurse and assessed by the GP.	70	100%	0	0

Table 3.4 Round 2 of consensus	on six modified int	ervention components
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3.10 Discussion

Most intervention strategies reported in the literature to improve hypertension management for older people with diabetes were deemed applicable to a local context by health professionals in Nanchang, China. Eight of the 24 intervention components targeted collaboration between hospitals and community health centres, reflecting the deficits of care services in managing hypertension and

diabetes in the primary care system in China and in other low- and middle-income countries, and in the approaches to build these care services (Wang et al., 2015; Wu & Lam, 2016). The consensus on providing patients with referrals to GPs in community health centres rather than to medical specialists in hospital outpatient clinics prior to discharge may reflect the strong government promotion of these centres for those managing chronic diseases in China (Lin et al., 2015; Miao et al., 2016; Shi et al., 2015).

A two-way vertical referral system between different levels of health facilities underpinned by the principles of collaboration among health professionals using the integrated care delivery model (Miao et al., 2016; Shi et al., 2015) would be ideal. The present Delphi study revealed that over half of GPs were not confident enough to review and adjust medications to provide a sustainable medication treatment for patients discharged from hospitals. Most participants (85.7 per cent) acknowledged that GPs should work collaboratively with specialists to adjust medications in response to item 21. This finding is consistent with a previous study, which indicated that GPs in China were not viewed as a specialty. Further, postgraduate medical training programs specific to GPs were largely underdeveloped (Miao et al., 2016). In China, GPs have not been well prepared to cope with the increased responsibility that has been traditionally undertaken by specialists in managing complex conditions. China had 0.14 GPs for every 1,000 community residents in 2015, fulfilling only a quarter of the required number of GPs outlined in the World Health Organisation recommendations (Wu et al., 2016). In addition, the number of GPs in China only accounts for 6.2 per cent of the total number of physicians, which is far from the 50 per cent achieved in high-income countries. Conversely, in the UK, at least 10 years of medical training-including undergraduate and postgraduate education—is required and lifelong continuing education support are provided to ensure a high quality of practice.

Fourteen of 24 intervention components targeted pharmacological and non-pharmacological interventions at the point of care on discharge from hospital to home and in the follow-up care at community health centres. Intervention strategies included medication adjustment, individualised education and skill training to build patients' capacity and ability to change their behaviour, improve self-care and stimulate motivation to manage their conditions through regular telephone and face-to-face discussions. Although these intervention strategies have been widely recognised as 'best practice' in high-income countries, it may be difficult to adapt and embed them at the point of care in China due to a lack of protocols and resources to implement and monitor the process and outcomes (Miao et al., 2016; Shi et al., 2015). The insufficient numbers of pharmacists and dietitians identified in the study were examples of workforce shortages that impeded a multidisciplinary team approach to deliver best practice. The suggestion that the in-charge nurse was ideally placed to coordinate the referral to the community nurses for follow-up care after discharge was the indicator that participants wanted to establish a structure to enable and sustain coordination between hospitals and community

health centres (Lemetti et al., 2015; Wilkes et al., 2016). The in-charge nurse may need additional education, qualifications and training to undertake this new role.

The nurse coordinator as an integral role has been widely established in high-income countries to strengthen integration and communication of services between hospital and community sectors (Scholz & Minaudo, 2015). One study conducted at St Vincent's Hospital in Ireland reported that a nurse coordinator was able to provide a high quality of service and integration of care for elderly patients discharged from the emergency department (Wilkes et al., 2016). Although building collaboration between hospitals and community health centres to improve prevention and management of chronic disease is highly recommended in the 'Outline for the Planning of the China's National Medical and Health Service System (2015–2020)' (Lin et al., 2015), currently, the platforms and mechanisms to support planning are lacking. The present study is timely to explore the attitudes of health professionals on the feasibility of building an integrated care system through collaboration between hospitals and community health centres. An agreement rate of 75.7 per cent on item 7 in relation to referring patients from hospital to community health centres indicated participants' expectations to build an integrated primary healthcare system that can be accessed by patients. However, 24.3 per cent of participants still expressed uncertainty about whether referrals to community centres can be achieved in the absence of roles such as nurse coordinators, who are responsible for referrals from hospital to community health centres in Western countries. Through the nomination of an inpatient nurse as care coordinator and the development of a two-way referral letter in the present study, collaboration between hospitals and community health centres in providing timely, appropriate and continuous care for discharged patients was considered feasible.

Older people with chronic diseases are often discharged from hospital with complex care needs that require comprehensive care services across several settings to prevent complications and reduce readmission rates (Peiris et al., 2015; Wang et al., 2014). Successful hospital avoidance programs have been reported elsewhere, led by community nurses and supported by multidisciplinary teams (Adib-Hajbaghery et al., 2013). The present study confirmed these findings that community nurses have been recognised as having the potential to lead and coordinate hypertension management for older people with diabetes in follow-up care. However, the present study noted that abilities of community nurses in patient and medication assessment were questioned. The lack of confidence in community nurses may reflect the nursing workforce issue that only five per cent of nurses employed in community health centres in China have training specifically for community nurses must be established to support them in their new role in chronic disease management for older people. In Australia, community nurses (usually called practice nurses) in GP clinics are capable of undertaking patient and medication assessment as a result of the one-year postgraduate graduate diploma they received (Flinders University, 2018).

Six intervention components focus on older people's commitment to their own care by engaging them in establishing care goals, a self-care plan to achieve these goals and self-monitoring the process and outcomes. These self-care activities have previously shown a positive impact in motivating older people to take responsibility for their hypertension control, behavioural change for healthy lifestyle and preventing complications (Liang et al., 2014; Lin et al., 2014). The use of an intervention diary in this study might provide older people with opportunities to accurately document their health conditions and be aware of changes in their health conditions and support them to communicate with health professionals in follow-up visits. The utilisation and impact of the intervention diary were carefully observed in phase 2 of the study.

3.11 Limitations

The major limitation of this study is that health professionals were recruited from only one province of China, which limited the generalisability and representativeness of the findings. Further research will be needed to expand the investigation among other provinces in China to determine whether the responsibilities of health professionals identified in this study are applicable to other provinces.

3.12 Summary

A Delphi study provided health professionals with opportunities to review and modify an intervention protocol that would be implemented in the study context. An evidence-based hypertension management program for community-dwelling older people with diabetes built on cross-sector and interprofessional collaboration was viewed as applicable in Nanchang, China The intervention components in the protocol focus on three levels: improving the utilisation of community health centres through collaboration between these centres and hospitals; embedding care services at the point of care in hospital discharge and in the follow-up care in community health centres to enable older people to manage their health conditions; and older people's commitment to self-care. This study identified and standardised the responsibilities of health professionals across different levels in the health system and implemented an evidence-based hypertension intervention program through their consensus. The findings suggest that education and training support for GPs and community nurses is required to further build the capacity of community health centres to manage hypertension in older people with diabetes and reduce the burden on hospitals. The intervention protocol agreed by health professionals in the study context would facilitate practice changes in hospital discharge and follow-up care in community health centres for older people with hypertension and diabetes in Nanchang. The findings provide a direction for future development of a primary care approach built on collaboration between the different levels of health facilities and health professions in providing a continuum of care for older people with chronic diseases and multimorbidities in China.

Chapter 4

Method of Cluster Randomized Controlled Trial

Chapter 4 Method of Cluster Randomised Controlled Trial

4.1 Introduction

Previous chapters have described the background and rationale for the study. The findings of the literature review have identified eight essential intervention components in managing hypertension for people with diabetes, and implementation strategies through building collaboration between health systems and between health providers. A Delphi study has been conducted to determine the applicability of these intervention strategies identified from high-income countries on Chinese health context. Through two-rounds of questionnaires, health professionals in China has achieved consensus on the program. The findings of the Delphi study have informed the development of a hypertension management program for community-dwelling older people with diabetes that is applicable to the Chinese health context.

This chapter presents the method of cluster randomized controlled trial which has been published in the Trials Journal (Citation: Tu, Q., Xiao, L. D., Ullah, S., Fuller, J., & Du, H. (2018). Hypertension management for community-dwelling older people with diabetes in Nanchang, China: study protocol for a cluster randomized controlled trial. Trials, 19(1), 385. doi:10.1186/s13063-018-2766-). This chapter is presented as published in the journal, including abstract, background, aims, study design, inclusion and exclusion criteria, randomization, intervention description, study setting, participant recruitment, outcome measures, statistical methods and discussions.

Background

It is estimated that one third of adults (over 100 million) with type 2 diabetes around the world live in China (World Health Organisation, 2014). One third of the Chinese population are expected to be aged 60 years and above (430 million people) by the year of 2050 (Wang et al., 2014). The continuous growth of the older population will inevitably increase the incidence of hypertension and diabetes in this population group, resulting in an increased burden on the health care system. Hypertension frequently coexists with diabetes. It's reported that 50%-80% of people with diabetes are affected by the concurrent hypertension (Cheung & Li, 2012). People with comorbidity of diabetes and hypertension are associated with two times higher risk of developing cardiovascular disease and 7.2 times higher mortality rate compared to those who have diabetes only (Bakris & Sowers, 2014; Long & Dagogo-Jack, 2011). Clinical studies have indicated that cardiovascular events and hypertension-related mortality in people with diabetes can be significantly reduced by optimal hypertension management (Rabi et al., 2013; Siu et al., 2012). However, in China, only 14.9% patients with coexisting hypertension and diabetes have their blood pressure controlled and the disease burden on the health systems is widely reported (Song et al., 2016). Although a primary care approach to hypertension management is well recognized as the most cost-effective way to reduce the disease burden (Zhou et al., 2014), there are no practice guidelines for hypertension management at the community level in China and evidence on how to support the development of this care approach is lacking. This study will add research evidence to the international community to inform practice by exploring a post-discharge intervention to improve hypertension management for older people with diabetes co-delivered by health professionals working in hospital and primary care settings in Nanchang, China.

Factors associated with uncontrolled hypertension among older people with diabetes include patient factors (i.e. the lack of knowledge, skill and resources to perform self-care) and health care system factors (i.e. the lack of continuity of care and collaboration between different care providers) (Flynn et al., 2013; Roughead et al., 2011; Wang et al., 2014). Poor communication and collaboration between hospitals and community health centres exists in many low- and middle-income countries which leads to fragmented healthcare delivery for discharged patients (World Health Organisation, 2010; Wu & Lam, 2016; Xu et al., 2016). Although community health centres have been established in China to strengthen primary care, collaboration between these centres and hospitals is under developed. A study on healthcare referral services in four cities of China, including Nanchang, revealed that 57% of GPs never had communication with specialists (Zhou & Nunes, 2016). A population-based study showed that only 34% of residents considered the use of community health centres in Changsha, China (Zhang et al., 2015). The main factors contributing to the underutilization of primary care appear to be the lack of effective mechanisms to enable referrals to GPs from hospital specialists, and the lack of communication and collaboration between hospital care and primary care

providers (Xu et al., 2016; Zhou & Nunes, 2016).

In this study context, after hospital discharge, patients who are not managed by GPs and community nurses usually seek treatments in hospitals only when their conditions get worse (Wu & Lam, 2016). As limited time is available for each patient, the treatment at hospitals mainly focuses on medication, but without attention to non-pharmacological interventions, such as health education to improve patients' self-care capabilities. This acute and episodic treatment is not in line with contemporary self-care principles that encourage patients to actively engage in their chronic condition management through goal setting and regular review (Brown et al., 2007). Improvements in referral to and capacity building of the primary care system will enable patients to use primary care as the main source of care to improve both pharmacological and non-pharmacological interventions.

A body of evidence show that up to 50% of community-dwelling older people in the USA had one or more geriatric conditions such as incontinence, falls, malnutrition, cognitive impairment, and pressure ulcers (Cigolle et al., 2007; Inouye et al., 2007). These conditions compound the complexity of hypertension and diabetes, and contribute to adverse outcomes and hospital admission (Reuben et al., 2000). Community-dwelling older people who are susceptible to or have these geriatric conditions require primary care services to achieve a long-term control of these conditions, rather than relying on irregular outpatient clinic visit or admission to hospital.

Studies have demonstrated that close collaboration between hospitals and community health centres can provide patients with continuous and integrated care delivery, which is recognized as an effective approach to improve quality of care, decrease health care utilization and reduce costs associated with hypertension treatment (Li et al., 2016; Maruthappu et al., 2015; Xu et al., 2016). Randomized controlled trials in high-income countries with well-developed healthcare systems and health insurance schemes have demonstrated that multifactorial interventions delivered by a multidisciplinary team involving nurses and doctors had positive effects in hypertension management for older people with diabetes (Chen et al., 2015; Clark et al., 2011; Williams et al., 2012). This management often incorporates the following components: health education at hospital and community healthcare settings, healthy lifestyles (ie. weight loss, smoking cessation, salt and alcohol restriction, increased physical activity), medication adherence and intensification, timely medication adjustment and complication prevention, and continuous and rigorous follow-up visits in primary care (Chen et al., 2015; Conn et al., 2015; Fahey et al., 2005; Lin et al., 2014; Wu et al., 2010). Reports of intervention programs including a combination of the above components remain scarce in the low-and-middle income countries with lower health resources in primary care such as China.

In this study, collaboration between hospitals and community health centres will be developed to promote a primary care approach to managing hypertension for older people with type 2 diabetes.

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This collaboration will support the capacity building of the primary care system in chronic disease management. We hypothesize that a hypertension management program built on collaborative care among health professionals within and between hospitals and community health centres will improve blood pressure control among community-dwelling older people with diabetes in Nanchang, China.

Methods

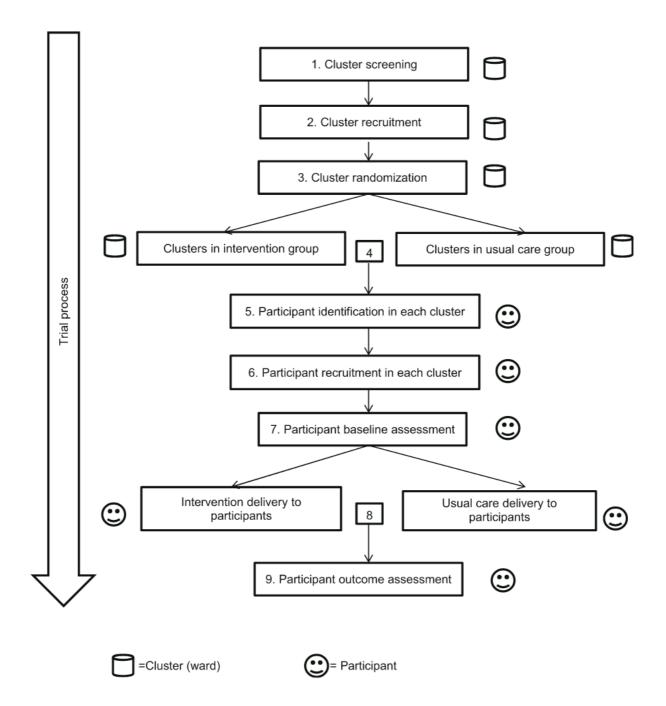
Study design

A cluster randomized controlled trial commenced at hospitals via discharge and continued at community health centres for six months in Nanchang, a capital city of Jiangxi Province in China. This cluster design minimized the risk of contamination between intervention and usual care groups and reflect the classification of public hospitals in China at three levels, namely community health centres, secondary hospitals and tertiary hospitals (Xiao, 2010). Tertiary hospitals were the final referral hospitals and provided more comprehensive care services for patients compared with secondary hospitals. The Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) that provided an overview of schedule of enrolment, interventions and assessments was presented in Figure 4.1. The timeline diagram was presented in Figure 4.2.

Figure 4.1 SPIRIT figure

	STUDY PERIOD							
	Cluster enrolment	Cluster allocation	Participant enrolment	Baseline data collection	Group assignment disclosed		Post-enrolment	
TIMEPOINT	-t4	-t3	-t2	-t1	0	Prior to discharge t1	3 months after discharge t2	6 months after discharge t3
ENROLMENT:								
1.Cluster screening and identification	X							
2.Cluster recruitment	X							
3.Cluster randomisation		X						
4.Eligibility screen of participants in each cluster			X					
5.Participant recruitment			X					
6. Informed consent of participants			X					
7.Baseline assessment of participants				Х				
8.Informing participants of group assignment					X			
INTERVENTIONS:								
1.Intervention at hospital						Х		
2.Intervention at community						Х	Х	
USUAL CARE:								
Usual care						X	Х	X
ASSESSMENT :								
1.Blood pressure (Baseline: medical rec community nurse and GP version)	cord; T2 and	T3: Interver	ntion record-	х			Х	х
2.Hypertension and diabetes-related health knowledge (Hypertension Knowledge Level Scale (HK-LS) and Diabetes Knowledge Questionnaire (DKQ))			х			Х	Х	
3.Medication adherence and health lifestyle adherence (Treatment adherence questionnaire of patients with hypertension (TAQPH))			Х			Х	X	
4.HbA1 and blood lipids (Baseline: medical record; T2 and T3: Intervention record- community nurse and GP version)			Х			Х	Х	
5.Quality of life (Hypertension scale of the system of Quality of Life Instruments for Chronic Diseases (QLICD-HY))			х			Х	X	
6. Adverse events and complications (Interv	ention diary- p	patient version)				Х	X
7. Unplanned hospital admission/the use diary- patient version)	of emergency	care service	(Intervention				X	X





Eligibility: inclusion criteria and exclusion criteria

Hospitals were eligible for recruitment if they had cardiovascular wards and geriatric wards that predominantly provide care services for older people with hypertension. Participants from these

wards were eligible for recruitment if they (1) received care for both type 2 diabetes and hypertension from one of the four hospitals selected to the study; (2) the reason for hospitalisation was uncontrolled hypertension and/or associated complications; (3) were diagnosed with coexisting type 2 diabetes and hypertension; (4) aged \geq 60 years; (5) fit for discharge justified by the specialist; (6) without cognitive impairment (assessed by the Mini-Mental State Examination); and (7) resided in residential areas where the 6 community health centres provide care services.

Participants were excluded if they were: (1) diagnosed with type 1 diabetes; (2) unable to participate in the study because of severe organ damage, disability, cognitive impairment and other lifethreatening disease; (3) unwilling to return to a community health service centre for follow-up visits; and (4) living outside of these six communities.

Ethical approval and consent to participate

The study protocol was approved by the Southern Adelaide Clinical Human Research Ethics Committee in Australia (Approval Number: 345.16) (See appendix 10) and the Department of Scientific Research Management at the Health and Family Planning Commission of Jiangxi Province, China (See appendix 11). All participants and health professionals delivering the interventions were given written information so that they can provide informed consent. Each participant and participating health facility was given a unique numerical code to ensure anonymity. Information provided by participants were collected in a de-identifiable form and treated confidentially. Data collected through this study were stored in a secure area in the University that the first author was enrolled in a PhD program. All study-related data were only be accessible to the researchers. This study was registered in Australia New Zealand Clinical Trials Registry (ID: ACTRN12617001352392. Retrospectively registered on 26 September 2017) (See appendix 12).

Randomization

Participants were recruited from hospitals and continue the trial at community health centres. Randomization was performed based on the ward clusters rather than participants. Health professionals involved in the study practice were in a single ward only, therefore the chance of contamination between intervention and usual care wards in the same hospital is very low. There were 6 secondary hospitals and 5 tertiary hospitals that provide in-patient care for people with diabetes and hypertension in Nanchang. As part of the ethics application processes, researchers in the project sent out invitations to all of these 11 public hospitals in Nanchang and informed them that two secondary hospitals and two tertiary hospitals would be randomly selected. The number of hospitals to be included in the trial was estimated on the sample size calculation. In total, six secondary hospitals and five tertiary hospitals agreed to participate. To ensure the selected hospitals are representative of the hospitals in Nanchang, two hospitals were randomly selected from each

level. There were two eligible wards in each participating secondary hospital and three eligible wards in each tertiary hospital. To ensure the selected wards are representative of the wards in each level of the selected hospitals, three wards from tertiary hospitals and two wards from secondary hospitals were randomly assigned to either intervention group or usual care group. The group assignment was undertaken by a PhD fellow who was not involved in the trial and blind to the wards. Patients who met the inclusion criteria in these participating wards were invited to the trial. There were six community health centres that provided chronic disease management for residents in Nanchang. The invitations were sent to these community centres and all of them agreed to participate in the trial. A flow chart of the randomization is shown in Fig.3.

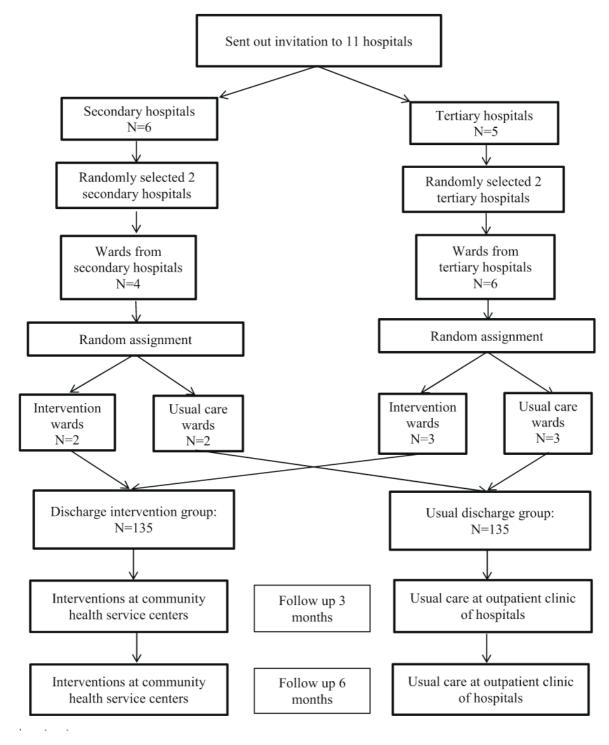


Figure 4.3 Flow chart of the randomization

Description of the interventions

The interventions were developed from a comprehensive literature review about effective hypertension management for older people with diabetes. The intervention startd from hospital with

individualised discharge education provided by the patient's in-charge nurse and the medical specialist (1st stage of intervention). After patients were discharged, and in addition to the usual follow-up in the hospital outpatient clinic, they would be referred to the community health centres to receive follow-up intervention over six months provided by general practitioners (GPs) and community nurses (2nd stage of intervention). Health professionals from both hospital and community health centres would be resourced to work in a collaborative way to implement the post-discharge interventions. A flow chart of the intervention protocol is as below (Figure. 4.4). Prior to the study, a workshop training would be provided to the participated health professionals to inform them the required interventions they need to implement. During the workshop, a "Guide to the implementation of hypertension management program for health professionals" (See appendix 13) would be delivered to them to improve the intervention fidelity.

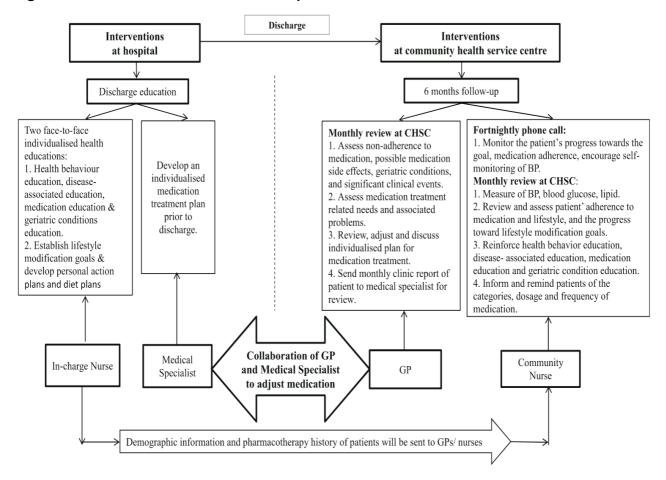


Figure 4.4 Flow chart of the intervention protocol

Stage 1: Interventions at hospital:

1.1. Individualised discharge education.

Patients were given two face-to-face individualised health education sessions specific to diabetic patients with hypertension by the in-charge nurse. The health education included health behaviour

education, disease-associated education and medication education with 15 minutes for each session. Patients were given a "Self-care booklet for older people with hypertension and type two diabetes" (See appendix 14) which was modified by the PhD candidate based on the published guidelines and documents of hypertension management for diabetes (American Diabetes Association, 2018; Chinese Medical Association, 2012; Dang & Lv, 2015; Diabetes Australia, 2018; World Health Organisation, 2010). A geriatrics conditions screening were also undertaken using the widely recognised evidence-based screening tool "Fulmer Spices Comprehensive Assessment Tool for Older Adults" (Aronow et al., 2014). Education on preventing and managing geriatric conditions were provided by the in-charge nurse based on the finding from the screening.

1.2. Lifestyle modification goals – intervention diary-patient version.

1.2.1. Patients were asked to establish lifestyle modification goals and develop personal action plans with the in-charge nurse. Patients were provided an "Intervention diary-patient version" (Appendix 15) to document their lifestyle modification goals, personal action plans, progress towards the goals, medication adherence, adverse events and unplanned hospital admission/ the use of emergency care service.

1.2.2. Patients were asked to discuss and establish their diet plan with the in-charge nurse. The diet plan was recorded in "intervention diary-patient version".

1.3. Individualised medication treatment.

Prior to discharge, patients discussed with the medical specialist and were given an individualized medication treatment plan according to their specific care needs and health conditions. Individualized medication treatment were recorded in the "intervention diary-patient version".

1.4. Referral to the community health service centre – intervention record-community nurse and GP version.

1.4.1. When patients were discharged from hospital, they were referred to a community health service centre by the in-charge nurse for regular follow-up over six months. An "Intervention record-community nurse and GP version" (Appendix 16) was sent to the community nurse by the in-charge nurse on discharge to record required post-discharge interventions and outcomes.

1.4.2. In order to establish collaboration and maintain communication among the doctor and nurse at hospital, the patient and the GP and nurse at the community health service centre, a two-way referral letter was developed (Appendix 17).

1.4.3. The in-charge nurse at the hospital contacted the GP and nurse in community health service

centre through a phone call and will fill in the two-way referral letter for patients. 1.4.4. The in charge nurse helped patients to contact the nearby community health service centre for the follow-up visit. Patients were advised of the community health service centre they were referred to, and the name and contacts of the GP and nurse in the community health service centre.

1.4.5. Data in relation to the patient's demographic information, pharmacotherapy history, and other clinical information were sent to the community nurse by the in-charge nurse on discharge.

1.4.6. Patients took the referral letter and discharge abstract to the community health service centre for the follow-up visit.

1.5. Monitoring

The in-charge nurse at the hospital kept track of the patient's referral progress through making phone call with the patients and community nurses to ensure patients were seen at the community health service centre.

Stage 2: Regular follow-up interventions over six months at community health centres:

2.1. Fortnightly phone call:

Patients received a fortnightly phone call at home from the community nurse to monitor their progress towards setting goals and medication adherence.

2.2. Monthly community health service centre visit:

Patients were asked to visit the community nurse and GP at the community health service centre every month for follow-up visits:

2.2.1. Patients received blood pressure measurement every month by the community nurse.

2.2.2. Patients received a review and assessment from the community nurse on their adherence to medication and lifestyle recommendations, and their progress toward lifestyle modification goals.

2.2.3. Patients received reinforced health education from the community nurse to improve their selfmanagement ability and treatment adherence. Patients were given health education on preventing or treating geriatric conditions based on the "Fulmer Spices Comprehensive Assessment Tool for Older Adults".

2.2.4. Patients received an assessment from the GP on their clinical outcomes, problems of nonadherence to medication, medication side effects, drug therapy problems, drug-related needs and clinical events occurred. 2.2.5. Patients were asked to discuss individualized treatment plan and medication adjustment with the GP.

2.2.6. Patients were asked to document their medication changes in the "intervention diary-patient version".

2.2.7. Patients were reminded the categories, dosage and frequency of medication required to be taken prior to the next visit by community nurse.

2.3. GP and medical specialist collaboration.

The GP discussed with the medical specialist at hospital via email or telephone when necessary to adjust medication. BP, HbA1c and lipid readings were recorded by the community nurses and formatted as monthly report and then sent to medical specialists for review. Urgent symptoms were communicated to the medical specialist immediately for additional orders by the GP.

Usual care

In the usual care group, patients received routine discharge education at hospital. After they were discharged, they went to their usual outpatient clinic of the hospital to receive follow-up and outcome measures at three months and six months. They were not referred to the community health service centre. They were asked to record the number of adverse events and unplanned hospital admission/the use of emergency care service during three months and six months follow-up in a usual care table (Appendix 18). The researcher recorded the HbA1c, and lipid levels close to the three and six months follow-up from the patients' medical record.

Outcome measures

Primary outcome

The primary outcome was systolic blood pressure at six months follow-up adjusted for baseline value. At each measurement point, blood pressure was measured three times at 5-minute intervals on the participant's right arm in a sitting position. The average of the three blood pressure readings were calculated as the final BP reading for each group at each time point, which minimized measurement error. Participants could be affected by the possibility of 'white coat hypertension' during the study. In order to reduce measurement bias, electronic BP device was used to record BP measurements per patient, with the same appropriate-sized cuffs, the same arm, and the same posture.

Secondary outcomes

Secondary outcomes were the following outcomes adjusted for baseline value: (1) hypertension and diabetes-related health knowledge score measured by the combination of the Hypertension Knowledge Level Scale (HK-LS) (Erkoc et al., 2012) and Diabetes Knowledge Questionnaire (DKQ) (Hu et al., 2013); (2) medication adherence and health lifestyle adherence score measured by the treatment adherence questionnaire of patients with hypertension (TAQPH) (Ma et al., 2012); (3) HbA1c and lipid values; (4) quality of life score measured by the hypertension scale of the Quality of Life Instruments for Chronic Diseases (QLICD-HY) (Wan et al., 2012); (5) the incidence of adverse events and complications associated with hypertension, diabetes, treatments and geriatric syndromes recorded by patients/or carers in the "intervention diary-patient version"; and (6) the incidence of unplanned hospital admission/the use of emergency care service due to uncontrolled hypertension, diabetes and geriatric syndromes recorded by patients/or carers in the "intervention diary-patient version".

Through the study, we hoped to identify the challenges that patients faced in their hypertension management in the community healthcare settings and to evaluate how to overcome these challenges by improving the capacity of the primary care system. Hence, two open ended questions were included for patients upon the study completion: (1) Are you satisfied with the follow-up provided by the GP and community nurse in the community health service centre? (If not, please explain the reason); (2) Did you encounter any difficulties of care in the community health service centre after discharge (If yes, please list the difficulties you encountered).

Sample size

The sample size calculation was based on the primary outcome and was estimated on the basis of an earlier randomized controlled trial study in relation to hypertension management for diabetic patients (Edelman et al., 2010). In this earlier study, the researchers found a 7.3 mmHg significant reduction in systolic blood pressure (SBP) with a standard deviation of 12.1 mmHg and an intraclass correlation coefficient (ICC) 0.05 in the intervention group (Edelman et al., 2010). Since randomization in the present study was done by wards (clusters), the sample size was adjusted to take into account the design effect. The present study was designed to have 80% power to detect a difference of 7.3 mmHg SBP between the group means when the standard deviation is 12.1 mmHg. This assumed that a sample size of 5 clusters per group with 25 participants per cluster would complete the study and the ICC is 0.05, giving a design effect of 1.48. The ICC also reflected the situation that the hospitals in the study were from the same city under the same hospital administration standard; therefore, each cluster was unlikely to differ from the others with respect to the variable of interest. Each cluster was of equal size. Assuming an attrition rate of 10%, we would require 27 participants per cluster. In total, 10 clusters with 270 participants were recruited.

Participant recruitment

Recruitment posters were presented in the patient activity rooms in the participating wards. An information pack including information sheet, consent form and other study-related documents (i.e. Intervention diary-patient version; usual care table) was displayed on a table placed under the poster for potential participants to view. Potential participants were asked to return their decision on participation via a response slip to a drop box in each participating ward. On receiving the response slip, a research recruiter who was blinded to the group allocation and had no interest in the outcome of the study contacted the patients to confirm their eligibility to participate. One of the project team members, who knew the allocation, provided detailed information related to the study and had the participants sign the consent form. Although the allocation was known to the project team member, the risk of selection bias and influences on the measure of baseline outcome was minimal because the participants were informed that refusal to participate in this study did not alter the caring relationship between them and the hospitals. Participants were reminded that they can discontinue participation in the study at any time without any influences on their usual care.

Data collection

At baseline, the in-charge nurse distributed the questionnaires to participants or their family caregiver. They completed the questionnaires once the consent form is signed and before the individualized discharge education is provided. The patient's in-charge nurses at the hospital provided assistance to participants should they have any questions about the questionnaire. Clinical outcomes (BP, HbA1c and lipid values) were directly recorded from the health record of patients by a research assistant.

At three months and six months follow-up, community nurses distributed the questionnaires to participants in the intervention group when they visit the community health service centre. Community nurses were available to assist patients should they have any questions about the questionnaire. In the usual care group, a nurse in the medical specialist clinics distributed the questionnaire to participants when they visit outpatient clinic at three months and six months follow-up. The nurse was available to assist patients should they have any questions.

Completed questionnaires were placed in a prepared sealable envelop to maintain confidentiality. The researcher prepared a drop box in each ward, community health service centre and outpatient clinic. Participants returned the sealed questionnaires to the drop box. The research assistants collected completed questionnaires on a weekly basis.

Quality control procedures

Quality of data collection was ensured during the whole study phases. Two one-hour workshops and ongoing support at each participating site were provided to the health professionals to allow them to discuss, understand and follow the study protocol. Research assistants were employed to distribute and collect the questionnaires. Consent forms, questionnaires and other data collection documents were checked for completeness. Data at three time-points (baseline, three and six months follow-up) were checked using the birth date of patients to ensure the data are matched correctly. The quality of the study was overseen by the PhD supervision team and the representative of the Department of Scientific Research Management at Health and Family Planning Commission of Jiangxi Province, China. The data entered in the SPSS was checked to prevent input errors by the other two PhD fellows who were not involved in this study. The compliance of patients with the interventions was optimized by a phone call from the nurse at the community service centre to remind them of the follow-up visits at community health service centre.

Blinding and allocation concealment

Participants did not know their group allocation during the recruitment and baseline data collection. The research recruiter who was blinded to the group allocation and had no interest in the study assisted the recruitment of participants. Allocation was disclosed to participants after the baseline data collection. Due to the nature of the study interventions, health professionals who delivered the intervention knew group allocation during the trial. However, the statistician involved in the data analysis was blinded to the group allocation.

Intervention fidelity

Intervention fidelity refers to the extent that proposed interventions are delivered as planned in the protocol. The items of interventions recorded by both patients and community health professionals included: (1) Intervention diary patient version; (2) Intervention record-community nurse and GP version. Compliance with required interventions was matched using these two tools.

Risk to participants

As the program was quality improvement of practice in nature and is required by hospital administration and regulation in China, there were no foreseen risks to participants. Proposed interventions were included in daily practice and replaced conventional practice which was less well-organized and might take longer time. For example, the conventional patient education was replaced with individualized patient education using an education guide developed by the researcher. The interventions would provide well-organized discharge education for patients.

Dissemination plan

All the participants and health professionals were informed of the final research results via a newsletter. Participants did not have any control in the immediate reporting and future use of data collected for the purposes of the research. No individual was identifiable in the future publications and research report in order to protect participants' identities.

Dealing with contingencies

Possible contingencies were the following: (1) Patients refused to participate in the project; the strategy to deal with this was to extend the recruitment period to gain sufficient sample size. (2) Unexpected tasks that health services need to deal with, such as outbreak of infectious disease; the strategy to deal with this was to temporarily cease the trial and recommence when the health service returns to normal. The Department of Scientific Research Management at Health and Family Planning Commission of Jiangxi Province, China, would deal with the contingencies that may occur during the study.

Statistical methods

Statistical analysis was performed using Statistical Package for Social Science (SPSS) version 23 and STATA software version 14. To test the effectiveness of the intervention on the primary and secondary outcomes, a multivariate multilevel mixed-effects linear regression model was used to analyze outcomes. This was due to the hierarchical structure of the data and based on the consideration of the correlations between participants' repeated measurements over time. Because the participants were nested within hospital wards, we fit a three-level mixed model with random intercepts at both the cluster and the participant-within-cluster levels. Thus, models accounted for the clustering in wards, participants within clusters and over time using mixed command. Wards and participants within wards were treated as random effects. The main effects were group (intervention or comparison), time (baseline, three and six months) and group x time interaction. A small-sample correction to the restricted maximum likelihood estimator was used to improve the inference for the fixed parameters and is available in STATA mixed command. Models were adjusted by baseline value and confounders that include age, gender, body mass index (BMI), duration of hypertension, duration of diabetes, smoking status and education level (Bland & Altman, 2011; Vickers & Altman, 2001). A univariate model was also used for unadjusted estimates. The level of significance was set at p<0.05. Where appropriate, 95% confidence intervals (95% CIs) will be reported along with pvalues.

Data analysis was performed according to the intention-to-treat principle. Participants who withdrew or did not complete the six months follow-up were included in the analysis. Multiple imputation technique was used for large missing data.

Discussion

The transition between hospital care to community care is a critical period in the care of elderly people with diabetes and hypertension who often have complex medical problems. The incidence rate of adverse events after discharge and the readmission rate are high due to the inappropriate self-care behaviors of patients and lack of timely monitoring of patients conditions by health professionals (Munshi et al., 2016; Roughead et al., 2011). It has been reported that within a week after hospital discharge, primary health care is required by 80% of patients (Roughead et al., 2011). Continuity of care through follow-up in primary care as the first-contact for patients after discharge can bring positive outcomes for older patients (Lin et al., 2014; Roughead et al., 2011). The transition from passive care to proactive and preventive care can be achieved through establishing a care continuum in the current health systems in China and other low- and middle-income countries. Currently, most patients in China only visit doctors when the symptoms of diseases appear. Many complications do not show symptoms in the early stages when they are easier to treat and so the best treatment period may be delayed or missed. By establishing continuous care after discharge, diseases-related complications can be prevented or detected earlier and so promptly treated in the primary care system.

Hypertension and diabetes management after discharge is a process that requires lifelong adjustments to non-pharmacological and pharmacological interventions due to the chronic nature of these conditions. Lack of adherence to pharmacological and non-pharmacological treatment have been identified as key barriers to optimal hypertension control. Medication adherence is positively associated with hypertension control and reduction in the risk of complications (Shen et al., 2017). However, only 20%- 60% patients in China comply with antihypertensive drugs (Wei et al., 2013). Nearly half of people with diabetes and hypertension are likely to discontinue their medication treatment in the first six months since discharge or when their symptoms diminish (Wang et al., 2014; Wei et al., 2013). Among the patients who adhere to medications, 50% of them take their medications in an incorrect way (Wang et al., 2014). Therefore, long term medication management is required.

As a chronic disease, hypertension requires life-long medication treatment. Older patients whose memory function decline are more likely to forget taking medications as prescribed and to experience side effects and adverse reactions. Inappropriate medication management can leads to repeat hospital admission. In a study involving 86 patients who were hospitalized, 49% of hospital admission were due to medical error (Roughead et al., 2011). Therefore, it is important to prevent medication-related problems. In this study, health professionals at community health centres will regularly monitor patients' medication compliance, deal with the side effects of medication and adjust medical therapies to achieve continuity in optimal medication management.

Therapeutic lifestyle changes (TLC) have demonstrated effectiveness in the control of hypertension and improved quality of life among older people [28]. However, a community-based cross sectional study in Alexandria found only 1 in 10 patients can follow the recommended lifestyle modifications such as dietary change, exercise adjustment and weight control (Parajuli et al., 2014). Factors associated with poor self-management include a lack of understanding of the care plan and low confidence and motivation to make healthy choices. Health education can address these barriers by equipping patients with the motivation, self-care skills and knowledge to manage their chronic conditions. Considering the low level of health knowledge among older people, a sustainable and structured follow-up, including regular health education (involving positive behavior changes and medication compliance), and professional health counselling are required for older patients who are discharged. In addition, the monthly monitoring of conditions for older people in community settings can ensure early detection of their functional decline, which prevents hospital readmission. A study in Canada found that hypertension-related hospital admissions of older patients was reduced by 9% during 10 weeks by implementing a community-based education program (Wei et al., 2013). Therefore, a sustainable health system is built through promoting service improvements in primary care, such as intensive follow-up to support older patients to maintain their adherence to medical treatment and healthy lifestyle.

Previous hypertension management programs in China have been mostly hospital-based or community-based that only target either pharmacology or non-pharmacology interventions (Lin et al., 2014; Song et al., 2016). This is first trial in China to build integrated care based on the collaboration and coordination between hospitals and community health centres to support older people to manage diabetes and hypertension at home using multifactorial interventions. In addition, this study synthesizes latest evidence and includes the combination of effective intervention components on hypertension management for people with diabetes, which differs from the previous studies in China that only tested single intervention components (Wong et al., 2015; Yu et al., 2014).

The program, if effective, will have an immediate application to hypertension management in the healthcare system in China. In addition, this study uses hypertension and diabetes as an entry point to improve chronic disease management in primary care. Success of this intervention program, that transfers patients from hospital to community health centres, can also be applied to the management of other chronic diseases for hospitalized patients.

Limitations of this study are the following. First, the trial will be undertaken in 10 clusters only and hence sampling bias may occur, which means that the findings may not represent the population. Second, as an open-label study, the patients and health professionals will be aware of the groups they are assigned to and their allocated treatment during the trial. Patient bias may occur when they complete the self-reported questionnaires. Third, the duration of follow-up at community health

service centre is relatively short (only six months). The long-term effects of this intervention program will need to be explored in a future study.

4.2 Summary

This chapter presents a published protocol that describes the method of the cluster randomized controlled trial in the present study. A cluster randomized controlled trial involving ten wards from four hospitals in Nanchang was randomly allocated to either intervention group (N=5) or usual care group (N=5). 27 participants were recruited from each ward and the estimated sample size was 135 patients in each group. The intervention included individualized self-care education prior to discharge and six months follow-up in Community Health Centres. Health professionals from both hospitals and Community Health Centres was resourced to collaborate on the implementation of the postdischarge interventions that reinforce self-care. The primary outcome is systolic blood pressure at six months follow-up adjusted for baseline value. Secondary outcomes are self-care knowledge, treatment adherence, HbA1c and lipid levels, quality of life, the incidence of adverse events and the incidence of unplanned hospital readmission at six months follow-up adjusted for baseline value. A multilevel mixed effect linear regression model will be used to compare the changes in health outcomes between intervention and usual care groups. This study will determine whether collaborative care among health professionals between hospitals and community health centres will improve hypertension management for older people with diabetes in the study sites. The program, if effective, will have an immediate application to hypertension management in the healthcare system in China. The next chapter will present the findings of the program.

Chapter 5

Results from a cluster randomized controlled

trial

Chapter 5 Results from a cluster randomized controlled trial

5.1 Introduction

The previous chapter presented a study protocol for a cluster randomized controlled trial (RCT) designed to evaluate the effectiveness of the hypertension management program. In this chapter, participants' social demographics and clinical characteristics are presented. Findings from the cluster RCT are also analysed and explored. In addition, participants' responses to the open-ended questions regarding their satisfaction with the program are also presented.

5.2 Demographic and clinical characteristics of participants

Between December 2016 and August 2017, 270 hospitalised older people who met the selection criteria in the cluster RCT were recruited and randomly assigned to either the intervention group or usual care group. Of the 270 participants, 13 were lost (five in the intervention group and eight in the usual care group) by the end of the study. Based on intent-to-treat analysis, their last completed results were carried forward and included in the final analysis.

In the intervention group, five participants did not continue the intervention. Of these five who did not continue the six-month follow-up, one died, two withdrew from the study for personal reasons, and two were lost to follow-up. In the usual care group, eight participants did not complete the six-month study. Of these, two withdrew, two were lost and three died. A total of 130 participants from the intervention group and 127 participants from the usual care group completed the six-month follow-up. The flow of participants through each stage of the trial is presented in Figure 5.1.

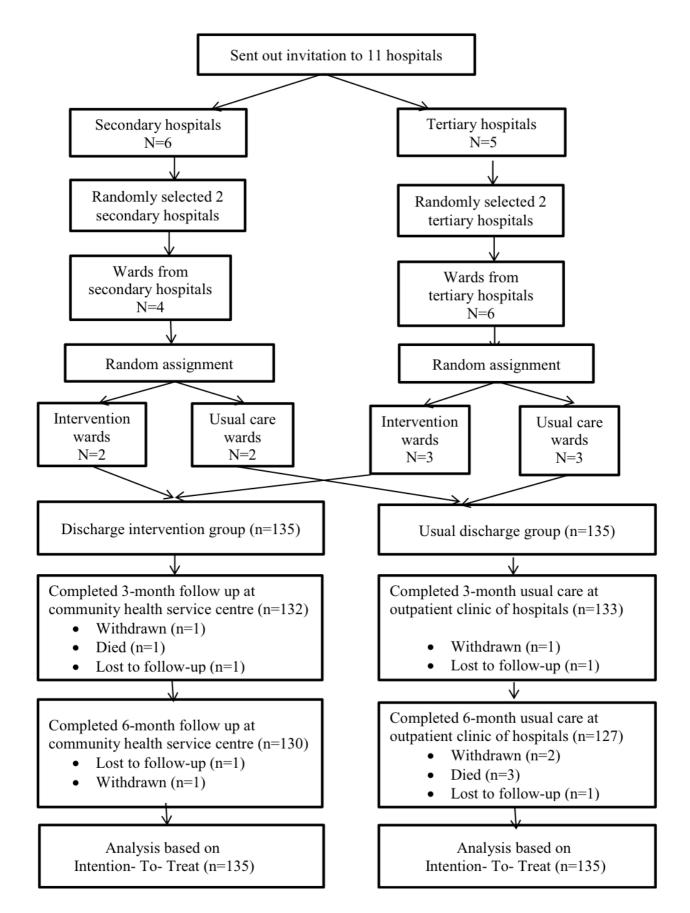


Figure 5.1 Flow of participants through the study

5.2.1 Demographic characteristics of participants

The mean age of participants in the present study was 70.9 (SD = 5.8) years and the range of the age was 60–88 years. Approximately, 55 per cent were male and 45 per cent were female. Twothirds (66%) of participants were married while others were single (6.7%), divorced (10.7%) or widowed (16.7%). The mean body mass index (BMI) was 24.0 (SD = 3.8). The average duration of hypertension and diabetes diagnosis was 9.3 (SD = 6.8) and 9.4 (SD = 6.0) years, respectively. A total of 65 (24.0%) participants reported that they were former smokers and 48 (17.7%) were current smokers. Half the participants did not complete the nine years' basic education. Most (73.7%) of participants were on polypharmacy, indicating the concurrent use of five or more medications. Besides hypertension and diabetes, the large majority (96.2%) of participants were diagnosed with more than two health conditions. More than two-thirds (68.5%) of participants had medical insurance for urban workers. The demographic information of participants was collected at baseline and summarised in Table 5.1.

	Total (n = 270)	Intervention (n = 135)	Control (n = 135)	p-value
Age, mean (SD) Gender, n (%)	70.9 (5.8)	70.4 (5.6)	71.5 (6.0)	0.14 0.80
Male Female	148 (54.8) 122 (45.1)	73 (54.1) 62 (45.9)	75 (55.6) 60 (44.4)	
BMI kg/m2, mean (SD)	24.0 (3.8)	23.7 (3.9)	24.3 (3.8)	0.22
Marital status, n (%) Single Married Divorced Widowed	18 (6.7) 178 (65.9) 29 (10.7) 45 (16.7)	9 (6.7) 90 (66.7) 17 (12.6) 19 (14.1)	9 (6.7) 88 (65.2) 12 (8.9) 26 (19.3)	0.57
Smoking status, n (%) Current smoker Ex-smoker None smoker	48 (17.7) 65 (24.0) 157 (58.1)	26 (19.2) 31 (22.9) 78 (57.7)	22 (16.2) 34 (25.2) 79 (55.5)	0.78
Education level, n (%) < 9-year basic education High school Bachelor Master and above	129 (47.7) 102 (36.2) 34 (12.5) 5 (1.8)	62 (45.9) 52 (38.5) 17 (12.6) 4 (3)	67 (49.6) 50 (37.0) 17 (12.6) 1 (0.7)	0.56
Caregiver support, n (%) yes no	233 (86.3) 37 (13.7)	117 (86.6) 18 (13.3)	116 (85.9) 19 (14.0)	0.85
Duration of hypertension years, mean (SD)	9.3 (6.8)	9.2 (6.8)	9.4 (6.8)	0.88
Duration of diabetes year, mean (SD)	9.4 (6.0)	9.3 (6.0)	9.4 (5.9)	0.96

Polypharmacy, n (%) yes no	199 (73.7) 71 (26.2)	104 (77.0) 31 (23.0)	95 (70.4) 40 (29.6)	0.21
Total number of diseases n (%)				0.63
<3 ≥3	10 (3.7) 260 (96.2)	4 (2.9) 131 (97.0)	6 (4.4) 129 (95.5)	0.51
Medical insurance, n (%) Medical insurance for urban residents	185 (68.5)	91 (67.4)	94 (69.6)	0.69
Medical insurance for urban workers	85 (31.4)	44 (32.5)	41 (30.3)	

Note: (1) Chi-square test was used for comparison of proportion including gender, marital status, smoking status, education level, caregiver support, polypharmacy, total number of diseases and medical insurance. (2) Independent t-test was used for comparison of continuous data including age, BMI, duration of hypertension and duration of diabetes.

5.2.2 Health conditions besides hypertension and diabetes between groups

Neurological diseases were the most frequently reported health conditions, including diabetic peripheral neuropathy. Other health conditions were arteriosclerosis, renal diseases, cardiovascular diseases, fatty liver, hyperlipidemia, eye diseases, cerebrovascular diseases and cerebrovascular diseases. The chi-square statistic is 4.8 with p- value of 0.673. There was no statistical difference in the number of complications between the intervention and usual care groups. Figure 5.2 presents the baseline complications associated with hypertension and diabetes in the intervention and usual care groups.

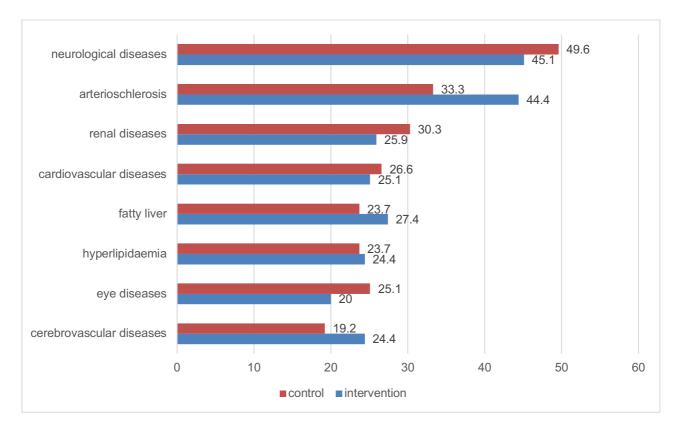


Figure 5.2 Comparison of other health conditions besides hypertension and diabetes in both groups

Data are presented in percentage and compared through Chi-square test

5.2.3 Baseline antihypertension medications between groups

Calcium channel blockers were the most frequently prescribed antihypertension medications, followed by angiotensin receptor blockers, angiotensin-converting enzyme inhibitors, diuretics and beta blockers. The chi-square statistic is 4.1 with p- value of 0.385. There was no statistical difference between the number of antihypertension medications prescribed for patients in the intervention and usual care groups at baseline. Figure 5.3 presents the baseline antihypertension medications for the two groups.

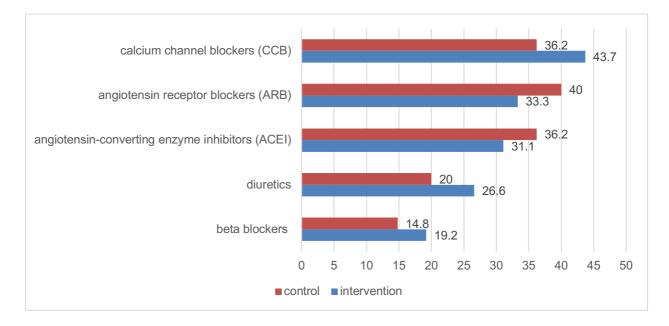


Figure 5.3 Comparison of baseline antihypertension medications between groups

Data are presented in percentage and compared through Chi-square test.

5.2.4 Baseline oral antidiabetic medications between groups

Alpha-glucosidase inhibitor was the most frequently prescribed oral antidiabetic medication, followed by biguanides, insulin secretagogues and insulin sensitiser. The chi-square statistic is 1.0 with p-value of 0.780. There was no statistical difference between the number of oral antidiabetic medications taken by participants in the intervention and usual care groups at baseline. Figure 5.4 presents the comparison of baseline antidiabetic medications between the two groups.

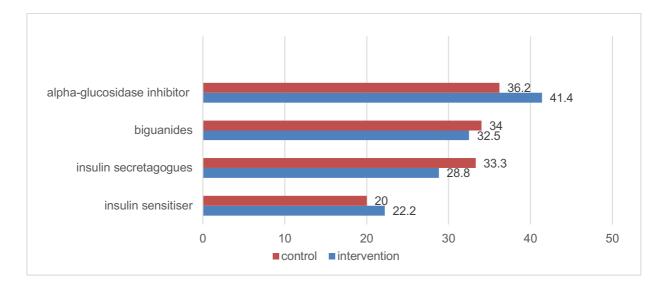


Figure 5.4 Comparison of baseline oral antidiabetic medications between groups

Data are presented in percentage and compared through Chi-square test.

5.2.5 Baseline clinical characteristics of participants

The baseline clinical characteristics of participants are presented in Table 5.2. At discharge, their mean blood pressure was 136.1/81.0 mmHg which achieved the recommended blood pressure goal of 140/90 for elderly people according to the American Geriatrics Society (AGS) and American Diabetes Association (ADA) consensus report on hypertension management for elderly people with diabetes (American Diabetes Association, 2018; American Geriatrics Society Expert Panel on Care of Older Adults with Diabetes et al., 2013; Solini & Grossman, 2016). Mean pulse pressure difference (defined as SBP minus DBP) was 55.1 mmHg, which was higher than the normal range of 40 mmHg. The raised mean pulse pressure might reflect the age-related arterial stiffness common in the older population. The mean HbA1c at baseline was 8.1 per cent, which was higher than the HbA1c goal of 7–7.5 per cent (ADA/AGS consensus report 2012). As HbA1c reflects blood glucose levels over the past two to three months, the mean HbA1c (8.1%) indicated that participants' blood glucose was not controlled in the previous months and the quality of diabetes care was unsatisfactory. The mean fasting glucose was 7.1 mmol/L and was in the recommended range of 5.0–8.3 mmol/L for older people with diabetes, which demonstrated that the blood glucose of participants was well managed during hospitalisation.

Clinical variables	The total	Intervention	Usual care	P-
	(n = 270)	group	group	value
		(n = 135)	(n = 135)	
SBP, mmHg	136.1 (11.6)	136.6 (12.1)	135.6 (11.1)	0.664
mean (SD)				
DBP, mmHg	81.0 (9.9)	81.4 (10.3)	80.6 (9.5)	0.694
mean (SD)				
HbA1c, %	8.1(1.0)	8.1 (0.9)	8.1(1.0)	0.661
mean (SD)				
Fasting glucose, mmol/L	7.1 (0.85)	7.2 (0.8)	7.1 (0.9)	0.425
mean (SD)				
LDL mg/dl	104.5 (25.9)	105.1 (24.7)	103.9 (27.0)	0.638
mean (SD)				
HDL, mg/dl	40.8 (11.7)	40.4 (12.3)	41.1 (11.2)	0.483
mean (SD)				
Hypertension knowledge	13.3 (3.85)	13.4 (3.8)	13.3 (3.9)	0.741
mean (SD)				
Diabetes knowledge	13.0 (4.6)	12.8 (4.5)	13.2 (4.6)	0.512

Table 5.2 Baseline clinical characteristics of participants

mean (SD)				
Treatment adherence	86.4 (12.7)	86.3 (12.7)	86.5 (12.7)	0.804
mean (SD)				
Quality of life	170.2 (19.4)	170.0 (19.7)	170.4 (19.2)	0.774
mean (SD)				

Note: (1)The total score of hypertension knowledge = 22; (2) total score of diabetes knowledge = 24; (3) total score of treatment adherence = 112; total score of quality of life = 235; (3) abbreviations: CG = usual care group, IG = intervention group, SBP = systolic blood pressure, DBP = diastolic blood pressure, HbA1c = haemoglobin A1c, FBG = fasting blood glucose, TC = total cholesterol, LDL = low-density lipoprotein, HDL = high-density lipoprotein.

5.2.6 Comparison of demographic and clinical characteristics between groups

Similar demographic and clinical characteristics were present between the intervention group and the usual care group. No statistically significant differences were identified between the two groups for all demographic and clinical characteristics (P>0.05) (see Tables 5.1–5.2).

5.3 Outcomes from the cluster RCT

5.3.1 Systolic blood pressure

Figure 5.5 shows changes in the mean systolic blood pressure (SBP of each group at the three time points over the six-month follow-up period. The intervention group demonstrated a statistically significant decrease of mean SBP over time compared to usual care group (see Figure 5.5). In the intervention group, mean SBP significantly decreased from 136.7 mmHg at baseline to 133.2 mmHg at three months, and 132.8 mmHg at six months. In the usual care group, a statistically significant increase in mean SBP over the three time points was observed. Mean SBP in the usual care group increased from 135.5 mmHg at baseline to 137.1 mmHg at three months; and 142.4 mmHg at six months.

Based on the linear mixed-effect model, the mean difference in SBP between the intervention group and the usual care group was -5.0 mmHg (95% CI, -8.5 to -1.4 mmHg) at three months (P = 0.005) and -10.7 mmHg (95% CI, -14.2 to -7.1 mmHg) at six months (P < 0.001) (see Table 5.4).

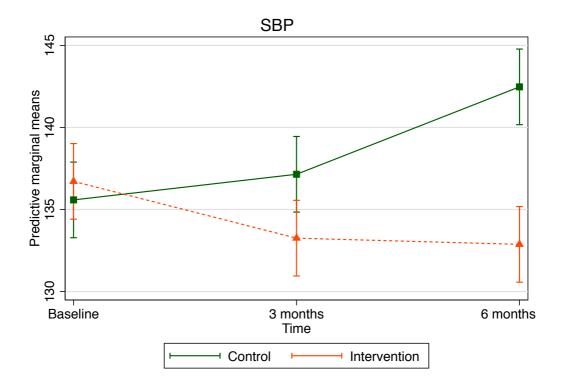


Figure 5.5 Mean SBP changes from baseline to six months by group

5.3.2 Diastolic blood pressure

Figure 7.6 shows the mean diastolic blood pressure (DBP of each group at the three time points over the six-month study period. In the usual care group, a slight increase of mean DBP from 80.3 mmHg at baseline to 80.8 mmHg at three months was observed, but the change was not statistically significant. However, the increase from 80.3 mmHg at baseline to 81.8 mmHg at six months showed a statistically significance. The intervention group demonstrated a statistically significant decline in mean DBP over time, from 81.6 mmHg at baseline to 79.6 mmHg at three months, and 79.0 mmHg at six months (see Figure 5.6).

Based on the linear mixed-effect model, the estimated mean reduction in DBP over three months and six months in the intervention group compared with the usual care group were -2.4 mmHg (95% CI, -4.4 to -0.3, P = 0.008) and -4.1 mmHg (95% CI, -6.2 to -2.0, P < 0.001) (see Table 5.4).

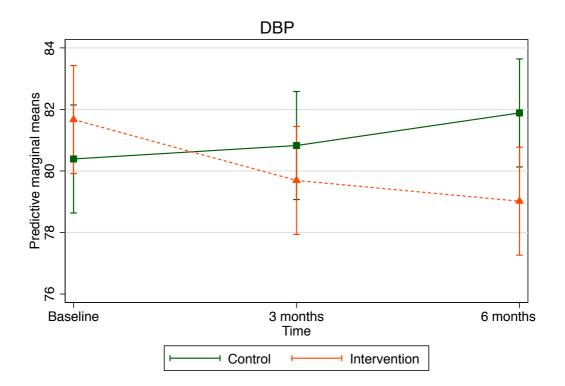


Figure 5.6 Mean DBP changes from baseline to six months by group

Proportion of participants who had achieved hypertension control

In the intervention group, 60.7 per cent of participants achieved their blood pressure control goals (< 140/90 mmHg) at six months (see Figure 5.7). However, in the usual care group, only 38.5 per cent of participants achieved their goals at six months. Participants in the intervention group were 3.9 times more likely to achieve their blood pressure goal of < 140/90 mmHg at six months than

those in the usual care group (P < 0.001). The proportion of participants who achieved blood pressure control at three months was not significantly different between the two groups (P = 0.145). Similarly, 71.1 per cent of participants in the intervention group had achieved the goal of SBP < 140 mmHg at six months, while only 43.0 per cent of participants in the usual care group achieved this goal. The odds were five times higher that intervention group achieved the SBP goal of < 140 mmHg at six months compared to the usual care group (P < 0.001). The proportion of participants who achieved DBP < 90 mmHg was no different between intervention and usual care groups at both three and six months (P = 0.303 and P = 0.538 respectively).

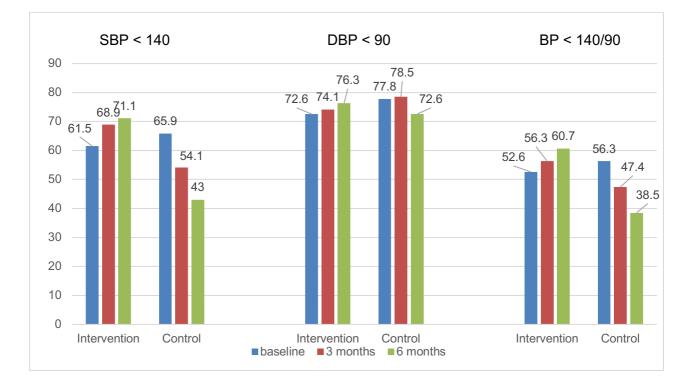


Figure 5.7 Percentage of participants who achieved hypertension control

Target	Adjusted OR at three months, (95%CI)	P- value	Adjusted OR at six months, (95%Cl)	P- value
SBP < 140	2.3	0.008	5.0	0.000
	(1.2, 4.5)		(2.6, 9.8)	

DBP < 90	0.6	0.303	1.3	0.538
	(0.2, 1.5)		(0.5, 3.0)	
BP < 140/90	1.6	0.145	3.9	0.000
	(0.8, 3.4)		(1.9, 8.2)	

Abbreviations: CG = usual care group, IG = intervention group, SBP = systolic blood pressure, DBP = diastolic blood pressure, OR = odds ratio; (2) Odds ratios are reported from logistic models. Adjusted for confounding variables including age, gender, BMI, smoking status, living status, marital status, caregiver support, duration of hypertension, duration of diabetes, polypharmacy, medical insurance and education level.

5.3.3 HbA1c

Figure 5.7 presents the trends of changes in mean HbA1c over time, by study groups. The intervention group demonstrated a statistically significant decrease in mean HbA1c over time compared to the usual care group (see Figure 5.7). In the usual care group, there was a statistically significant decrease in mean HbA1c from 8.1 per cent at baseline to 7.2 per cent at three months. However, this reduction was not sustained, and the mean HbA1c increased to 7.7 per cent at six months. In the intervention group, mean HbA1c significantly decreased from 8.1 per cent at baseline to 7.4 per cent at three months, and 7.2 per cent at six months (see Figure 5.7).

Based on the linear mixed-effect model, the estimated mean difference in HbA1c change between the intervention and usual care groups was 0.1 per cent (95% CI, 0.0 to 0.3, P = 0.035) at three months and -0.4 per cent (95% CI, -0.6 to -0.2, p < 0.001) at six months (see Table 5.4).

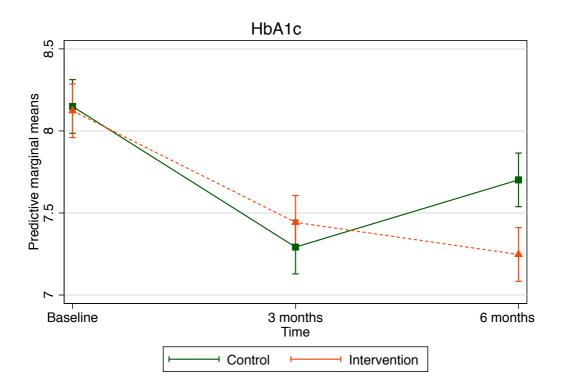


Figure 5.8 Mean HbA1c changes from baseline to six months by group

5.3.4 Fasting blood glucose

Figure 5.8 presents the changes in fasting mean blood glucose over the six-month study period for intervention and usual care groups. In the usual care group, mean fasting blood glucose significantly increased from 7.1 mmol/L at baseline to 7.2 mmol/L at three months and 7.6 mmol/L at six months. In the intervention group, the mean fasting blood glucose significantly decreased by 0.2 mmol/L at

three months from 7.2 mmol/L at baseline to 7.0 mmol/L at three months. However, it significantly increased to 7.1 mmol/L at six months.

The between-group effects of the intervention program in the fasting glucose was -0.4 mmol/L (95% CI, -0.7 to 0.0, P = 0.016) at three months and -0.6 mmol/L (95% CI, -0.9 to -0.2, p < 0.001) at six months (see Table 5.4).

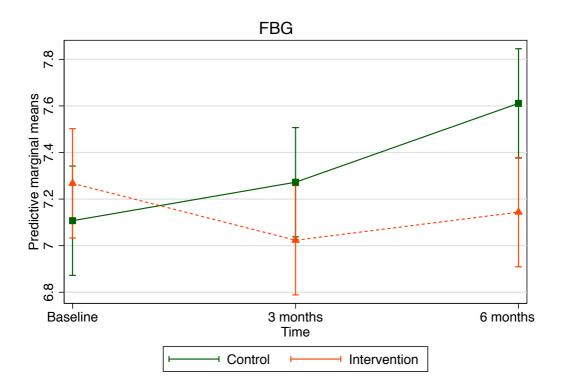


Figure 5.9 Mean fasting blood glucose changes from baseline to six months by group

5.3.5 Low-density lipoprotein

Figure 5.10 presents the changes in mean low-density lipoprotein over the six-month study period for the intervention and usual care groups. In the usual care group, mean low-density lipoprotein increased from 103.0 mg/dl at baseline to 112.3 mg/dl at three months, but mean LDL reduced to 109.8 mg/dl at six months. The intervention group demonstrated a steady, statistically significant reduction in mean low-density lipoprotein from 106.0 mg/dl at baseline to 97.9 mg/dl at three months and 94.5 mg/dl at six months.

Based on the linear mixed-effect model, the estimated mean difference in low-density lipoprotein change between the intervention and usual care groups was -17.4 mg/dl (95% CI, -21.5 to -13.3, P < 0.001) at three months and -18.3 mg/dl (95% CI, -22.4 to -14.1, P < 0.001) at six months (see Table 5.4).

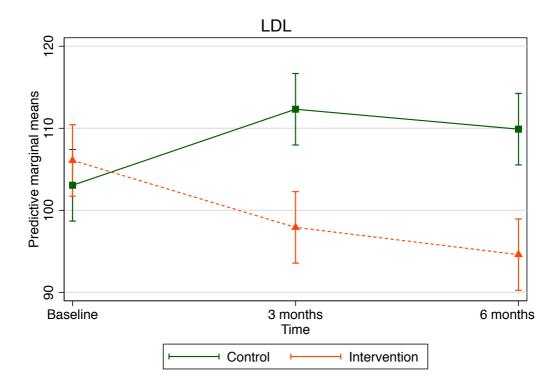


Figure 5.10 Mean low-density lipoprotein changes from baseline to six-month by group

5.3.6 High-density lipoprotein

Figure 5.11 presents the changes in mean high-density lipoprotein over the six-month study period for the intervention and usual care groups. The usual care group demonstrated a steady, statistically significant increase in mean high-density lipoprotein from 41.5 mg/dl at baseline to 42.5 mg/dl at three months, and 44.0 mg/dl at six months. A similar trend in change of mean high-density lipoprotein was observed in the intervention group over time. The intervention group demonstrated a statistically significant increase in mean high-density lipoprotein from 40.1 mg/dl at baseline to 42.8 mg/dl at three months and 43.7 at six months.

Based on the linear mixed-effect model, the estimated mean difference in high-density lipoprotein change between the intervention and usual care groups was 1.8 mg/dl (95% CI, 0.0 to 3.6, P = 0.058) at three months and 1.0 mg/dl (95% CI, -0.7 to 2.9, P = 0.25) at six months (see Table 5.4).

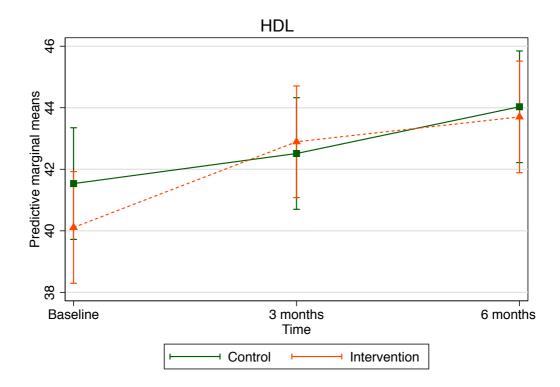


Figure 5.11 High-density lipoprotein changes from baseline to six months by group

5.3.7 Hypertension knowledge

Hypertension knowledge was measured using the hypertension knowledge level scale. In this scale, a higher score indicates a higher level of hypertension knowledge. Figure 5.12 presents the changes in the mean score of hypertension knowledge over the six-month study period for the intervention and usual care groups. In the usual care group, there was a slightly, statistically significant increase in the mean score of hypertension knowledge from 13.4 at baseline to 14.4 at three months, and 14.0 at six months. The intervention group had a greater increase in the mean score over time compared with the usual care group. The intervention group demonstrated a statistically significant increase in crease in mean score of hypertension knowledge from 13.3 at baseline to 16.7 at three months and 17.9 at six months.

Based on the linear mixed-effect model, the estimated mean difference in the changes of hypertension knowledge between the intervention and usual care groups was 2.4 (95% CI, 1.6 to 3.2, p < 0.001) at three months and 3.9 (95% CI, 3.1 to 4.7, p < 0.001) at six months.

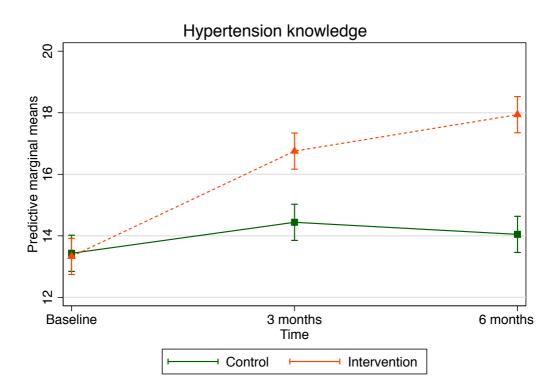


Figure 5.12 Mean score of hypertension knowledge changes from baseline to six months by group

5.3.8 Diabetes knowledge

Diabetes knowledge was measured by the diabetes knowledge questionnaire. In this scale, a higher score indicates a higher level of diabetes knowledge. Figure 5.13 presents the changes in the mean score of diabetes knowledge over the six-month study period for the intervention and usual care groups. In the usual care group, there was a slightly, statistically non-significant improvement in the mean score of diabetes knowledge from 13.2 at baseline to 13.9 at three months, but a statistically significant improvement to 14.1 at six months. The intervention group had a greater improvement over time compared with the usual care group. The mean score of diabetes knowledge in the intervention group demonstrated a statistically significant increase from 12.7 at baseline to 15.9 at three months and 17.1 at six months.

Based on the linear mixed-effect model, the estimated mean difference in the changes of diabetes knowledge between the intervention and usual care groups was 2.5 (95% CI, 1.5 to 3.6, P < 0.001) at three months and 3.5 (95% CI, 2.4 to 4.5, P < 0.001) at six months.

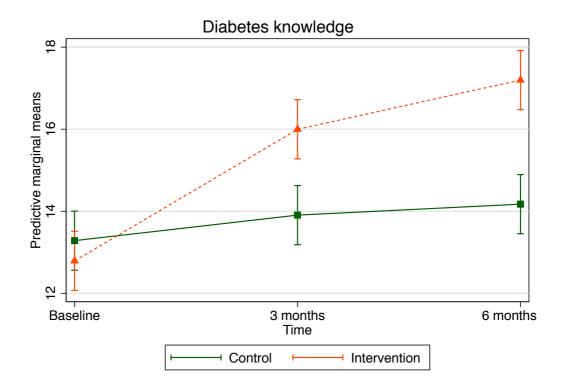


Figure 5.13 Mean score of diabetes knowledge changes from baseline to six months by group

5.3.9 Treatment adherence

Treatment adherence was measured using the treatment adherence questionnaire of patients with hypertension. In this scale, a higher score indicates a higher level of adherence. Figure 5.14 presents the changes in the mean score of treatment adherence over the six-month study period for the intervention and usual care groups. In the usual care group, there was a statistically significant reduction in the mean score of treatment adherence from 86.6 at baseline to 83.7 at three months and 81.3 at six months. In contrast, the intervention group demonstrated an improvement in treatment adherence over time compared with usual care group. The mean score diabetes knowledge in the intervention group significantly increased from 86.3 at baseline to 91.8 at three months and 93.9 at six months.

Based on the linear mixed-effect model, the estimated mean difference in the changes of treatment adherence between intervention and usual care group was 8.4 (95% CI, 5.8 to 11.0, P < 0.001) at three months and 12.9 (95% CI, 10.4 to 15.5, P < 0.001) at six months.

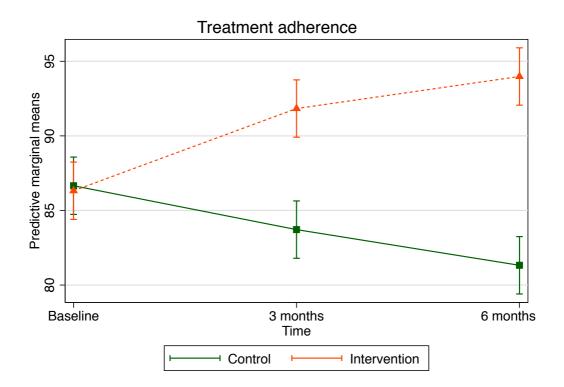


Figure 5.14 Mean score of treatment adherence changes from baseline to six months by group

5.3.10 Quality of life

Quality of life was measured using the hypertension scale of the system of quality of life instruments for chronic diseases. In this scale, a higher score indicates a higher quality of life. Figure 5.15 presents the changes in the mean score of quality of life over the six-month study period between intervention and usual care groups. In the usual care group, there was a statistically significant reduction in the mean score of quality of life from 170.3 at baseline to 165.6 at three months and 161.7 at six months. In contrast, quality of life in the intervention group gradually increased over time. In the intervention group, the mean score of quality of life showed a statistically significant increase from 170.1 at baseline to 173.0 at three months and 179.9 at six months.

Based on the linear mixed-effect model, the estimated mean difference in the changes of quality of life between intervention and usual care group was 7.5 (95% CI, 4.4 to 10.5, P < 0.001) at three months and 18.3 (95% CI, 15.2 to 21.4, P < 0.001) at six months.

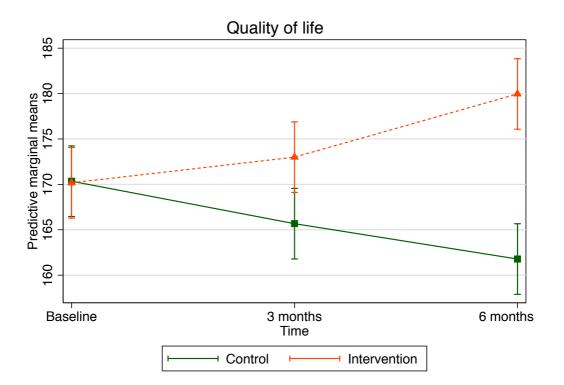


Figure 5.15 Mean score of quality of life changes from baseline to six months by group

The summary of changes in outcome measures at three and six months in the cluster RCT (as discussed above) is presented in Table 5.4.

Outcome	Groups	Baseline	3	6	Within-gr	roup effect		Between-g	roup effect		
measures			months	nths months	3 months vs. baseline (95%CI)	6 months vs. baseline (95%CI)	Differences at 3 months (95%CI)	p-value	Differences at 6 months (95%CI)	p-value	
SBP	IG	136.7	133.2	132.8	-3.4 (-5.9, -0.9) †	-3.8 (-6.3, -1.3)†	-5.0 (-8.5, -1.4)	0.005	-10.7 (-14.2, -7.1)	<0.001	0.006
	CG	135.5	137.1	142.4	1.5 (-0.9, 4.0)	6.8 (4.3, 9.3) †					
DBP	IG	81.6	79.6	79.0	-1.9 (-3.4, -0.5)†	-2.6 (-4.1, -1.2)†	-2.4 (-4.40.3)	0.008	-4.1 (-6.2, -2.2)	<0.001	0.004
	CG	80.3	80.8	81.8	0.4 (-1.0, 1.8)	1.4 (0.0, 2.9) †					
HbA1c	IG	8.1	7.4	7.2	-0.6 (-0.8, -0.5)†	-0.8 (-1.00.7) †	0.1 (0.0, 0.3)	0.035	-0.4 (-0.6, -0.2)	<0.001	0.000
	CG	8.1	7.2	7.7	-0.8 (-0.9, -0.7) †	-0.4 (-0.5, -0.3) †					
FBG	IG	7.2	7.0	7.1	-0.2 (-0.4, 0.0) †	-0.1 (-0.3, 0.1)	-0.4 (-0.7, 0.0)	0.016	-0.6 (-0.9, -0.2)	<0.001	0.020
	CG	7.1	7.2	7.6	0.1 (0.0, 0.4)†	0.5 (0.2, 0.7)					
LDL	IG	106.0	97.9	94.5	-8.1 (-11.0, -5.2) †	-11.4 (-14.3, - 8.5) †	-17.4 (-21.5, - 13.3)	<0.001	-18.3 (-22.4, - 14.1)	<0.001	0.005

Table 5.4 Changes in outcomes at three and six months

	CG	103.0	112.3	109.8	9.2	6.8					
					(6.3, 12.1)†	(3.9, 9.7)†					
HDL	IG	40.1	42.8	43.7	2.7	3.5	1.8	0.058	1.0	0.250	0.000
					(1.4, 4.1) †	(2.2, 4.9)†	(0.0, 3.6)		(-0.7, 2.9)		
	CG	41.5	42.5	44.0	0.9	2.4					
					(-0.3, 2.2)	(1.1, 3.8)†					
Hypertension	IG	13.3	16.7	17.9	3.4	4.6	2.4	<0.001	3.9	<0.001	0.000
knowledge					(2.8, 3.9) †	(4.0, 5.1) †	(1.6, 3.2) †		(3.1, 4.7) †		
	CG	13.4	14.4	14.0	1.0	0.6					
					(0.4, 1.5) †	(0.0, 1.1) †					
Diabetes	IG	12.7	15.9	17.1	3.2	4.4	2.5	<0.001	3.5	<0.001	0.000
knowledge					(2.4, 3.9) †	(3.6, 5.1) †	(1.5, 3.6)		(2.4, 4.5)		
	CG	13.2	13.9	14.1	0.6	0.8					
					(-0.1, 1.3)	(0.1,1.6) †					
Treatment	IG	86.3	91.8	93.9	5.5	7.6	8.4	<0.001	12.9	<0.001	0.000
adherence					(3.6, 7.3) †	(5.8, 9.4) †	(5.8,11.0)		(10.4, 15.5)		
	CG	86.6	83.7	81.3	-2.9	-5.3					
					(-4.7, -1.1)	(-7.1, -3.5)					
					†	+					
Quality of life	IG	170.1	173.0	179.9	2.8	9.7	7.5	<0.001	18.3	<0.001	0.025
					(0.6, 5.0) †	(7.6, 11.9) †	(4.4, 10.5)		(15.2, 21.4)		
	CG	170.3	165.6	161.7	-4.6	-8.5					
					(-6.8, -2.5)	(-10.7, -					
					†	6.3) †					

Note: (1) Abbreviations: CG= usual care group, IG = intervention group, SBP = systolic blood pressure, DBP = diastolic blood pressure, HbA1c = haemoglobin A1c, FBG = fasting blood glucose, TC = total cholesterol, LDL = low-density lipoprotein, HDL = high-density lipoprotein, ICC = intraclass correlation coefficient. (2) Adjusted for confounding variables including age, gender, BMI, smoking status, living status, marital status, caregiver support, duration of hypertension, duration of diabetes, polypharmacy, medical insurance and education level. (3) † The mean difference is significant in the mixed-effect linear regression model. (4) ICC: intraclass correlation coefficient that measures the degree to which outcome measurements from participants in a cluster are correlated.

5.3.11 Adverse events

Ten adverse events that most frequently occurred during the six-month trial are reported in Table 5.5. The number of adverse events was reported by a higher percentage of participants in the usual care group than in the intervention group. Adverse events such as dizziness, headache, sleep difficulties, blurred vision, pins and needles, nausea, cough, falls, and swelling of legs or ankles, but nor fatigue, occurred more frequently in the usual care group than in the intervention group. The usual care group had a 1.5 times higher incidence of dizziness than the intervention group over the six months (P = 0.043). The usual care group had a 1.7 times higher incidence of headache than with the intervention group over the six months (P = 0.019). The usual care group had a 1.8 times higher incidence of pins and needles (P = 0.027). The incidence rate of falls and fall-related injuries in the usual care group was 2.2 times higher than it was in the intervention group (P = 0.026). The incidence rate of fatigue, sleep difficulty, blurred vision, nausea, swelling of legs or ankles did not show statistical significance between the two groups. No adverse events or injuries were stated to have occurred as a direct result of participating in the study.

Adverse events	Control group n (%)	Intervention group n (%)	IRR (95% CI)	p-value
Dizziness	40 (29.6%)	26 (19.2%)	1.5 (0.9, 2.6)	0.043
Headache	38 (28.1%)	22 (16.3%)	1.7 (0.9, 3.0)	0.019
Fatigue	22 (16.3%)	30 (22.2%)	0.7 (0.4, 1.3)	0.135
Sleep difficulty	29 (21.5%)	20 (14.8%)	1.4 (0.7, 2.7)	0.101
Blurred vision	26 (19.3%)	24 (17.8%)	1.0 (0.5, 1.9)	0.389
Pins and needles	29 (21.5%)	16 (11.9%)	1.8 (0.9, 3.5)	0.027
Nausea	23 (17.0%)	18 (13.3%)	1.2 (0.6, 2.5)	0.220
Cough	26 (19.3%)	15 (11.1%)	1.7 (0.8, 3.5)	0.044
Swelling of legs or ankles	20 (14.8%)	15 (11.1%)	1.3 (0.6, 2.7)	0.202
Falls and fall-related injuries (e.g., fracture)	18 (13.3%)	8 (5.9%)	2.2 (0.9, 5.9)	0.026

Table 5.5 Comparison between groups of reported adverse events at six months (10 most
reported adverse events)

Note: (1) IRR = incidence rate ratio. Data are presented in frequency (%). (2) IRR was calculated based on Poisson regression analysis.

5.3.12 Unplanned hospital readmission or the use of emergency care services

The number of participants who experienced unplanned hospital admission or emergency care services at six months in the usual care group was 25 (18.5 per cent) compared with 46 (34.1 per

cent) in the intervention group (see Figure 5.16). Participants in the intervention group showed a significantly lower number of unplanned hospital admission/emergency care services at six months than the usual care group (P = 0.008). The usual care group had 1.8 times the incidence of hospital readmission or emergency care services than the intervention group over the six months (P = 0.006). The incidence rate of hospital readmission in the usual care group was 2.4 times higher than the intervention group (P = 0.008). The incidence rate of emergency care services in the usual care group was 1.9 times higher than it was in the intervention group (P = 0.014).

at six months	5	•	0,	
Adverse events	Control	Intervention	IRR (95% CI)	p-value
	Group, n (%)	Group, n (%)		

24 (17.7%)

31 (22.9%)

46 (34.1%)

2.4 (1.1, 5.6)

1.9 (1.0, 3.7)

1.8 (1.1, 3.1)

0.008

0.014

0.006

at six months	
Table 5.6 Comparison between groups of hospital readmission/emergency care service use	е

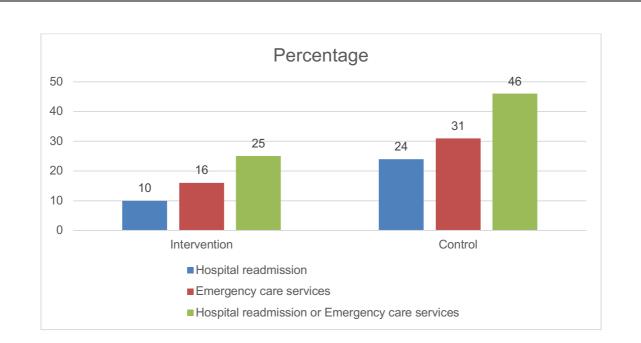


Figure 5.16 Comparison between groups of hospital readmission/emergency care service use at six months

5.4 Content analysis of the open-ended questions

10 (7.4%)

16 (11.8%)

25 (18.5%)

Unplanned hospital

Unplanned hospital

Emergency care services

admission or emergency

readmission

care services

At the completion of the trial, patients in the intervention group were asked to respond to two openended questions:

- (1) Are you satisfied with the follow-up provided by the GP and community nurse in the community health centres? (If not, please explain the reason.)
- (2) Did you encounter any difficulties of care in the community health centres after discharge?(If yes, please list the difficulties you encountered.)

Inductive content analysis was used to identify categories arising from the data. Positive experience was achieved if participants were satisfied with the services provided by the health professionals in the present study and did not encounter difficulties in receiving services in the community health centres after discharge. Most participants in the current study reported positive experiences during the six months' follow-up at community health centres. Participants also reported concerns and suggested ways to resolve these issues. Findings from the content analysis are presented in Table 5.7.

Table 5.7 Content analysis of open-ended questions

Category	Examples from participants	Suggestions from participants		
Positive comments on the trial	 Through the health education at community health centre, I know more about my disease progression. I know the healthy diet I should take. I engage in physical activity and I know how to manage my medications. 			
	2. I feel safe at home after discharge, as I receive services from the community health centre. I can get consultations I need from staff there. This is quite different than my previous experiences when I was discharged from hospital. I could not receive any services from them previously.			
	 I have more time and opportunities to discuss with staff at the community health centre about my conditions and concerns. Now, I know what I can do and what I cannot do in managing my conditions. 			
	 Whenever I need to see the GP, I can just ring staff to make appointment, I don't have to wait for a long time to get appointment to see specialists at hospital. 			
Barriers to care services in he community	 I cannot go to community health centre to see doctors and nurses during the day because of my swelling legs. My son has full-time work and cannot help in most times when I need him. 	 Provide home visit and home care when needed. Home delivery of medications. More health professionals 		
	 If I need to refill prescriptions, I have to wait for my son to help me. 	employed at community centres—government		
	 Some medications, for example insulin and Glucophage are prescribed by the specialist. I cannot obtain from GPs at the community health centre. I have to go to hospital to get these. 	commitment to increase medication supply at the community health centre.		
	 I had a headache this morning when I got up. My son was working at that time. I felt helpless as I did not know who I should contact. 	- -		

	5.	I have to wait for a long queue to see my GP. If my GP has to serve many patients, then the consultation time with my GP will be shortened.		
	6.	I live alone, and I am unable to measure my blood pressure appropriately. I need someone to help me to measure my blood pressure.		
Barriers to health education	1.	I found the contents of education sometimes is very difficult to understand.	1.	Use plain language in health education that is suitable for
	2.	I was told too many medicine-related vocabularies that I have		individual education level.
		never heard before.	2.	Use pictures and photographs ir
	3.	I feel difficulty in following instructions from the community		the education.
		nurse sometimes due to my health conditions. I need my wife to be with me and help me.	3.	Group education to allow interactions and with others.
			4.	Engage family members in self- care education.
The need to have a designated GPs and community nurse	1.	The GP and community nurse I visited every month are not the same people. They don't really understand the changes of my conditions.	1.	Need to appoint in-charge GP and in-charge nurse for the patient during the follow-up.
Financial hardship	1.	Sometimes I have to stop the medical treatments because I could not afford them.	1.	Improve government subsidies for medication treatment for
	2.	Medication is expensive. I feel stressed when I cannot meet the payment for medication treatment.		community-dwelling older people

5.5 Analysis of intervention fidelity

Intervention fidelity is described as the degree to which the intervention is delivered in line with the planned protocol (Gearing et al., 2011). Strategies to improve intervention fidelity include:

- (1) a theoretical framework-informed study design
- (2) an explicitly described protocol to implement the intervention
- (3) training and support for health professionals who deliver the intervention
- (4) carefully monitoring the process and outcomes of the intervention (Breitenstein et al., 2010; Horner et al., 2006; Horner, 2012).

The present study considered these strategies. First, the hypertension management program was informed by the chronic care model and the PET model. Second, the study protocol of the cluster RCT described detailed interventions. These were documented in 'A guideline for health professional to implement the hypertension management program' and 'A booklet for older people enrolled in the hypertension management program'. Third, a workshop at each intervention site was provided to enable health professionals to implement the hypertension management program was also provided through information provision, problem-solving and site visits by the PhD student when needed. The process and outcomes of the program were carefully monitored using the 'Intervention diary—Patient version', 'Intervention record—Community nurse and GP version' and data collection at three time points. In addition, participants' responses regarding their satisfaction with the program were sought via open-ended questions to complement the monitoring of the program.

Compliance with the study protocol was mainly analysed based on information collected from the 'Intervention diary—Patient version' and 'Intervention record—Community nurse and GP version'. All intervention diaries were collected at three months and six months for analysis. The completion of intervention items recorded by service recipients and service providers were compared. The matching of these intervention items was viewed as a compliance measure. Findings are summarised in Table 5.8 and explained in the Chapter 6.

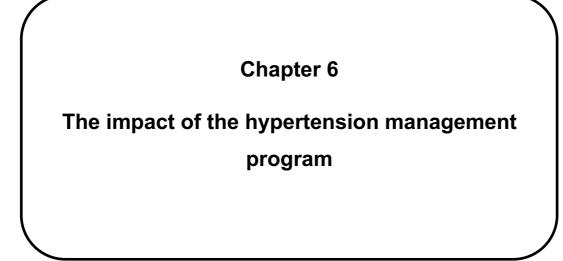
Table 5.8 Compliance with the study protocol based on information from the patient andmedical professional intervention records

Items	Intervention record— Community nurse and GP version	Intervention diary— Patient version
Health behaviour education, disease- associated education, medication education and geriatric conditions education by in-charge nurse	Prior to discharge	Yes
Develop an individualised medication treatment plan prior to discharge by specialist	Prior to discharge	Yes
Assess patients' problems of non- adherence to medication, possible medication side effects, geriatric conditions and significant clinical events by GP	Monthly	Yes
Assess whether patients' drug-related needs are being met and any drug therapy problems present by GP	Monthly	Yes
Review, adjust and discuss individualised plan for medication treatment by GP	Monthly	Yes
Telephone call (monitor patients' progress towards the goal, medication adherence, encourage blood pressure self-monitoring) by community nurse	Fortnightly	Yes
Measure of blood pressure, blood glucose and lipids by community nurse	Monthly	Yes
Review and assess patients' adherence to medication and lifestyle, and the progress towards lifestyle modification goals by community nurse	Monthly	Yes
Reinforce health behaviour education, disease-associated education, medication education and geriatric condition education by community nurse	Monthly	Yes
Inform and remind patients of the category, dosage and frequency of medication by community nurse	Monthly	Yes
Send monthly clinic report of patient to medical specialist for review by community nurse	Monthly	Yes

In Stage 1 of the program (in hospital), records from discharge nurses and patients achieved a 100 per cent match, an indicator of compliance with the required intervention components at the hospital prior to discharge. In Stage 2 of the program (community health centres), records from community nurses and GPs, and records from patients in the intervention group also matched well. However, as only 113 out of 135 patients submitted their diaries, compliance with required intervention diaries, 10 were readmitted to hospital, five were withdrawal from the study, and seven were on leave during visits.

5.6 Summary

This chapter has presented the findings from a cluster randomized controlled trial designed to evaluate the effectiveness of a hypertension management program for older people with diabetes in Nanchang, China. A total of 270 older people (135 in each group) were recruited into the trial. At the completion of the trial, the intervention group demonstrated a statistically significant decrease of mean SBP of 10.7 mmHg (95%CI: -14.2 to -7.1, P < 0.001) and a mean DBP of 4.1 mmHg (95% CI: -6.2 to -2.0, P < 0.001), compared to the usual care group. Findings also demonstrated significant improvements of HbA1c, LDL, hypertension knowledge, diabetes knowledge, treatment adherence, quality of life, reduced adverse events and hospital readmission in the intervention group compared to the usual care group. There was no significant difference on HDL between the two groups. The analysis of intervention fidelity reveals compliance with intervention protocol. Chapter 6 will interpret and discuss the results presented in this chapter.



Chapter 6 The impact of the hypertension management program

6.1 Introduction

Chapter 5 presented findings from a cluster randomized controlled trial designed to evaluate the hypertension management program for older people with diabetes. Findings support the hypothesis that the evidence-based hypertension management program developed in the project can improve blood pressure control in people aged years 60 and over with diabetes as compared to usual care. The primary outcome measure was SBP at six months' follow-up. The finding revealed that the intervention was effective in controlling SBP, as evidenced by a significant decrease in mean SBP (-10.68 mmHg; 95% CI: -14.24 to -7.13 mmHg) in the intervention group compared to the usual care group. The secondary outcome measures included diastolic blood pressure (DBP, HbA1c, fasting glucose, LDL, HDL, hypertension knowledge, diabetes knowledge, treatment adherence and quality of life at six-months' follow-up. Findings also demonstrated effective controls of DBP, HbA1c, fasting glucose and LDL control at six-months' follow-up in the intervention group compared to the usual care group. There was no significant difference in HDL between the two groups. Further, findings showed significant improvements of hypertension and diabetes knowledge, treatment adherence and quality of life in the intervention group, compared to the usual care group. In addition, findings demonstrated reduced adverse events and hospital readmission. This chapter discusses the impact of the hypertension management program.

6.2 Impact of the intervention on hypertension control

In the present study, the positive impact of the hypertension management program on the control of hypertension was evident and indicated by the higher proportion of participants with normal blood pressure (< 140/90) at six-months' follow-up in the intervention group (70.3%) after discharge from hospital compared to the usual care group (44.4%) (p < 0.001, see Table 5.6). Although both the intervention and usual care groups showed similar rates of controlled blood pressure (< 140/90) at the discharge point (52.6% in intervention group and 56.3% in usual care group; see Table 5.6), participants with normal blood pressure declined 8.9 per cent at three months (from 56.3% to 47.4%) and 17.8 per cent at six months (from 56.3% to 38.5%) in the usual care group. Conversely, the intervention group demonstrated a 3.7 per cent increase in the number of participants with normal blood pressure at three months (from 52.6% to 56.3%) and an 8.1 per cent increase at six months (from 52.6% to 60.7%). The proportion of participants who achieved blood pressure < 140/90 was not significantly different between the two groups at three months (P = 0.145, see Table 5.3), but

there was a significant difference at six months (P = 0.000, see Table 5.3). These findings indicate that the intervention effect appeared after three months. The findings further support the need to provide this patient population with at least a six-months' follow-up support after discharge to sustain the hypertension control.

The results further support findings from previous studies that primary care is an effective approach to supporting older people to sustain self-care at home (Heisler et al., 2012; Willard-Grace et al., 2015). The results also support that an integrated care system built on collaboration between hospitals and community health centres is a suitable care model to maintain continuity of care for this population (Bayliss et al., 2015). However, unlike previous studies that initiated integrated care by GPs in primary care in China (Qian et al., 2017), the present study explored the hospital-initiated integrated care (discussed in Chapter 7).

The positive impact of the program on hypertension control in the present study is similar to that of other community-based interventions reported in previous studies (Edelman et al., 2015; Lin et al., 2014). In the study by Edelman et al. (2015), intervention components were limited to nonpharmacological treatments without medication intervention. In their study, the proportion of patients who achieved the SBP goal in the intervention and usual care groups were 19.2 per cent and 20.1 per cent respectively, without achieving significant difference. However, in the study by Lin et al. (2014) in China—who designed intervention to target both pharmacological and non-pharmacologic treatment-71 per cent of patients in the intervention group achieved the SBP goal of < 140, compared to 32 per cent in the usual care group. This study demonstrated better outcomes than those reported by Edelman et al (2015). It should be noted that the mean age of participants in these studies were younger than those in the present study. Age is an indicator of additional difficulties in hypertension control (Bosu et al., 2017). The better outcome in hypertension control in the present study, compared to the previous studies, may be attributed to the intervention design that targeted the healthcare system using an integrated care model that emphasises collaboration between hospitals and community health centres and multiple component intervention interventions (discussed in Chapter 7). The findings were likely to be sustained after six months duration as the intervention was imbedded in the routine practice due to the support of local government. As a multilevel and multi- component intervention in nature, it is very difficult to determine the components of the intervention that were effective. The cost-effectiveness was not evaluated in the current trial, but health service integration has been seen as a way to lower healthcare costs in many countries (Xu et al., 2016).

In the present study, for the proportion of patients who achieved the DBP goal of < 90 mmHg, there was no significant statistical difference between the two groups at both three months and six months. Findings may reflect the features of ISH in older people, which is characterised by increased SBP

and pulse pressure difference (Wallace et al., 2007). It was estimated that more than 65 per cent of people with hypertension aged 60 years or over and more than 90 per cent of those aged older than 70 had ISH (Nguyen et al., 2012). As age increases, arteries and arterioles become thicker and less elastic, which results in higher SBP and reduced diastolic pressure (Pinto, 2007).

The positive impact of the program on SBP control in the present study supports other studies. In a prospective RCT in UK, researchers evaluated the effectiveness of community pharmacist-led regular monitoring and consultations for people with the multimorbidity of hypertension and diabetes. They found a significant improvement in SBP control over 12 months (Fu, Zhao, Zhang, Chai, and Goss 2018). However, researchers also found that the intervention did not result in DBP control. In an RCT in Spain, researchers evaluated the effectiveness of individualised health education for people with the multimorbidity of hypertension and diabetes. The education was delivered in urban community health centres over two years; the study reported a statistically significant reduction in mean SBP (3.0 mmHg), but not in mean DBP (Salinero-Fort et al., 2011). Compared to the above two studies, the current study demonstrated a greater reduction of mean SBP (10.7) at six months. The better outcomes might be attributed to the multicomponent intervention that included health education, support for self-care and individualised medication treatment.

Studies have revealed that individualised medication treatment is a key component of effective intervention for patients with uncontrolled hypertension. In an RCT in the US, researchers evaluated a team approach to improving hypertension management for patients with uncontrolled hypertension in GMCs in primary care settings (Edelman et al., 2010). The intervention included (1) individualised plans for medication treatment and lifestyle changes developed by the pharmacist and primary care internist; and (2) tailored education sessions by the nurse. After a one-year intervention period, patients in the intervention group had a greater SBP reduction (7.3 mmHg) than the usual care group. The success of this study might be attributable to the individualised intensification of medication treatment and the longer duration of each education session (two hours). In a Brazilian study (Paula et al., 2015), patients in the intervention group who received pharmaceutical care from a clinical pharmacist had an SBP reduction of 23.4 mmHg over three years compared to the usual care group. The considerable reduction in SBP found in this study might be attributable to the length of intervention and the higher level of SBP (156 mmHg) at baseline.

6.3 Impact of the intervention on blood glucose control

Intervention in the present study also demonstrated a positive impact on blood glucose control. This supports previous findings that intervention targeting blood pressure control may have a spillover effect on diabetes control (Powers et al., 2009). It is widely recognised that patient behaviour required for effective hypertension and diabetes care overlap in several areas (Long & Dagogo-Jack,

2011). In the present study, both the intervention and usual care groups showed uncontrolled HbA1c at baseline, an indicator of uncontrolled blood glucose in the past three months or prior to their hospitalisation (HbA1c reflects blood glucose levels over the preceding two to three months) (Sherwani et al., 2016). A reduction of mean HbA1c at three and six months was also observed in both groups compared to the baseline HbA1c. The usual care group demonstrated a greater mean reduction of HbA1c at three months (-0.8%, see Table 5.4) than the intervention group (-0.6%, see Table 5.4). The between-group difference at three months might be attributable to the hospital treatment considering that HbA1c is related to blood glucose levels over the past two to three months.

A mean HbA1c decline of 0.4 per cent was observed in the intervention group compared to the usual care group at six months (see Table 5.4). The result indicate that the program contributes to sustained blood glucose control beyond the three-month follow-up after discharge. The positive impact of the intervention on HbA1c control identified in the present study differs from previous studies. In an RCT in the US, researchers identified no significant difference in mean HbA1c between the intervention and usual care groups, although the intervention group recorded a significant impact on hypertension control (Edelman et al., 2010). The result might be due to the well-established primary care system in the US that supports glycaemic management at facilities for both the intervention and usual care groups. Therefore, it is less likely that a difference in HbA1c would be observed between the groups. In another US RCT, researchers evaluated a nurse-led telephone intervention over 12 months among 359 African Americans (Crowley et al., 2013). The interventions included quarterly medication management intensification and monthly self-management support. Results revealed no significant differences in HbA1c over the 12 months between the intervention and usual care groups. Analysis of the detailed intervention in the study revealed that although GPs replied to 76 per cent of nurses' reports on patient conditions in the study, only 18 per cent of their replies were associated with medication changes. The lack of direct assessment by the GPs and medication adjustment based on their assessment might explain the lack of significant improvement of HbA1c control in the RCT. In another large RCT in the UK, researchers evaluated the differences between tight and a less-tight blood pressure control treatment regimens among 1,148 patients with hypertension and newly diagnosed diabetes in a four-year period (Holman et al., 2008). The positive impact of the intervention on HbA1c and fasting glucose were not observed in the short term but were in the fourth year for HbA1c and the third year for fasting glucose.

The differences in mean fasting glucose between the intervention and usual care groups were 0.4 at three months and 0.6 at six months (see Table 5.4). These differences were statistically significant. It should be noted that the fasting glucose began to rise in the intervention group after three months' intervention. This finding was consistent with the results of previous RCTs, in which the effect of education intervention in glycaemia control was diminished from the eight month (Davies et al.,

2008). The findings may indicate that intervention might have a limited duration and periodical reinforcements of health education is needed.

6.4 Impact of intervention on low-density and high-density lipoprotein

A high level of low-density lipoprotein is recognised as a contributing factor to coronary heart disease and other cardiovascular diseases (Mahdy Ali et al., 2012). Conversely, high-density lipoprotein is viewed as a protective factor against coronary heart disease (Mahdy Ali et al., 2012). A positive impact of intervention on the reduction of mean low-density lipoprotein at three and six months was observed in the intervention group in the present study (from 106 at baseline to 97.9 at three months and 94.5 at six months; see Table 5.4). On the contrary, the usual care group demonstrated an increased mean low-density lipoprotein at three and six months compared to the baseline mean lowdensity lipoprotein (from 103 at baseline to 112.3 at three months and 109.8 at six months; see Table 5.4). The difference of mean low-density lipoprotein between the two groups is significantly different. The reduction of low-density lipoprotein might be associated with healthy diet, physical exercise and compliance with medication treatment to lower low-density lipoprotein in the intervention group. Findings of the present study are similar to an RCT study by Willard-Grace (2015) that assessed the effect of health coaching for people with the multimorbidity of hypertension and diabetes. In this study, low-density lipoprotein was reduced by 27.9 mg/dL among people receiving health coaching compared with a reduction of 18.1 mg/dL for those without health coaching. The greater reduction in low-density lipoprotein in this study compared to the present study may be due to the higher mean low-density lipoprotein level at baseline (147.0 mg/dL) and relatively younger mean age (52.7 years). It was reported that low-density lipoprotein level was negatively associated with ageing.

An incremental change in mean high-density lipoprotein was observed in both the intervention and usual care groups in the present study. However, the differences of mean high-density lipoprotein between the two groups at three and six months were not statistically significant. The results may due to the several reasons. First, the intervention might have had a limited influence on participants' consumption of food with rich high-density lipoprotein. Second, participants may have had a limited choice of food with rich high-density lipoprotein due to financial difficulties, as indicated in their responses to the open-ended questions. Findings of the present study on high- and low-density lipoprotein are similar to those of Allen et al. (2011). Interventions in their study included a 12-month comprehensive aggressive pharmacologic treatment and health behaviour counselling. No significant difference was reported between groups for high-density lipoprotein. The results may be attributable to the ceiling effects, as a well-controlled high-density lipoprotein (50.8 mg/dL) was shown at baseline in that study.

6.5 Impact on hypertension knowledge and diabetes knowledge

The intervention showed a positive impact on the mean scores of hypertension knowledge at three and six months in the present study. The intervention group demonstrated a significant improvement in hypertension knowledge at both time points compared to the usual care group. Moreover, a continuous improvement of hypertension knowledge across the three time points was also observed in the intervention group, an indicator of knowledge retention. A slight improvement of hypertension knowledge was observed in the usual care group at three months. This may be attributable to usual health education prior to discharge from hospital. However, the usual care group demonstrated a declined mean score of hypertension knowledge at six months, evidence of poor knowledge retention. Diabetes knowledge was increased in both groups, but the intervention group showed a significantly higher mean score of diabetes knowledge than the usual care group. Again, the finding is evidence that the program has a positive impact on knowledge retention.

Several factors may have contributed to the positive impact on hypertension knowledge and diabetes knowledge. First, the intervention was built on individualised health education and targeted participants' real learning needs to address daily self-care challenges. Second, patients were motivated to learn, as they were encouraged to establish self-management goals and received verbal persuasion through regular telephone support and follow-up visits to community health centres. They were also given opportunities to apply their knowledge to self-care throughout the program and received regular feedback from community nurses on their actions and outcomes.

Previous studies suggested that disease-specific education might lead to positive changes in health outcomes. In an RCT study conducted in Guangzhou, China by Lu et al. (2015), participants were randomly assigned to one of the three different community-based programs of group education sessions over two years: (1) monthly interactive education group, (2) monthly didactic lecture group, and (3) self-learning group. Greater improvement in hypertension-related knowledge scores was observed in the interactive education workshop group compared with the two other groups. The present study confirms these findings, with further evidence that interaction with community nurses is more effective as an education strategy in improving and retaining health knowledge for patients.

6.6 Impact on adherence to treatment

The hypertension management program implemented in the present study showed a positive impact on treatment adherence for the intervention group at three and six months. Moreover, a continuous improvement in treatment adherence across the three time points was also observed in the intervention group, an indicator of better treatment adherence throughout the follow-up period. A gradual decline in treatment adherence scores from baseline to six months was observed in the usual care group, which might due to the lack of individualised health education on disease-related knowledge provided by health professionals in community health centres. Findings support previous studies that patients with disease-related knowledge demonstrate an ability to transfer this knowledge into action, such as treatment adherence (Giena et al., 2018).

The present study also confirmed findings from a cross-sectional study in China that medication adherence was significantly associated with better SBP control (P < 0.001) (Yue et al., 2015). A significant improvement in adherence to both healthy lifestyle and medication treatment is a likely reason for better blood pressure control in the present study. A previous systematic review and meta-analysis found that controlled blood pressure was associated with a combined improvement in adherence to medication and lifestyle changes (Conn et al., 2015). Findings in the present study also identified the positive association between improved treatment adherence and reduced blood pressure (Wu et al., 2018).

In the present study, a decline of medication adherence in the usual care group might reflect the difficulties in achieving optimal medication adherence for older people due to the higher intensity and complexity of treatment regimes. Further, most participants had other chronic conditions besides diabetes and hypertension. Polypharmacy and multiple daily doses of medication were identified among this patient population that required not only self-care capability, but also help seeking needs-based advice and medication adjustment from GPs in community health centres. A previous study reported that elderly patients were prone poor adherence to medications in the presence of long-term multimorbidity such as hypertension and diabetes (Yue et al., 2014). The present study considered barriers to medication adherence and designed intervention diaries to assist participants to improve adherence through self-evaluation.

The present study also supports the findings of Yu and colleagues in China (2014), in which eight individualised lifestyle consultation sessions were provided by community health centre GPs for people with the multimorbidity of diabetes and hypertension in a three-month trial. The study demonstrated a significant improvement in adherence to physical activity and resulted in reduced blood pressure. However, it was a short trial and was not a parallel RCT study, but a waitlist control design. A late group served as the usual care group and was conducted after the intervention had been completed. This design potentially resulted in bias in terms of a lack of equivalence between the intervention and usual care groups.

Studies identified that behavioural change to adhere to medication treatment and health lifestyle cannot be achieved in a short-term intervention or a single visit to health clinics (Conn et al., 2015). The present study demonstrated that a six-month follow-up after discharge from hospital was required to achieve an optimal outcome in treatment adherence. Health professionals in community health centres need sufficient time to interact with participants to understand the challenges they

face in changing behaviour, and repeatedly address these challenges at each follow-up to achieve an appropriate treatment adherence. The present study confirmed with a systematic review that treatment adherence could only be achieved through persistent intervention across multiple followup visits (Conn et al., 2015). The improvement in treatment adherence in the present study also supported a cross-sectional study that care services in community settings were more likely to reduce non-adherence than those at hospitals (Zhang et al., 2018). The prolonged interactions between patients and health professionals in community care settings may contribute to greater trust between these groups, leading to increased compliance with treatment and behavioural change advice from health professionals.

6.7 Impact on quality of life

Findings revealed that intervention had a positive impact on quality of life. Mean scores of quality of life at three and six months increased in the present study. Moreover, a continuous improvement in quality of life across the three time points was also observed in the intervention group, an indicator of better health conditions. A gradual decline in the quality of life score from baseline to six months was observed in the usual care group. This may be attributable to poor health conditions due to a lack of care support in the community after discharge from hospital.

In the present study, quality of life was measured using the hypertension-related quality of life scale, which includes four broad domains: physical function, psychological function, social function and a specific domain on hypertension-related symptoms and side effects. The main reasons for the higher guality of life in the intervention group in the present study include better hypertension control, adherence to treatment and reduced adverse events (symptoms and side effects) in the intervention group as discussed above. Findings support a systematic review and meta-analysis that verified the effects of antihypertensive treatment on the quality of life of individuals with hypertension (Souza et al., 2016). In their study, adherence to non-pharmacological and pharmacological treatment improves quality of life by 2.45 and 9.24 points respectively which was consistent with our findings (Souza et al., 2016). The improved quality of life measurement in the present study was higher than that reported in the systematic review. The combination of non-pharmacological and pharmacological intervention in the present study might have contributed to the better outcomes. Findings were also in line with a quasi-experimental trial in Chongqing, China, in which researchers evaluated a two-year integrative strategy of health services for patients with hypertension in rural areas (Miao et al., 2016). The study implemented collaboration between physicians from different health systems and individualised lifestyle and health coaching for patients. The study demonstrated positive effects on both quality of life and hypertension control.

6.8 Impact on adverse events and unplanned hospital readmission or emergency care services

In the present study, the positive impact of the program on the control of adverse events and unplanned hospital readmission or emergency care services at six months was evident. The number of participants who experienced unplanned hospital admission or emergency care services at six months in the usual care group was 46 (34.1%) compared with 25 (18.5%) in the intervention group (p < 0.001; see Table 5.6).

Adverse events, unplanned hospital readmission or emergency care of patients are usually associated with complications and cardiovascular events related to uncontrolled hypertension, blood glucose and medication side effects (Emons et al., 2016; Qayed & Muftah, 2018). Several factors might have contributed to the positive impact. First, the intervention group demonstrated improved self-care knowledge and adherence to treatment and better-controlled hypertension. Second, their knowledge and skills might have enabled them to identify and report early signs and symptoms of medication side effects and hypertension- or/and diabetes-related complications, granting them timely treatment in the community setting. Findings were in line with a systemic review that identified a 10 mmHg reduction in SBP was associated with a significantly lower risk of morality, cardiovascular disease events, stroke events, albuminuria, and retinopathy (Toklu & Bangalore, 2015); therefore, patients reported a low rate of hospital admission or emergency care services.

Hospital readmission of patients often results from a lack of self-understanding of illnesses or treatment plans and difficulty following self-care instructions (including medication use and follow-up care) (Dye et al., 2018). The intervention in the present study that addressed these barriers might have explained the lower hospital readmission compared with usual care group. In an RCT study in China, researchers evaluated the effect of community-based health management on the health of older people in a six-month period (Chao et al. (2012). Findings revealed no significant difference in hospital admissions between the intervention and usual care groups. In the present study, the significant difference in hospital admissions between the intervention and usual care groups might be attributed to individualised health education for participants in preventing hypertension- and diabetics-associated complications and side effects of medication treatment. In addition, the establishment of integrated care in the present study and the participation of health professionals in the hospital offsetting the care deficits of community care might also have played a role. However, a cluster RCT conducted in the UK by Fletcher et al. (2004) found the admission rate of older people did not differ between the hospital management and primary health service care. This finding might be due to the UK's well-established primary care system. However, in China, the primary care system is underdeveloped and collaboration between community health centres and hospitals is necessary to improve care services.

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6.9 Satisfaction with the intervention program

Findings of the present study aligned with previous studies—collaboration between hospitals and community health centres in care provision was highly valued by community-dwelling older people in China with the multimorbidity of hypertension and diabetes (Shi et al., 2015; Wei et al., 2013; Wong et al., 2017). Most patients in the intervention group commented that the intervention program was useful and expressed satisfaction with the health care they received. Benefits of the program they perceived included (1) sufficient time and opportunities to consult with GPs and community nurses about concerns and difficulties they faced in self-care; (2) continuum of care; and (3) coordination between GPs and specialists based on their comparisons with their previous experiences as outpatients of hospitals. In addition, waiting time was much shorter, and attitudes of GPs and community nurses were better at community health centres compared to those of staff at outpatient clinics of hospitals. Similar findings were reported by National Heart Foundation of Australia (2016). In this study, patients seeking care from community health centres demonstrated a higher level of satisfaction. Findings on the satisfaction with primary care in the present study were consistent with a cross-sectional study that compared patients' perception of the quality of primary care in China using a primary care assessment tool (Hu et al., 2016). Researchers reported that patients were more likely to report satisfactory experiences on quality of primary care than hospital patients were in terms of contact time with healthcare providers, access to care resources, ongoing care and comprehensive services (Hu et al., 2016).

In the present study, participants' positive comments on primary care provided evidence that collaboration between hospital specialists and community health centre GPs could provide adequate pharmacological treatment for older people with the multimorbidity of hypertension and diabetes. Moreover, community health centres were viewed as ideal care settings in which to provide non-pharmacological interventions for this patient population. However, a study in China reported that collaboration between community health centres and hospitals accounted for less than 10 per cent of care services in the community (Li et al., 2016). Programs that foster collaboration between community health centres are in high demand to improve patients' satisfaction with primary care in China.

6.10 Issues identified in the intervention program

Issues raised by participants in the intervention program included: (1) barriers to care services in community health centres; (2) barriers to health education; (3) the need to have designated GPs and community nurses; and (4) financial hardship. Most comments were associated with barriers to care services in community health centres. As participants were older people, they faced difficulty attending appointments with GPs and refilling prescriptions due to declined mobility. They expected

to have home visits from GPs and community nurses and home delivery of medication. The findings support previous studies on barriers to health services in primary care (Liang et al., 2018; Zhou & Nunes, 2016), but added evidence of expectations of services from older people's perspectives. This finding supports the World Health Organisation report that physical disabilities, restricted mobility or other conditions (e.g., urinary incontinence) are the main challenges for older people attempting to access healthcare services and achieve self-care (Carvalho et al., 2017). Greater individualised support for this population, especially for those who live alone, is urgently needed.

The comments on the insufficient number of GPs also supported previous studies that reported a low GP-to-patient ratio in China. Currently, there is a major shortage of GPs in community health centres. It was estimated that there is only one GP per 12,000 people in China, which is far from the goal of one GP per 2,000 people, as recommended by the World Health Organisation to achieve high-quality universal health coverage (Yu et al., 2017). The low GP-to-population ratio contributed to limited patient–GP interaction, explaining the low quality of health services perceived by patients. Insufficient human resources at community health centres limit the accessibility of chronic condition management in community settings.

Barriers to health education might reflect the education background and mean age of participants in the intervention group. Nearly half of participants (45.9%) did not completed China's basic nine-year education: evidence of a low literacy level. Their mean scores of hypertension knowledge (13.4) and diabetes knowledge (12.8) at baseline were relatively low compared to participants in other studies (Hu et al., 2013; Wan et al., 2012). In addition, participants had a mean age of 70.4 years and might have different learning styles than members of other age groups. Therefore, they expected more individualised education and engagement of their carers or family members in health education. It was reported that communications between patients and health providers had a significant influence on hypertension control (Tavakoly Sany et al., 2018). Health professionals who care for older people with a low education background need to develop communication skills to improve health education. Medical terminology should be avoided during consultations and plain language and pictures should be provided to facilitate greater understanding.

The expectation of being cared for by the same GP and community nurse in the intervention program supports a study by Li et al. (2016). Li and colleagues found that patients preferred a community GP with whom they were familiar and wanted to consult with the same GP at each visit. Patients' trust in GPs and community nurses was viewed as a contributing factor to positive outcomes in chronic condition management in community health centres (Li et al., 2016).

The financial burden perceived by participants in the present study supported the findings of previous studies (Le et al., 2012). Although universal health coverage was announced and implemented in China recently, there is still considerable space for improvement in medical insurance for patients

(Yu, 2015). There are two medical insurance schemes in China: Urban Worker Basic Medical Insurance (UWBMI) and Urban Resident Basic Medical Insurance (URBMI) (Chen et al., 2014). Patients with UWBMI have a higher medication reimbursement and lower out-of-pocket costs for medications compared to patients with URBMI. URBMI is associated with a high proportion of out-of-pocket payment and people with this kind of insurance were more likely experience financial hardship (Hu et al., 2012). The systems of medical insurance must be optimised for chronic disease management to allow people have access to needed primary care services. This responsibility lies with policymakers.

6.11 Factors affecting intervention fidelity

Intervention fidelity has been recognised as an important determinant that affects the implementation, quality and outcomes of interventions in RCTs (Gearing et al., 2011; Spillane et al., 2007; Wickersham et al., 2011). Assessing intervention fidelity is necessary to discuss factors affecting the outcomes of the trial and inform future study designs for improved quality of trials. A lack of consideration of intervention fidelity may be associated with a threat to both internal and external validity (James et al., 2017). Strategies that are widely embedded to the study design to improve intervention fidelity include (1) applying a theoretical framework to the study design; (2) describing study protocol in a consistent way for service providers and recipients; (3) providing training and support for service providers during the intervention; and (4) carefully monitoring the process and outcomes of the intervention (Breitenstein et al., 2010; Horner et al., 2006; Horner, 2012). Different approaches to monitoring intervention fidelity are reported in the literature: audiotaping, videotaping, provider self-report checklists and participant self-report questionnaires (Borrelli, 2011). In the present study, "Intervention Diary-Patient version" and "Intervention Record-Community nurse and GP version" were used to monitor intervention fidelity for providers and patients in the six-month follow-up study. In addition, participants' satisfaction with interventions was also explored to complement the assessment of the intervention fidelity. These written strategies require fewer resources and lower costs than other monitoring strategies.

The compliance with intervention components in Stage 1 of the program at hospital indicated that embedding individualised health education and referrals to community health centres in routine discharge activities was possible. Compliance with intervention components in Stage 2 of the program (in community health centres) also indicated the viability of follow-up support for older people who required ongoing support to manage their hypertension and diabetes at home after discharge. Several factors may explain the high level of fidelity and quality of interventions in the study. First, health professionals' consensus on implementing the interventions was obtained prior to the study through a two-round Delphi consultation process. Second, the strong support of local government ensured partnership between hospitals and community health centres. Third, ongoing

fidelity monitoring, including regular site visits and problem-solving support provided by the researcher (the PhD candidate), facilitated intervention fidelity in the present study. Fourth, community health centres viewed this program as a valuable opportunity to develop health services in chronic disease management and attract patients to their services. The hypertension management program was embedded into their routine practices. In addition, the research team played a key role in ensuring the quality of interventions. They provided health professionals at each intervention site with a workshop prior to the study to address issues of implementation and protocol fidelity. The importance of fidelity and use of the intervention diary to record their interventions was explained to health professionals in the intervention group during the workshop.

6.12 Summary

This chapter discussed the findings of a cluster RCT designed to evaluate a hypertension management program for older people with the multimorbidity of hypertension and diabetes who required follow-up support in community settings after discharge from hospital in Nanchang, China. The present study's findings were compared with the literature. Findings support those of previous studies: a primary care approach to hypertension management for older people with diabetes and other chronic conditions showed a positive effect on health outcomes and quality of life for the study population. Unlike previous studies that mainly focused on intervention in community care settings, the present study targeted collaboration between community health centres and hospitals. In addition, the program targeted older people rather than the general patient population across different age groups. For these reasons, the program and the evidence generated from the evaluation of the program have contributed new knowledge to the study field. Chapter 7 will present the need for Multillevel- and Multicomponent (ML-MC) intervention to target both healthcare system and self-care of older people.

Chapter 7

Multi-Level and Multi-Component nature of the hypertension management program

Chapter 7 Multi-Level and Multi-Component nature of the hypertension management program

7.1 Introduction

Chapter 6 discussed the impact of the hypertension management program on study outcomes. The positive impact on the study outcomes was attributed to the integrated care informed by the chronic care model. This integrated care model was built on collaboration between hospitals and community health centres to implement the evidence-based hypertension management program. The chronic care model applied to the present study emphasises healthcare system factors that shape individual (informed and activated patients) and healthcare provider factors (prepared, proactive practice team) (Improving Chronic Illness Care, 2006). This chapter discusses the Multillevel- and Multicomponent (ML-MC nature of the hypertension management program in the present study, which adds new knowledge to the implementation of the chronic care model in the study field in China.

7.2 Overview of Multillevel- and Multicomponent in this study

It is widely reported that factors that contribute to hypertension control are derived from multiple levels, including patients, patient–provider interaction and organisations (Lebeau et al., 2014). Previous studies have confirmed that multilevel interventions were more effective than interventions that targeted only one or two levels (He et al., 2017). For example, single-level interventions that target individual lifestyle behavioural change were unsuccessful in changing behaviour in the absence of support from healthcare services (Mikkelsen et al., 2016). Multilevel- and Multicomponent (ML-MC) interventions in the present study refer to interventions that target two or more levels that affect hypertension management (Mikkelsen et al., 2016). A recent systematic review and meta-analysis that included 100 RCT studies suggested that ML-MC interventions simultaneously targeting all contributors to hypertension were the most effective due to the synergistic effects of multiple intervention components, compared with the interventions targeting only part of these contributors (He et al., 2017; Mills et al., 2018; Trude et al., 2018). However, ML-MC has not been well studied in middle- and low-income countries such as China due to the underdeveloped primary care system in chronic disease management. The present study adds new knowledge to the study field by exploring hypertension management programs that have ML-MC characteristics.

The present study targeted organisational-level intervention through hospital-initiated collaboration with primary care providers and access to primary care for follow-up support for the study population.

The present study also considered the interactions between health professionals and patients in hospital and primary care settings. These interventions contributed to building therapeutic relationships to motivate participants to change behaviours, engage in self-care, adjust medication and reduce clinical inertia. At the individual patient level, the present study implemented components to improve self-care, including self-management through goal setting, motivation, beliefs, knowledge and skill in self-care, self-monitoring and help-seeking. The ML-MC interventions applied to the present study are illustrated in Figure 7.1.

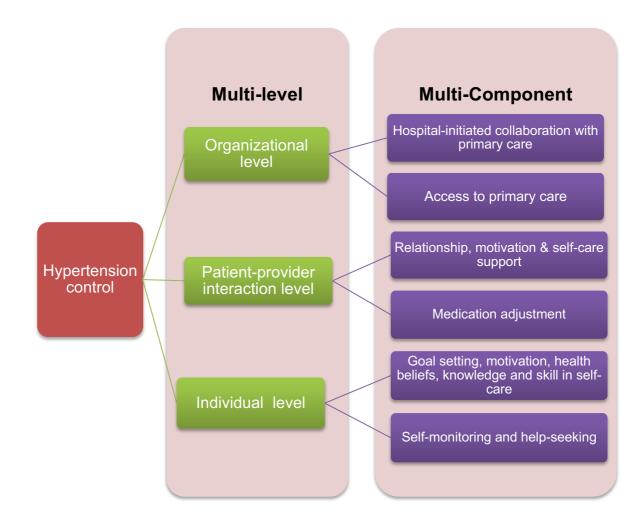


Figure. 7.1 ML-MC interventions applied in this study

In a systematic review and meta-analysis that investigated the effect of lifestyle intervention in people with diabetes, the difference in SBP change was only 0.16 mmHg (Chen et al., 2015). It was also reported that lifestyle modification alone was usually not sufficient to achieve target blood pressure. Thus, medication treatment was required to complement the healthy lifestyle changes (Cheung & Cheung, 2014). In the present study, researchers considered the importance of integrating medication treatment with lifestyle modifications to control blood pressure among older people with diabetes. The mean change of SBP between the intervention and usual care groups achieved –

12.58 mmHg (95% CI, -16.16 to -9.00 mmHg) at six-months' follow-up, a better outcome than that of the study by Chen and colleagues. In another systematic review and meta-analysis, nurse-led interventions, including components of adoption of treatment algorithms, nurse prescribing and nurse-led clinics, demonstrated a mean reduction of 5.8 mmHg compared with doctor-led usual care that only targeted medication intervention. Nurses usually had more contact time with patients and more opportunities to build therapeutic relationships with patients in chronic condition management (Norouzinia et al., 2015). Therefore, they were in an ideal position to support patients to improve self-care and motivate them to comply with intervention (Norouzinia et al., 2015). The present study incorporated nurses as crucial team members (both in hospital and community settings) to provide individualised patient education, reinforce education and support patients to self-monitor their health and achieve self-care goals. The higher mean change of SBP achieved in the present study compared to previous studies might be attributable to nurses' contributions.

Patients targeted in the present study were older people with a mean age of 70.9 years. They also had an average of four morbidities in addition to diabetes and hypertension. These included osteoarthritis, stroke, hypercholesterolemia, coronary disease, chronic bronchitis and rheumatism. To support this patient population to manage their health conditions effectively, a multicomponent intervention that included management and/or prevention of geriatric syndromes and adverse events was incorporated in the intervention. These intervention strategies addressed the World Health Organisation guidelines (2017) on integrated care for older people. The significantly reduced adverse events and unplanned hospital readmission or emergency care services in the intervention group might be attributed to the multicomponent intervention that targeted ageing-associated health conditions in the present study.

7.3 Organisational-level intervention

World Health Organisation has advocated the implementation of chronic disease management via a primary healthcare approach (World Health Organisation, 2013). Experience from high-income countries has demonstrated the effectiveness of community-based hypertension management (Ferdinand et al., 2012). However, the primary care system in China is still underdeveloped. Patients with chronic diseases mainly approach medical specialist at hospitals for medication treatment, which overlooks non-pharmacological interventions (Xu et al., 2016). A downward referral from hospital to community is rare in China (Li et al., 2017).

7.3.1 Hospital-initiated collaboration with primary care

Although the primary care approach is strongly suggested as the most cost-effective and sustainable approach to hypertension management for people with diabetes and other chronic conditions, barriers to achieving this approach are widely reported in China and other low- and middle-income countries with underdeveloped primary care systems (Wong et al., 2017). The most common reasons for patients to visit specialists in hospitals rather than GPs are perceptions that GPs do not have the same qualifications and experience as specialists have to manage their health conditions and that community health centres lack the resources to provide the care they need (Wu & Lam, 2016). Unlike previous studies that utilised insurance or gatekeepers to access specialists via GPs in high-income countries, the present study tested hospital-initiated referrals for patients to visit GPs and community nurses in the follow-up intervention, supported by well-designed discharge planning (Tu et al. 2018). The hospital-initiated collaboration with primary care not only built the public's trust in GPs and community nurses, it also contributed to the capacity building of community health centres. Conditions that enabled the success of hospital-initiated primary care approach are discussed in Sections 7.3.2–1.3.4.

7.3.2 Achieving integrated care

The World Health Report 2006 stated that optimising chronic disease management such as hypertension and diabetes requires a shift towards the service delivery of community-based and patient-centred care (Jo Delaney, 2018; World Health Organization, 2006). Since China's 2009 healthcare reform, the Chinese government has issued a series of health policies to establish an integrated health system to improve healthcare services and resource sharing across different levels of healthcare facilities in chronic disease management (World Bank, 2016). Findings from the present study demonstrate that the integration of care services from community health centres and hospitals can improve hypertension control. Two interrelated approaches can achieve integrated care: vertical and horizontal integration. Horizontal integration requires a multidisciplinary team to ensure high-quality care at each level of a healthcare organisation (i.e., integration of care services provided by a multidisciplinary team across tertiary hospitals) while vertical integration focuses on the continuum of care through collaboration between health professionals from different levels of healthcare organisations (i.e., integration of care services provided by health professionals across primary care facilities, secondary and tertiary hospitals) (World Health Organisation, 2016). The present study built on both horizontal integration (multidisciplinary collaboration at the same level) and vertical integration (collaboration between tertiary or secondary organisations and community health centres).

Most studies in the literature recommend mandating health insurance and gatekeepers to access specialist care as intervention mechanisms to achieve vertical integration in high-income countries (Garrido et al., 2011). In the present study, vertical integration was achieved through a voluntary two-way referral system (when required) and well-designed discharge planning, which required implementation by both hospitals and community health centres. Vertical integration enables the redistribution of healthcare delivery from hospitals to community health centres and indicates an

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opportunity to improve access to care and increase the efficiency of health systems for long-term treatment (World Health Organisation, 2016). In the present study, participants' positive comments regarding the convenience and timely support received from GPs and community nurses at community health centres further supported the need to develop a primary care approach to managing hypertension and diabetes for this older population. Findings confirmed previous studies that accessibility to primary care, more specifically shorter geographical distances to primary care services, was associated with better control of blood pressure (Huang et al., 2016). In the present study, participants in the intervention group were referred to community health centres within walking distance of their homes so they were more likely to comply with follow-up intervention.

The findings support previous studies on integrated care delivery models in China, in which a twoway vertical referral system between different levels of health facilities was used to enhance hypertension management (Miao et al., 2016; Shi et al., 2015). However, in this model, patients were recruited in community care settings and the collaboration was initiated by GPs in these centres to gain support from hospital specialists to manage patients with uncontrolled hypertension (Miao et al., 2016). The present study extended this model to hospitalised older people with uncontrolled hypertension. Vertically integrated care pathways in the present study referred patients from hospitals to community health centres to ensure continuum of care, reinforce self-management skills through needs-based patient education, monitoring of health conditions, and timely intervention to medication adjustment or changes in health conditions. Vertically integrated care pathways in the present study also enabled GPs at community health centres to refer patients with complex treatment needs to specialists in the outpatient department in a timely manner. Among the 135 participants from the intervention group, 37 per cent were referred to specialists during the six-month trial. Common reasons for referral were hypertension and diabetes-related complications and geriatric syndrome. The evidence further supports that vertically integrated care is greatly needed in the Chinese context where the primary care system is underdeveloped. Most participants (85%) in the intervention group complied with follow-up intervention at community health centres and provided positive feedback on the services. The evidence reveals that vertically integrated care is achievable through well-designed intervention.

In the present study, horizontal integration was achieved through collaboration between health professionals to deliver care services within the organisation (e.g., GPs working with nurses at community health centres to implement follow-up visits or specialists working with in-charge nurses to implement discharge planning). Horizontally integrated care pathways ensured high-quality care at the point of service through clear role and responsibility identification for health professionals. A systematic review and meta-analysis including 100 articles found that team-based care interventions with clearly defined responsibilities for team members were most effective for blood pressure control (Mills et al., 2018). In the present study, the roles and responsibilities of health professionals from

various disciplines were allocated after a comprehensive literature review and a two-round Delphi study. The consensus on task sharing and responsibilities enabled successful horizontal integration.

Findings from the present study also supported previous Canadian research that had a horizontal integration component ((McLean et al., 2008). In the Canadian study, collaboration between a community pharmacist and nurses in the intervention group demonstrated a greater reduction in SBP at six months (5.6 mmHg) than in the usual care group. The findings support that an intervention built on intra- or interdisciplinary collaboration is more likely to produce better blood pressure control than interventions from a single group of health professionals. Without medication adjustment, health education alone might not achieve the desirable hypertension control among people with diabetes (Willard-Grace et al., 2015).

The inadequate organisation of a healthcare system and disproportionate allocation of health resources have been identified as the most important reasons for unsuccessful hypertension management (Khatib et al., 2014). Achieving integrated care through vertical and horizontal integration in a healthcare system is strongly recommended to achieve availability, accessibility, acceptability and high-quality care in chronic disease management (Campbell et al., 2013; Levesque et al., 2013). Considering the widely reported healthcare disparities in chronic disease management within a country or in a global context, barriers to affordable treatment, and equitable and high-quality care in hypertension management for older people with diabetes are substantial. Many more studies in this field are needed to identify practical solutions.

The integrated care explored in the present study not only increased patient use of community care settings, it also made more efficient use of human resources for health (e.g., GPs, community nurses, specialists and hospital in-charge nurses). Intervention delivery in the present study, which exploited the vertical-horizontal synergy of different care facilities and disciplines in the current health system in China, addressed the nation's fragmented health services. Therefore, to manage chronic diseases in a country like China with an underdeveloped primary care system, building an integrated healthcare delivery system through collaboration between hospitals and community health centres was believed to be a promising way to strengthen and improve access to primary care.

7.3.3 Utilising existing networks to implement the program

A lack of collaboration between hospital and primary care providers may be a major barrier to referring patients to community health centres upon discharge from hospital. In a survey of older people in 11 high-income countries, 41 per cent of participants reported that they experienced gaps in hospital discharge planning in the past two years (Osborn et al., 2014). The gaps may be greater in low- and middle-income countries like China with underdeveloped primary care systems. As

hospitals receive more medical resources than community health centres do, referrals are usually from community settings to hospitals in China; reverse referral is uncommon (Li et al., 2017). Hospitals usually help community health centres resolve complex cases or emergency cases. In a study by Zhang et al. (2017), continuum of care was achieved across village, town and county healthcare organisations. Doctors at county hospitals provided doctors at village and town health facilities with monthly lectures and discussions on complex cases to help them improve their health services. These kinds of networks also existed in the study context—Nanchang, China—and enabled hospital-initiated referrals for patients to receive follow-up support at community health centres.

As the collaboration was initiated by health professionals from hospitals in the present study, it had a positive impact on patients' perceptions of community health centre services and reassured patients of their ongoing support from specialists (when required). The hospital-initiated patient referrals to GPs and community nurses are much needed considering the widely reported negative attitudes to primary care and the lack of public trust in GPs and community nurses in China (Zhang et al., 2017). The collaboration between primary care and hospitals tested in the present study supports the viability of collaboration between community health centres and hospitals to support discharge planning for hospitalised older people with multimorbidity of hypertension and diabetes.

Currently, care services for the study population are particularly fragmented in China. Integrated care built on collaboration between hospitals and community health centres for the study population has not been achieved due to the underdevelopment of the primary care system and the lack of strategies to foster effective collaboration. Older people living with the multimorbidity of hypertension and diabetes have characteristics of long duration, multiple causation and other ageing-related chronic conditions (e.g., geriatric syndromes) (Xu et al., 2016). With the increasing prevalence of hypertension, diabetes and the rapidly ageing population in China, the Chinese government is taking action to achieve a primary care approach to chronic condition management and patient-centred integrated care for this population (Huang et al., 2016). Evidence from the present study contributes to the further development of integrated care for the population in China and other countries with a similar sociocultural context.

Three models of collaboration between hospitals and community health centres were recently reported in China: medical consortium model, direct management model, and loose collaboration model (Xu et al., 2016). The hospitals and community health centres in the present study were directly administered by the local government. Community health centres in the present study had affiliation with hospitals in research, teaching and training for medical and nursing students, and health professionals. Therefore, the hospital-initiated referrals in the present study were practical and achievable. However, in the loose collaboration model and medical consortium model,

community health centres are independent organisations that are not affiliated to hospitals (Xu et al., 2016). The degree of healthcare resource integration in these two models was lower than it was in the direct management model.

7.3.4 Providing detailed follow-up intervention guidance for GPs and community nurses

Several challenges may occur when patients are referred from hospital to community health centres for follow-up support. Insufficient information about patients provided by in-charge nurses during the referral process might cause inappropriate treatment in the follow-up. To overcome these challenges, the follow-up intervention in the present study was clearly conveyed to GPs and community nurses through the 'Intervention record-Community nurse and GP version' and structured discharge summaries. With these written documents, GPs and nurses at community health centres were able to clearly understand the patient's conditions and the follow-up interventions required. Care plans that did not achieve agreement between health providers across different health organisations may influence the quality of referral provided for older people (Blank et al., 2013). Communicating a clear diagnosis and follow-up treatment to community health centres ensures a continuum of care for patients and reduces the potential for treatment error when patients navigate across health systems. It was identified that, without sufficient information conveyed to community health centres, referrals would take longer, which might lead to delayed consultations with specialists (Coiera, 2006; Manias et al., 2015). Moreover, repeated medical tests due to lack of insufficient information during the referral period had consequences on healthcare costs and patients' low satisfaction with care services (Tao et al., 2017).

The present study supports the previous RCT conducted by Zhang et al.(2017), which employed a care coordinator to manage patients with hypertension. In their study, inpatient treatment was provided to patients through the village–town–country health system. Patient health records, medical records and other health-related documents were shared among all health providers across the system. However, detailed discharge planning and follow-up intervention guidance was not shared among these health providers to further manage follow-up patients. The present study adds new knowledge to the field by exploring task sharing in a care team to ensure effective information sharing to support the implementation of discharge planning for the study population.

7.4 Patient-provider interaction level intervention

Clinical inertia refers to the failure of healthcare providers to initiate or intensify treatment when treatment goals are not achieved (Huebschmann et al., 2012). Many elderly people with the multimorbidity of hypertension and diabetes fail to achieve hypertension and glycaemic control promptly and are delayed in receiving treatment intensification due to clinical inertia (Reach et al.,

2017). Clinical inertial has been globally acknowledged as a major cause of uncontrolled hypertension (Adeniyi et al., 2016; Kika et al., 2016). It was found that patients with hypertension in some European countries encountered clinical inertia from their physician in up to 85 per cent of visits. Clinical inertia is associated with health system factors (i.e., lack of care coordination and poor collaboration between health professionals across organisations), healthcare provider factors (e.g., lack of time, failure to recommend follow-up and lack of communication with patients) and individual factors (e.g., polypharmacy and medication side effects) (Aujoulat et al., 2014). In China, clinical inertia often happens when patients are discharged from hospital due to the lack of follow-up in primary care settings (Huang et al., 2016).

The present study targeted post-discharge clinical inertia by developing follow-up support at community health centres for the study population. Moreover, the lack of open communication between patients and health providers is another barrier to treatment intensification. Through monthly follow-up visits at community health centres and fortnightly telephone calls, communication between patients and health providers was achieved in the present study. In addition, clinical inertia in China often occurs due to unclear division of tasks in a care team, leading non-implementation of recommended interventions (Wang et al., 2018). The present study addressed this issue by conducting a Delphi study with health professionals to reach a consensus on task sharing in a care team.

One key factor contributing to the successful hospital-initiated collaboration with community health centres was the establishment of the nurse coordinator's role. This professional referred patients from hospital to community health centres and coordinated the transition during discharge planning. A lack of coordination and communication between hospitals and community health centres is considered the main obstacle to ensuring the fluidity of this pathway and the implementation of continuum of care (De Regge et al., 2017; Van Houdt et al., 2013; Vermeir et al., 2015; Wang et al., 2016). Bridging communication across healthcare organisations through nurse coordinators ensures that GPs and nurses at community health centres receive information in a timely manner, and have opportunities to clarify the interventions documented in the intervention record.

7.5 Individual level intervention

The hypertension management program in the present study targeted the individual capability building for self-care, which reflected the component of 'informed and activated patients' in the chronic care model applied to the study (Davy et al., 2015; Sendall et al., 2016). Health professionals' role in the present study was to create ideal conditions to support behavioural change in the study population.

7.5.1 Motivating patients to self-care

Findings support previous studies that patients with better treatment adherence demonstrate better hypertension control (Yue et al., 2015). Treatment adherence requires motivation to self-care to achieve and sustain lifestyle modifications and optimal medication treatment (Bérubé et al., 2016). Self-care is an indispensable part of hypertension management and is built on patients' intrinsic capabilities (Zinat Motlagh et al., 2016). A previous study demonstrated that intrinsic capability is more important to patient behavioural change, while improved health education by itself does not improve blood pressure control and treatment adherence (Bennett et al., 2009). In the self-care approach, patients need to become informed and activated participants in their care, be given relevant education materials, and build the confidence and skills needed for such active participation (Bennett et al., 2009). A World Health Organisation report (2003) has suggested that improvement in self-management capacity has a far greater impact on people's health outcomes than any improvement in specific medical treatments. Motivation refers to 'brain processes that energize and direct behaviour' (Michie et al., 2011, p. 4). In hypertension control, motivation encompasses readiness to change involves patients' knowledge about consequences of non-adherence to medication treatment and lifestyle modification, decision-making, goal setting, planning for action, taking actions, evaluating outcomes and reflecting on outcomes (Bennett et al., 2009).

Collaborative goal setting has been widely recognised as effective in improving patient behavioural change (Wallace et al., 2016). Patients' engagement in goal setting through consultations and discussions with health professionals over time was another key factor in the present study's success. Without the support of health professionals in goal setting, patients are likely to set ambitious and impractical goals that exceed their abilities (Kangovi et al., 2017). It has been reported that older people's motivation in maintaining appropriate self-management behaviour may not be achieved if health professionals do not provide feedback on current problematic self-management behaviours (Choi et al., 2014). Older people with low education are more likely to encounter difficulties and require the sustained support of health professionals. In the present study, each patient consulted with health professionals at community health centres monthly to ensure SMART (specific, measurable, achievable, relevant and timely) goals (Johnson et al., 2014).

In a realistic review, researchers reported that health interventions that focused on patients' intrinsic processes—such as improvement of self-care motivation and confidence—were the most effective in increasing patients' chronic disease self-management capabilities (Hooft Susanne et al., 2016). The review also demonstrated that without professional motivation, education alone targeting extrinsic processes of patients was not sufficient to ensure behavioural change (Himmelfarb et al., 2016; Hooft Susanne et al., 2016). Behavioural change is jointly determined by three factors: motivation improvement, education reinforcement and skill enhancement (Michie et al., 2011). The present study addressed these three key predictors through regular telephone calls with patients and follow-up consultations at community health centres.

The present study addressed intrinsic capability by supporting patients to set achievable self-care goals prior to discharge from hospital, taking actions to meet the goal and using an intervention diary to monitor their progress and outcomes in the follow-up period. The present study also emphasised the importance of extrinsic mechanisms to reinforce motivation to achieve self-care through fortnightly telephone conversations and monthly face-to-face discussions at community health centres. Many intervention studies focused on extrinsic mechanisms such as health education with minimal components of intrinsic factors (Heisler, 2008). For example, Nazli et al. (2008) interventions mainly included education for people with diabetes. The study reported limited impact on knowledge and self-management behaviours. Many studies intended to improve self-care in older patients exclusively through education about medication adherence and health lifestyles. However, most of these studies have been unsuccessful because of the lack of specific, personalised goals and action plans (Lee & Park, 2017).

7.5.2 Building capability for self-care

Capability, as informed by the chronic care model, refers to the development of patients' knowledge and skills to improve their health behaviours in chronic disease management (Davy et al., 2015; Improving Chronic Illness Care, 2006). Individualised health education to target participants' learning needs played a key role in developing capabilities for hypertension management. Intervention delivery in the present study was health education tailored to the unique experiences and conditions of patients in the intervention group. Findings from the present study support those of previous studies—individualised education interventions were more effective than the non-individualised interventions (Suhonen et al., 2008). Coaching patients on how to monitor blood pressure and other health conditions, adhere to medication and make lifestyle changes was also a key factor that improved the self-monitoring skills of patients in the intervention group.

Studies report that patient engagement in self-care action plans (via consultation with health providers) was an important part of developing capability to self-care (Vahdat et al., 2014). In the present study, self-care plans in the form of making lifestyle changes and improving medication adherence were discussed by health professionals. These professionals played a coaching role in supporting participants to self-care, from planning to implementing the plan. It has been widely recognised that coaching generates better outcomes than health education alone, particularly for people with uncontrolled hypertension (Bennett et al., 2009; Thom et al., 2015). In the present study, coaching components shared some similarities with a study by Thom and colleagues in the US (2015). In their study, intervention participants with poorly controlled diabetes and hypertension were provided with 12 months' coaching by medical assistants to improve medication adherence. Similarities with the present study include telephone coaching and face-to-face coaching during clinical visits. The topics of coaching between the studies were also similar, involving facilitating an

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understanding of medication in terms of the name, purpose, strength and dosage and addressing the barriers to medication adherence. The differences were that medical assistants were used for coaching, rather than the nurses in the present study. Further, the present study involved monthly in-person visits and fortnightly telephone contact with patients, while Thom et al. implemented three-monthly in-person visits and monthly telephone contact. The present study aligns with Thom et al. (2015) in that the mean number of days of adherence to medication was significantly increased in the intervention group compared to the usual care group. However, the previous study did not report changes in clinical outcomes using SBP and DBP as indicators. Therefore, the association between coaching and hypertension control was unknown. The present study, by exploring the impact of coaching on hypertension control, adds new knowledge to the study field.

7.6 Strengths and limitations

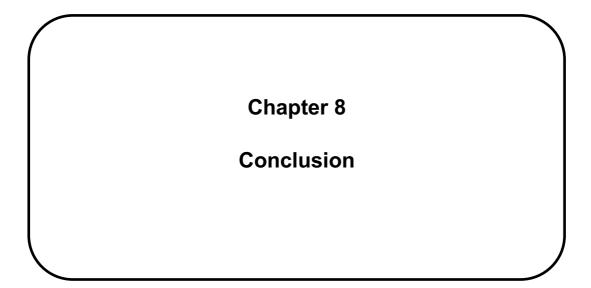
A high retention rate was maintained in both groups over the six-month trial, with only five participants of 135 withdrawing from the intervention group and eight of 135 from the usual care group. The higher retention rate in the intervention group suggests positive interaction between participants and health professionals, and a high level of patient acceptance and satisfaction. The present study also demonstrated internal validity by controlling confounding variables. The application of a cluster RCT prevented study contamination resulting from health professionals treating patients in both study groups. It is anticipated that the intervention program can be replicated in other communities and provinces in China. Further, the trial design enhanced confidence that the positive impact of the intervention on the study outcomes can be attributed to the joint effort of health professionals in both communities and hospitals.

The study design also considered the effects of regression to the mean through research design, data collection and data analysis. Regression towards the mean is a commonly reported statistical phenomenon in health care that refers to a tendency of extreme values measured at baseline to move closer to the population average in subsequent time points (Yu & Chen, 2015). Changes in the usual care group provide an estimate of the change caused by regression to the mean. Any extra change in the intervention group compared to the usual care group can be attributed to the effect of the intervention. Therefore, first, the cluster RCT design was selected and identified as a preferable way to manage the impact of regression to the mean. Second, during data collection, the blood pressure of each patient was measured three times at each point, and the average blood pressure was recorded. Third, baseline values of blood pressure were adjusted at the time of data analysis. The program was developed through a literature review of current research evidence and was modified through a two-round Delphi study with an expert panel to ensure the acceptance of the intervention components and implementation strategies in a local context.

The study has serval limitations. First, the follow-up period was relatively short: only six months. It is not known if the effect of this intervention program is sustainable in a longer follow-up period. Therefore, the long-term effects of this intervention program require further empirical exploration. Second, the study was conducted in 10 clusters in Nanchang, a capital city of Jiangxi Province in China; hence, sampling bias existed. The study population and settings may not be representative of the broader population and settings in Jiangxi province, China, which may limit generalisability. Third, as an open-label study, the patients and health professionals were aware of the groups to which they were assigned and their allocated treatment during the trial. Patient bias may occur when participants complete the self-reported questionnaires. However, the other clinical outcomes were measured using automated devices with a standard protocol and are unlikely to have been biased.

7.7 Summary

This chapter has discussed the ML-MC nature of the hypertension management program developed and evaluated in this PhD project in Nanchang, China. The discussion has enhanced understanding of the impact of the ML-MC program on the study outcomes presented. Further, it has emphasised the importance of designing ML-MC interventions in a healthcare system to strengthen the primary approach to supporting older people to manage the multimorbidity of hypertension, diabetes and other chronic conditions. The implications of the study on policy, practice and research are discussed in Chapter 8.



Chapter 8 Conclusion

8.1 Introduction

This thesis has presented the development and evaluation of an evidence-based and theoryinformed hypertension management program for older people with diabetes who require follow-up support in community care settings after discharge from hospital. A modified Delphi study based on a comprehensive literature review was conducted to develop the intervention program and gain consensus from an expert panel on the applicability of the program in Nanchang, China. The effectiveness of the program on hypertension control for the study population was evaluated using a cluster RCT. A widely recognised chronic care model that fosters integrated care across care settings was applied to the program design. Discussions on the impact of the program on blood pressure control, blood glucose control, health knowledge, treatment adherence, and quality of life for the study population have been presented in the thesis. Discussion has also been extended to the ML-MC elements to enable a primary care and integrated care approach to the study population, as opposed to the hospital-centred and fragmented care services in the current healthcare system. This chapter provides a summary of this research, implications and future research.

8.2 Summary of the study

The rationale for exploring hypertension control for older people with diabetes in the present study is well established. However, the study also addresses the management of diabetes and other chronic conditions, such as geriatric syndromes, in the study population. Globally, around threequarters of people with diabetes also have hypertension (Edelman et al., 2015). Hypertension is usually poorly controlled in populations with diabetes, especially in low- and middle-income countries (Grossman & Messerli, 2011). The prevalence of uncontrolled hypertension is higher in older people, as advanced age is a strong predictor of uncontrolled hypertension among diabetic patients (Chew et al., 2012). Evidence shows that up to 75 per cent of cardiovascular disease incidence in diabetes can be attributable to hypertension (Arya, 2003; Chen et al., 2010; Gilbert et al., 2011; Sowers et al., 2001). In China, the primary care system is largely not sufficiently developed to manage chronic diseases. The follow-up care services for this population to sustain self-care and monitor their conditions after hospital discharge were poorly developed. Hospitals are under increasing pressure to provide inpatient care services for patients with uncontrolled hypertension and diabetes (World Health Organisation, 2014; Wu & Lam, 2016). Older people comprise a large portion of hospital inpatients (Zhao et al., 2011). Underdeveloped primary care services in chronic disease management also contribute to the lack of follow-up support for older people with the multimorbidity of hypertension and diabetes to sustain hypertension control after discharge (Xu et al., 2016).

A literature review identified evidence-based and effective intervention components and implementation strategies to control hypertension among people with diabetes. Eight intervention components were identified in the literature review:

- a. lifestyle modifications
- b. close monitoring and surveillance of conditions
- c. treatment adherence
- d. medication review, adjustment and intensification
- e. health education on diseases
- f. timely referral for further treatment
- g. partnership with patients in goal setting and action plan development
- h. motivation in self-care.

These components target healthcare system factors, healthcare provider factors and individual factors affecting hypertension management for people with diabetes. Strategies applied to implement interventions in effective intervention studies comprised a team approach and collaboration across healthcare facilities.

Theoretical frameworks and care models applied to effective intervention studies were analysed to identify a suitable theoretical framework to inform the program design. The chronic care model described by researchers from the MacColl Institute for Healthcare Innovation in the US was viewed as relevant to the present study, as it emphasises six domains in a healthcare system that shape individual factors (informed and activated patients) and healthcare provider factors (prepared, proactive practice team) in chronic disease management (Dunn & Conard, 2018; Grover & Joshi, 2014; Sendall et al., 2016). The six domains were health system, community, delivery system design, self-management support, decision support and clinical information system (Dunn & Conard, 2018; Sendall et al., 2016). The six domains were incorporated into the evidence-based hypertension management program in the present study.

The effective intervention components and implementation strategies were considered and incorporated into the hypertension management program for older people with diabetes who were ready to be discharged from hospital and required follow-up support in primary care in Nanchang, China. Considering potential barriers to the intervention components in the Chinese context (i.e., underdeveloped primary care system), a modified Delphi study was conducted with an expert panel to gain consensus on the applicability of the proposed program. Consensus on the program was achieved through a two-round Delphi study. Six intervention items—the roles of pharmacists and

dietitians, and community nurses' role in motivational interviewing, medication treatment, and assessment of lab results of patients—failed to achieve consensus. This was due to the limited health competency of health professionals in China compared with those in high-income countries. Other options were recommended to replace these rejected intervention items. Feedback and comments from the panel helped the modification and revision of the proposed program.

The hypertension management program in the present study targeted older people with diabetes who require follow-up support in community care settings after discharge from hospital. The program included a two-stage intervention. In Stage 1, individualised discharge education was provided by hospital medical specialists and in-charge nurses. A referral to a community health centre was made by the in-charge-nurse. In Stage 2, six-months' follow-up was provided by community nurses and GPs. Health professionals from both hospitals and community health centres worked collaboratively to implement the hypertension management program.

A cluster RCT was conducted to test a hypothesis that the hypertension management program built on collaboration between hospitals and community health centres in Nanchang, China-could achieve greater blood pressure control in people aged 60 years and over with diabetes than those receiving the usual care. The study randomly allocated 10 wards from four hospitals in Nanchang to either an intervention group (N = 5) or a usual care group (N = 5). In total, 270 patients were recruited. The intervention included individualised self-care education and medication management prior to discharge and in the six-month follow-up at community health centres. A multilevel mixedeffect linear regression model was applied to compare the changes in health outcomes between the intervention and usual care groups. This evidence-based and comprehensive hypertension management program demonstrated (1) improved hypertension control; (2) improved knowledge of self-management of hypertension and diabetes; (3) improved treatment adherence; (4) improved quality of life; and (5) reduced readmission to hospitals, usage of emergency care services and adverse events for older people with comorbidities of hypertension and diabetes in community settings. There was no significant difference on HDL between the two groups. Barriers perceived by patients during the community care-led follow-up were (1) barriers to treatment and care in the community; (2) the need for designated GPs and community nurses; and (3) financial hardship.

8.3 Implications

Findings from the development and evaluation of the theory-informed and evidence-based hypertension management program have implications for policy and resource development, healthcare service development, professional development and research in China. The implications are discussed in Sections 8.3.1–8.3.4.

8.3.1 Implications for policy development

Little research evidence for the effective use of primary care services to support hypertension management for older people with diabetes and other chronic conditions was found for the Chinese context. This is an important gap in facilitating evidence-informed policy to meet the care needs of this population in China (Wang et al., 2016). The findings of the study demonstrated the success of applying an integrated care model with a primary care focus to improve care for older people with the multimorbidity of hypertension and diabetes and other chronic conditions who have been discharged from hospital and require follow-up support. The research evidence generated from the present study has implications for policy advocacy as elaborated in Sections 8.3.1.1–8.3.1.5.

8.3.1.1 Implication for policy to shift chronic disease management from hospitals to community health centres

Findings of the present study further confirm the value of the current direction of health reforms in China: shifting chronic disease management from hospitals to community health centres (World Bank, 2016). Findings will provide policymakers with practical solutions for this shift. The applicability and feasibility of the interventions demonstrated in the present study strongly suggest a need to mandate follow-up support in primary care through policy changes for the target population. Moreover, policy to support follow-up in community health centres for older people needs to emphasise two-way referrals between hospitals and community centres to optimise the treatment and continuum of care for this population. The policy needs to consider organisational structure and human resources to support the referrals and collaboration between hospitals and community health centres.

8.3.1.2 Implication for policy to mandate follow-up support for older people with the multimorbidity of hypertension and diabetes

Findings from this study have implications for the delivery of follow-up support for older people with the multimorbidity of hypertension by community health centres. The follow-up support, as tested in the present study and supported in the literature, led to reduced hospital readmission and adverse events after discharge. As most older people have multiple chronic conditions and lack self-care ability, they are susceptible to complications, adverse events and additional health problems after discharge. The readmission rate to hospital after discharge for this population is higher than it is for other age groups (Berry et al., 2018). This suggests that interventions during hospitalisation may fail in the absence of follow-up support in primary care settings. Nurses played a key role in coordinating and leading individualised discharge planning in the present study and other similar studies (Wong et al., 2014; Wong et al., 2005). Policy changes should value the contributions of this group of health professionals. The finding on reduced hospital readmission and adverse events in the present study and other studies supports the need to mandate nurse-coordinated discharge planning for older people with the multimorbidity of hypertension and diabetes and other chronic conditions.

8.3.1.3 Implication for policy to strengthening primary care system

The lack of follow-up support for older people with the multimorbidity of hypertension and diabetes identified in the present study and other studies in China is due to the weakness in the primary healthcare system and the lack of policies to remedy this (World Health Organisation, 2013). Contemporary health policy on chronic disease management emphasises the importance of the primary care approach to hypertension and diabetes management. It was well recognised that primary care-based interventional programs in community health centres could lead to better clinical outcomes and reduce long-term complications compared with acute care in hospital (Young & Clegg, 2010). This study provided policymakers with evidence of how collaboration between hospitals and community health centres could have a positive impact on hypertension management for older people with diabetes and other chronic conditions. Therefore, policy development needs to emphasise the value of joint efforts across health facilities, health professionals and disciplines in supporting older people to manage hypertension and diabetes. Creating policies that foster partnerships between different levels of healthcare organisations is paramount.

8.3.1.4 Implication for policy to improve affordable care services

As mentioned by the patients in the present study, a significant challenge for implementation of this intervention program is the affordability of medication and services. Previous studies also reported that insufficient insurance coverage is a risk factor in hypertension control (Zhang et al., 2016). Higher health insurance coverage is associated with improved medication adherence, which may translate into greater control of blood pressure. A previous study found that patients with Urban Employee Basic Health Insurance scheme (UEBMI had better management of non-communicable diseases than with those with Urban Resident Basic Medical Insurance scheme (URBMI policies (Feng et al., 2014). Therefore, it is highly recommended that the government level the reimbursement rate for more categories of medications and lower patients' out-of-pocket costs.

8.3.1.5 Implication for policy to improve medical equipment and categories of medicines

Quality of medical equipment and categories of medicines are factors that determine the care facility preferences of people with chronic diseases. As resources have been distributed disproportionately between hospitals and community health centres, health reform should allow greater financial and human resources to flow to primary care settings. Policymakers must consider raising their investment in medical equipment for health examinations and raising coverage for essential medicines for hypertension and diabetes in primary care facilities so that patients will be more willing to select primary care settings for treatment.

8.3.2 Implications for workforce development

In China, primary care has been advocated to relieve the burden on the acute care system. However, it has not been resourced to achieve this goal (Cheng et al., 2017). This study has highlighted the importance of allocating the necessary resources to support the primary care approach in managing

diabetes and hypertension. Participants' comments on their satisfaction with interventions in the present study indicated a shortage of health professionals in community health centres; participants' wishes to have home visits to monitor their conditions were not met. The findings of inadequate primary care workers are supported by those of other studies (Chen et al., 2014). Primary care practices will struggle to meet the care needs of the growing numbers of older people with chronic conditions if resource shortages continue.

It is likely that the shortage of qualified health professionals in community health centres will continue to be a problem in the absence of the promotion of professional careers and higher income for primary care providers (Song et al., 2015). Therefore, it is essential to improve primary care professionals' status, salaries and career prospects to attract high-quality candidates. Human resources are a fundamental cause of disproportionate resource allocation in hospitals. The connection between hospital and doctors needs to be loosened to allow a greater number of doctors to flow to primary care settings (Liu et al., 2017).

8.3.3 Implications for healthcare services development

Findings of the present study indicated that the usual care group—managed by specialists at hospital outpatient clinics—showed suboptimal outcomes in hypertension control, knowledge on self-management of hypertension and diabetes, treatment adherence, quality of life, readmission to hospitals, usage of emergency care services and adverse events. Reliance on the overburdened and relatively small number of hospital specialists to manage discharged patients is not sustainable to achieve desirable outcomes for the study population. Therefore, developing services in primary care settings to enable follow-up support for the study population is imperative (World Bank, 2016).

8.3.3.1 Implication for developing coordinated care services

Findings on hospital and community nurses' role as coordinator to improve collaboration between health professionals across care settings have implications for practice development. The results of this study also shed substantial light on the development of coordinated care services in China. Adoption and sustainability of this intervention will require a nurse coordinator in hospital and primary care settings to implement discharge planning. Nurse coordinators require an in-depth knowledge and understanding of community settings to provide referral services for older people and achieve seamless care during their treatment. These nurses need to be prepared through education and training to lead the coordination. Combining these two groups in a training program will enable them to build networks to enhance future collaboration.

8.3.3.2 Implication for enhancing health education for older people

The current study on health education demonstrates the study population's receptiveness to education and confirms the feasibility and effectiveness of it in practice. To embed health education

into routine practice, service providers need to provide older people with clearly written education materials, motivate them to learn, and monitor their progress and outcomes. The findings confirmed that support for older people with diabetes and hypertension to improve self-management skills was highly valued by patients and resulted in a significant improvement in their healthcare knowledge. These findings strongly support the importance of providing a high-quality structured education program to support the skills of self-management in all individuals. It also implies a need for structured ongoing support for health professionals who deliver the health education.

Improvement in health knowledge for older people with the multimorbidity of hypertension and diabetes is an important predictor to better care outcomes. Therefore, the educational content should aim to target this population in the community. As demonstrated in this study and supported by the findings of other studies, patient education is clearly needed to improve health knowledge and ability to self-care (He et al., 2016; Song et al., 2013). Developing evidence-based, accessible and understandable education resources for this study population is imperative.

8.3.4 Implications for further research

The current study has contributed to the growing body of research suggesting that a hypertension management program built on collaboration between hospital and community health centres has significant benefits for hypertension control for the study population in China. Despite the positive study findings, the program has identified several aspects that require further empirical exploration.

8.3.4.1 Implications for studies on older people with the multimorbidity of hypertension and diabetes in rural areas

The current study was conducted in Nanchang, a capital city in China. Therefore, the characteristics of participants and their responses to the interventions explored in the study might differ from those living in rural areas. It is unknown whether this study can be generalised to rural areas. Hospital-initiated hypertension management programs for older people with diabetes may need greater community engagement to address health lifestyles and self-management of health conditions in rural areas with lower healthcare resources (Li et al., 2018). Collaboration between hospitals and community health centres warrants further research to improve hypertension control in resource-poor settings.

8.3.4.2 Implications for studies on older people dependent on others to care for them

Patients in the present study were limited to those who live independently at home. Studies on older population who live at home and depend on family caregivers to care for them need to be considered. Family caregivers must participate in these kinds of studies to test the outcomes on hypertension management for this population of older people. Studies on older people admitted to nursing homes

also need to be explored. Workers in nursing homes need to be included as part of the study population to test the outcomes on hypertension management for this population of older people.

8.3.4.3 Implications for studies on other vulnerable populations living with the multimorbidity of hypertension and diabetes and other health conditions

The program might be implemented to other vulnerable populations living with the multimorbidity of hypertension and diabetes and other health conditions who require follow-up support after hospital discharge (e.g., older migrant workers, people with disabilities and homeless people who might experience financial hardship and lack the social networks to support self-management after discharge). Moreover, follow-up support should also be considered for older people from minority ethnic backgrounds who are unable speak Mandarin or cannot speak Mandarin well and depend on others to help them navigate healthcare services.

8.3.4.4 Implications for studies on cost-effectiveness of the program

The cost-effectiveness of the program remains unknown due to lack of economic analysis in the present study. A study on cost-effectiveness of program needs to be conducted, involving hospitals and community health centres in different regions and provinces to provide policymakers and the public with convincing, generalisable evidence. Factors that influence sustainability and scalability of the program should also be analysed in the cost-effectiveness assessment.

8.4 Conclusion

The care burden of older people living with the multimorbidity of hypertension and diabetes is rising in China, yet the primary care system's ability to respond to the disease burden in a proactive way is still lacking. This has led to a hospital-centred and fragmented care health system. To relieve the care burdens on hospitals and achieve a primary care and integrated care approach to hypertension management for older people with diabetes, an evidence-based and theory-informed hypertension management program built on collaboration between hospital and community health centres was developed and evaluated in Nanchang, China. Findings of this study provide strong evidence that collaboration between these health bodies in follow-up support for the study population can improve hypertension and diabetes control, increase knowledge on self-management of hypertension and diabetes, treatment adherence, quality of life, reduced readmission to hospitals, usage of emergency care services and adverse events for the study population. Findings from the study have implications for policy and resource development, health workforce development and healthcare services development. This research has also informed further studies to improve primary care for the most vulnerable and underserved populations living with hypertension and diabetes in a Chinese social context.

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Appendices

Appendix 1 Search strategy

PubMed

#1 Search ((hypertension[Title/Abstract]) OR hypertensive[Title/Abstract]) OR blood pressure[Title/Abstract]

#2 Search (Diabetes[Title/Abstract]) OR Diabetic[Title/Abstract]

#3 Search (((((((((((((((((((()) pertension management[Title/Abstract]) OR medication management[Title/Abstract]) OR medication adjustment[Title/Abstract]) OR self care[Title/Abstract]) OR chronic disease management[Title/Abstract]) OR discharge planning[Title/Abstract]) OR continuity of care[Title/Abstract]) OR integrated care[Title/Abstract]) OR education[Title/Abstract])

#4 #1 AND #2 AND #3

#5 Search (((((((randomized controlled trial[Publication Type]) OR controlled clinical trial[Publication Type]) OR randomized[Title/Abstract]) OR randomly[Title/Abstract])

#6 #4 AND #5

Study	1a	1b	2a	2b	3a	4a	4b	5	6a	7a	8a	9	10	11a	12a	13a	13b	14a	15	16	17a	20	21	22	25
Allen et al. 2011														-											
Ballary et al. 2008	\checkmark		\checkmark	\checkmark	\checkmark		\checkmark	?	\checkmark				\checkmark	\checkmark	\checkmark		\checkmark	\checkmark	\checkmark						
Crowley et al. 2013	\checkmark		\checkmark	\checkmark	\checkmark		\checkmark	?	\checkmark				\checkmark	\checkmark	\checkmark		\checkmark	\checkmark	\checkmark						
Dasgupta et al. 2017	\checkmark	\checkmark	\checkmark	-		\checkmark	\checkmark		-	\checkmark	\checkmark		\checkmark	?	\checkmark	\checkmark			\checkmark	\checkmark	\checkmark		\checkmark	\checkmark	\checkmark
Davies et al. 2008	\checkmark	\checkmark	\checkmark	\checkmark		\checkmark	\checkmark		\checkmark	-	\checkmark		\checkmark	?	\checkmark				\checkmark	\checkmark	\checkmark		\checkmark	\checkmark	\checkmark
Dobrosielski et al. 2012	\checkmark	\checkmark	\checkmark	\checkmark		\checkmark	\checkmark		\checkmark	-	?	?	?	?	\checkmark				\checkmark	\checkmark	\checkmark		\checkmark	\checkmark	\checkmark
Edelman et al. 2015	\checkmark	\checkmark	\checkmark	\checkmark		\checkmark	\checkmark		\checkmark	\checkmark	\checkmark		\checkmark	-	\checkmark				\checkmark	\checkmark	\checkmark		\checkmark	\checkmark	\checkmark
Edelman et al. 2010	\checkmark	\checkmark	\checkmark	\checkmark		\checkmark	\checkmark		\checkmark	\checkmark	\checkmark		\checkmark		\checkmark	\checkmark			\checkmark	\checkmark	\checkmark		\checkmark	\checkmark	\checkmark
Gabbay et al. 2013	\checkmark	\checkmark	\checkmark	\checkmark		\checkmark	\checkmark		-	-	?	?	?	?	\checkmark	\checkmark			\checkmark	\checkmark	\checkmark		\checkmark	\checkmark	\checkmark
Heisler et al. 2012	\checkmark		\checkmark	\checkmark	\checkmark		\checkmark	?	\checkmark	\checkmark			\checkmark	\checkmark	\checkmark	-	\checkmark	\checkmark	\checkmark						
Hotu et al. 2010	\checkmark	\checkmark	\checkmark			\checkmark	\checkmark				?	?	?	?	\checkmark		-		\checkmark	\checkmark	\checkmark	-	\checkmark	\checkmark	\checkmark
Houweling et al. 2011	\checkmark	\checkmark	\checkmark	\checkmark		\checkmark	\checkmark		\checkmark	\checkmark	\checkmark		\checkmark	-	\checkmark				\checkmark	\checkmark	\checkmark		\checkmark	\checkmark	\checkmark
Ishani et al. 2011	\checkmark	\checkmark	\checkmark			\checkmark	\checkmark						\checkmark	?	\checkmark				\checkmark	\checkmark	\checkmark		\checkmark	\checkmark	\checkmark
MacMahon et al. 2009	\checkmark	\checkmark	\checkmark			-	\checkmark		-	-				?	\checkmark					\checkmark	\checkmark	-	\checkmark		\checkmark
McLean et al. 2008	\checkmark		\checkmark		\checkmark		\checkmark	-	\checkmark				\checkmark	\checkmark	\checkmark		\checkmark	\checkmark	\checkmark						
Mons et al. 2013	\checkmark	\checkmark	\checkmark			\checkmark	\checkmark		\checkmark					?	\checkmark					\checkmark	\checkmark		\checkmark		\checkmark
Paula et al. 2015		\checkmark	\checkmark				\checkmark		\checkmark		?	?	?	?	\checkmark		-		\checkmark	\checkmark			\checkmark		\checkmark
Scain et al. 2009	\checkmark		-	_	\checkmark			?	\checkmark		-		\checkmark	\checkmark	\checkmark	-	\checkmark	\checkmark	\checkmark						
Simpson et al. 2011	\checkmark		\checkmark		\checkmark		\checkmark	?	\checkmark				\checkmark	\checkmark	\checkmark		\checkmark	\checkmark	-						
Wakefield et al. 2011	\checkmark		\checkmark	\checkmark	\checkmark			?	\checkmark				\checkmark	\checkmark	\checkmark		\checkmark	\checkmark	-						
Willard-Grace et al. 2015		\checkmark	\checkmark				\checkmark		\checkmark						\checkmark					\checkmark			\checkmark		\checkmark
Wong et al.2005	\checkmark		\checkmark	\checkmark	\checkmark				\checkmark				\checkmark	\checkmark	\checkmark		\checkmark	\checkmark	\checkmark						
Wong et al. 2014	\checkmark		\checkmark		\checkmark		\checkmark	-	\checkmark				\checkmark	\checkmark	\checkmark		\checkmark	\checkmark	_						
Xia et al. 2014	\checkmark		_	\checkmark	-	-	-	-	\checkmark	_	_		\checkmark	\checkmark	\checkmark	\checkmark	_	\checkmark	_						
Xiao et al. 2009		\checkmark	\checkmark				\checkmark		\checkmark	-	-	-	-	-	\checkmark	\checkmark	_	\checkmark	\checkmark		\checkmark	\checkmark	_	\checkmark	_
Yu et al. 2014		\checkmark	\checkmark				\checkmark	\checkmark	_	-	-	-	-	-	\checkmark	_	_	\checkmark			\checkmark	\checkmark	_		_

Appendix 2 CONSORT 2010 checklist of information to include when reporting a randomised trial

* ($\sqrt{}$): reported, (-): not reported, (?): uncertain

Questions included in the CONSORT

Section/Topic	ltem No	Checklist item
Title and abstract		
	1a	Identification as a randomised trial in the title
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)
Introduction		
Background and	2a	Scientific background and explanation of rationale
objectives	2b	Specific objectives or hypotheses
Methods		
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons
Participants	4a	Eligibility criteria for participants
	4b	Settings and locations where the data were collected
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed
	6b	Any changes to trial outcomes after the trial commenced, with reasons
Sample size	7a	How sample size was determined
	7b	When applicable, explanation of any interim analyses and stopping guidelines
Randomisation:		
Sequence	8a	Method used to generate the random allocation sequence
generation	8b	Type of randomisation; details of any restriction (such as blocking and block size)
Allocation	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing
concealment		any steps taken to conceal the sequence until interventions were assigned
mechanism	10	
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how
	11b	If relevant, description of the similarity of interventions
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses

Results		
Participant flow (a	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were
diagram is strongly		analysed for the primary outcome
recommended)	13b	For each group, losses and exclusions after randomisation, together with reasons
Recruitment	14a	Dates defining the periods of recruitment and follow-up
	14b	Why the trial ended or was stopped
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)
Discussion		
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses
Generalisability	21	Generalisability (external validity, applicability) of the trial findings
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence
Other information		
Registration	23	Registration number and name of trial registry
Protocol	24	Where the full trial protocol can be accessed, if available
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders

Appendix 3 Summary of risk of bias for studies included in the review based on the Cochrane's "Risk of Bias Tool for Randomized Controlled Trials"

Studies	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Allen et al. 2011	+	+	-	?	+	+	+
Ballary et al. 2008	+	+	?	?	+	+	+
Crowley et al. 2013	+	+	?	?	+	+	+
Dasgupta et al. 2017	+	+	?	?	-	+	+
Davies et al. 2008	+	+	?	?	+	+	+
Dobrosielski et al. 2012	?	?	?	?	-	+	+
Edelman et al. 2015	+	+	-	+	-	+	+
Edelman et al. 2010	+	+	+	+	+	+	+
Gabbay et al. 2013	?	?	?	?	-	+	+
Heisler et al. 2012	+	+	?	?	+	+	+
Hotu et al. 2010	?	?	?	+	+	+	+
Houweling et al. 2011	+	+	-	-	+	+	+
Ishani et al. 2011	+	+	?	+	+	+	+
MacMahon et al. 2009	+	+	?	?	+	+	+
McLean et al. 2008	+	+	-	+	+	+	+
Mons et al. 2013	+	+	?	?	+	+	-

Studies	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Paula et al. 2015	?	?	?	?	+	+	+
Scain et al. 2009	+	+	?	?	+	+	+
Simpson et al. 2011	+	+	?	?	-	+	+
Wakefield et al. 2011	+	+	?	?	+	+	+
Willard-Grace et al. 2015	+	+	+	+	-	+	+
Wong et al.2005	+	+	+	+	+	+	+
Wong et al. 2014	+	+	-	-	+	+	+
Xia et al. 2014	-	-	-	-	?	+	+
Xiao et al. 2009	-	-	-	-	?	+	+
Yu et al. 2014	-	-	-	-	?	+	+

*(+): low risk of bias, (-): high risk of bias, (?): uncertain risk of bias

Appendix 4 Summary of risk of bias for systematic reviews included in the review based on the ROBIS tool

Study	Domain 1: study	Domain 2:	Domain 3: Data	Domain 4:	Overall risk of bias
	eligibility	Identification and	collected and study	Synthesis and	of review
		selection of studies	appraisal	findings	
Chen et al. 2014	+	+	-	+	-
Clark et al. 2011	+	+	+	+	+
Hayashino et al.	+	+	+	+	+
2012					
Wu et al. 2010	+	+	+	+	+

*(+): low risk of bias, (-): high risk of bias, (?): uncertain risk of bias

*Questions from Domain 1:

1.1 Did the review adhere to pre-defined objectives and eligibility criteria?

1.2 Were the eligibility criteria appropriate for the review question?

1.3 Were eligibility criteria unambiguous?

1.4 Were all restrictions in eligibility criteria based on study characteristics appropriate (e.g. date, sample size, study quality, outcomes measured)?

1.5 Were any restrictions in eligibility criteria based on sources of information appropriate (e.g.publication status or format, language, availability of data)?

Questions from Domain 2:

2.1 Did the search include an appropriate range of databases/electronic sources for published and unpublished reports?

2.2 Were methods additional to database searching used to identify relevant reports?

2.3 Were the terms and structure of the search strategy likely to retrieve as many eligible studies as possible?

2.4 Were restrictions based on date, publication format, or language appropriate?

2.5 Were efforts made to minimise error in selection of studies? #

Questions from Domain 3:

3.1 Were efforts made to minimise error in data collection?

3.2 Were sufficient study characteristics available for both review authors and readers to be able to interpret the results?

3.3 Were all relevant study results collected for use in the synthesis?

3.4 Was risk of bias (or methodological quality) formally assessed using appropriate criteria?

3.5 Were efforts made to minimise error in risk of bias assessment?

Questions from Domain 4:

4.1 Did the synthesis include all studies that it should?

4.2 Were all pre-defined analyses reported or departures explained?

4.3 Was the synthesis appropriate given the nature and similarity in the research questions, study designs and outcomes across included studies?

4.4 Was between-study variation (heterogeneity) minimal or addressed in the synthesis?

4.5 Were the findings robust, e.g. as demonstrated through funnel plot or sensitivity analyses?

4.6 Were biases in primary studies minimal or addressed in the synthesis?

Appendix 5 Summary of the included studies

Study	Aims	Number of RCT studies included	Country where study was conducted	Interventions	Outcomes	Limitations
Clark et al. 2011	To identify the effectiveness of nurse- led interventions in the management of hypertension for diabetic patients.	11	UK: 6 Canada: 2 Hong Kong:1 USA:2	 Use of treatment algorithm Nurse prescribing Community monitoring Nurse- led clinics 	Greater reductions of SBP and DBP with nurse-led intervention compared with usual care (SBP: weighted mean differences -5.8 mmHg; DBP: -4.2 mmHg)	1.Less pooling of BP results than anticipated due to lack of absolute measures.2.Lack of blinding in the intervention delivered by health professionals.
Chen et al. 2014	To explore the effects of multifaceted lifestyle intervention including diet, exercise and education on risk factors of cardiovascular disease among diabetic patients.	16	Finland 1 Hongkong 2 Italy 3 Japan 1 New Zealand 1 Netherlands 1 UK 3 US 4	Change of lifestyle incorporates dietary education, reduced caloric intake, increased physical activities, and counseling and education regarding treatment adherence or disease monitoring.	The standardized difference in means of change from baseline significantly favored the intervention compared with the control group in SBP(-0.16, P<0.05), DBP(-0.27, p<0.001).	1.As there are diverse forms of lifestyle changes, little details of interventions were described in the methodology.2.Blinding of the participants and personnel who delivered the intervention.

Systematic reviews and meta-analysis

Study	Aims	Number of RCT studies included	Country where study was conducted	Interventions	Outcomes	Limitations
Hayashino et al. 2012	To assess the effectiveness of supervised exercise interventions on lipid profiles and BP control among diabetic patients	42	Italy: 4 Brazil:6 Norway USA:7 Canada:6 Denmark:3 Australia:5 Greece:3 Korea:2 Belgium:2 Netherlands:1 UK:1 France:1 Israel:1 Finland:4 India:2 Newzeland:1 Austria:1 Japan:1	Supervised exercises	Structured exercise produced significant reduction of SBP (2.42 mm Hg, P <0.001) and DBP (2.23mm Hg, P <0.001)	Only 5.6% reported concealed allocation, only 9.3% had blinded outcome assessments and 35.2% used intention- treat analysis. Publication bias Low quality of studies Heterogeneity
Wu et al. 2010	To assess the effect of telephone follow-up to improve glycaemic control in patients with Type 2 diabetes	7	US 5 UK 2		More intensive modes of follow-up may have better effects on glycaemic control, with a standardized mean difference of –0.84 (95% CI – 1.67 to 0.0) (Z= 1.97, P= 0.05),	Secondary outcome analysis was limited because of inconsistencies in data availability.

RCTs in a global context

Study and country	Study design	Participants and sample size	Framework	Key component of the Intervention	Outcomes	Professionals	Limitations
Allen et al. 2011 USA Community health centres	RCT IG, CG	Patients who had at least one of the following criteria within the past six months (1) an LDL-C \geq 100 mg/dl or LDL-C \geq 130 mg/dl if no diagnosed CVD or diabetes, (2) a blood pressure > BP 140/90 mm Hg or > 130/80 mm Hg if diabetic or renal insufficiency, or (3) if diabetic, a HbA1c 7% or greater or glucose \geq 125 mg.	Community- based participatory research (CBPR)	 12-months interventions: 1.Aggressive pharmacologic management, tailored 2.Educational and behavioural counselling for lifestyle modification, identification of barriers to adherence and control, phone follow-ups between visits and pre- appointment reminders. 	Reduction in SBP: IG: -8.9; CG: -2.7; between group differences in SBP: - 6.2 (P<0.05) Reduction in DBP: IG: -5.6; CG: -2.6; between group differences in SBP: - 3.1 (P<0.05)	Nurse practitioners/community health workers	Limited Generalizability as highly trained NPS and CHWs were used A sample of predominately Black women CG contaminated by IG Higher attrition rate in the IG (13%) than CG (9%), but the study was powered to account for a dropout rate of 25%

Study and country	Study design	Participants and sample size	Framework	Key component of the Intervention	Outcomes	Professionals	Limitations
		525					
Ballary et al. 2008 UK	Cluster RCT IG, CG	Adult patients of south Asian origin with type 2 diabetes	Unknown	24-month interventions: 1.Additional time	Between group difference in SBP (- 1.4, P=0·082),	Practice nurses, link workers and diabetes- specialist nurses	Missing data analysis using last observation carried forward
Community		Z diabetes		 with practice nurse and support from a link worker and diabetes-specialist nurse; follow up; Lifestyle education; 2.Practice nurse consulted GP for prescribing changes 	Between group difference in DBP (- 1·91; P<0.05)		method
Crowley et al. 2013 USA Primary care clinics	RCT IG, CG	African Americans with type 2 diabetes 359	Unknown	12-month intervention provided monthly self-management education (disease management knowledge, psychosocial factors of disease control and lifestyle) via telephone calls and guarterly medication	Reduction in SBP: IG: 0.9; CG: -2.1; between group differences: 3.0 (P = .11)	Nurses and primary care providers	Not face to face education Using model- derived outcome estimates may have biased the results toward the null. Little control of confounding

Study and country	Study design	Participants and sample size	Framework	Key component of the Intervention	Outcomes	Professionals	Limitations
				management facilitation via electronic nurse- primary care provider communication.			variables via sampling methods and statistical analysis.
Dasgupta et al. 2017 Canada Hospital	RCT IG, CG	Adults with diabetes and hypertension, body mass index (BMI) of 25 to 40 kg/m ² ; and absence of gait impairment. 347	Unknown	12-month physician- delivered step count prescription strategy and goal setting	SBP reduction within group: IG: -2.2; CG: 0.3: between group differences: -2.5 DBP reduction within group: IG: -1.4; CG: - 0.2; between group differences: -1.2	Physicians	Attrition bias, 79% participants completed
Davies et al. 2008 UK Primary care settings	Cluster RCT IG, CG	People with newly diagnosed type 2 diabetes 824	Psychological theories of learning: Leventhal's common sense theory, the dual process theory, and the social learning	12-month structured group education programme for six hours delivered in the community by two trained healthcare professional educators	SBP reduction within group: IG: -6.1; CG: - 6.2; between group 0.7 (P=0.6)	Trained healthcare professional educators	Unbalanced baseline data

Study and country	Study design	Participants and sample size	Framework	Key component of the Intervention	Outcomes	Professionals	Limitations
			theory				
Dobrosielski et al. 2012 USA Community	RCT IG, CG	Participants, aged 40 to 65 years, with T2DM and with untreated suboptimal BP or treated hypertension 140	Unknown	1.Supervised exercise, 3 times per week for 6 months2.Close monitoring of BP	SBP reduction within group: IG: -0.4; CG: - 0.8; between group 0.4 (P=0.8)	Nurses	Attrition bias
Edelman et al. 2015 USA Primary care practice	RCT IG, CG	Patients with diabetes and hypertension 377	Health Decision Model (HDM)	 1.A call from a nurse experienced in diabetes and hypertension management once every two months over a period of 12 months (for a total of 12 calls). 2.Tailored diabetes and hypertension- focused behavioural content 	SBP reduction between groups at 2 years: -0.9 (P=0.6); DBP: 0.4 (P=0.7)	Nurses	Two months frequency of contact is low to bring BP change.Attention control was used instead of usual care controls.The research design allowed patients having adequate BP control to attend the study, and this

Study and country	Study design	Participants and sample size	Framework	Key component of the Intervention	Outcomes	Professionals	Limitations
Edelman et	RCT	Patients with	Unknown	1.Interactive and	SBP reduction	Nurse/educator,	would restrict the change of BP Attrition bias at 2 years (69% in IG; 70% in CG) Limited
al. 2010 USA Primary care settings	IG, CG	diabetes and hypertension 239		tailored educational session over 12 months (medication, lifestyle, health knowledge) delivered by the nurse or educator. 2.Individualized plans for medication adjustment or lifestyle management developed by pharmacist and primary care internist	between groups: -7.3 (P<0.05); DBP: -3.8 (P<0.05)	pharmacist and primary care internist	generalizability Control group contaminated by intervention
Gabbay et al. 2013	RCT	Patients who had one or more of the	Case management	24-month interventions	Between group difference in SBP	Nurse case managers, diabetes nurse	Attrition bias (lost 32% participants)

Study and country	Study design	Participants and sample size	Framework	Key component of the Intervention	Outcomes	Professionals	Limitations
USA Primary care clinics	IG, CG	following: (1) HbA1c >8.5%; (2) blood pressure >140/ 90 mmHg; and/or (3) Low- density lipoprotein (LDL) >130 mg/dl. 545	model	 including: 1.review of the patient's clinical laboratory test results, lifestyle behaviour and medication adherence through motivational interviewing. 2. Referrals to a certified diabetes nurse educator or a dietitian were made when appropriate. 3. NCMs prompted the PCPs for medication titrations when necessary. 	was not calculated. SBP at 2 years: IG: 131; CG: 135 (P<0.05)	educator, dietitian	

Study and country	Study design	Participants and sample size	Framework	Key component of the Intervention	Outcomes	Professionals	Limitations
Heisler et al. 2012 USA Outpatient primary care clinics	Cluster RCT IG, CG	T2DM with persistent poor BP control and poor refill adherence or insufficient medication intensification	Self Determination Theory and social cognitive theory	 14-month interventions: 1.Motivational Interviewing 2.Medication adherence 3.Develop action plan 4.Regular follow-up 	Reduction in SB P at 20 months IG: -8.9 CG: -9.0 Between group difference 0.18 (P>0.05)	Pharmacists and primary care providers	Nil
Hotu et al. 2010 New Zealand Community	RCT IG, CG	Māori and Pacific patients with type 2 diabetes, aged 40–75 years, with diabetic nephropathy (>0.5 g proteinuria/24-h and serum creatinine 130– 300 µmol/I) and BP >130/80 mmHg.	Integrated, community- based model of care	Monthly community visits over 12 months by a nurse- led health-care assistant including 1.Lifestyle 2.Health knowledge about diseases and complications 3.Medication adherence	Reduction in SBP within group: IG: -21 (P<0.05); CG: -12 (P<0.05) Between group differences: IG vs CG at 12 months (P<0.05)	Health-care assistants, doctors, nurses	Nil

Study and country	Study design	Participants and sample size	Framework	Key component of the Intervention	Outcomes	Professionals	Limitations
		65		4.Medication adjustment by study doctor			
Houweling et al. 2011 Netherland Primary care setting	RCT IG, CG	Patients with diabetes 230	Unknown	14-month care by trained practice nurse who treated glucose levels, blood pressure and lipid profile according to a specified protocol. Practice nurses were permitted to prescribe 14 different medications and to adjust dosages for a further 30	Reduction in SBP; IG: -7.4; CG: -5.6; between group difference -0.18 (P=0.122) Percent of patients achieved BP<140/90 at end of intervention: IG 25.5%; CG:21.2%	Practice Nurses	Blinding bias Confounding factors: different amount of time given to each patient The amounts of patients followed up was less than required sample size.
Ishani et al. 2011 USA	RCT IG, CG	Had one or more of measures for HbA1c, LDL, or BP within the	Case management	Nurse case management over 12 months: 1. lifestyle	BP goal<130/80: lg: 40.6%; CG: 15.9% (P<0.001)	Nurse case managers and primary care providers	The few women and minorities enrolled Unbalanced
Primary care setting		study inclusion criteria (HbA1c > 9.0%, LDL		modification goal (weight loss, dietary changes, physical			baseline data No information

Study and country	Study design	Participants and sample size	Framework	Key component of the Intervention	Outcomes	Professionals	Limitations
		>100 mg/dl, and BP >140/90 mmHg) 550		activity, smoking cessation), personal action plan, medication adjustment 2.telephone contacts to monitor BP, address self- care difficulties.			about case manager to patient ratio that may affect the outcomes of trial No information about training for case managers to improve the integrate reliability in a trial
MacMahon et al. 2009 Ireland Hospital	RCT IG, CG	Patients who were failure to meet recommended targets for cholesterol (total cholesterol [4.8 mmol/L or LDL [2.6 mmol/L) or blood pressure (BP [130/80 mmHg) management, or both, after intervention in	Unknown	Intensive nurse- led diabetes care over 12 months including 1. lifestyle advice, medication adjustment, 2. feedback on vascular risk targets based on regular follow-up.	Reduction in SBP: IG: -10.5; CG: 1.7; between group difference in SBP (P<0.05) Reduction in DBP: IG: -5.9; CG: -0.5; between group difference in SBP (P<0.05) Percent of patients achieving BP target <140: IG: 71.3%;	Nurses	Nil

Study and country	Study design	Participants and sample size	Framework	Key component of the Intervention	Outcomes	Professionals	Limitations
		the hospital diabetes clinics.			CG:32.6% (P<0.05)		
McLean et al. 2008 Canada Community pharmacies	RCT IG, CG	People with type 1 or 2 diabetes and blood pressure >130/80 mm Hg at two visits 2 weeks apart aged 18 years or older 227	Unknown	Education (6-week intervals) with nurse-pharmacist team; referral to family physicians for BP assessment over 6 months	Reduction in SBP: IG: -10.1; CG: -5 Between group difference in SBP: -5.6 (P<0.05) BP goal: IG:54/115; CG:37/112	Pharmacists and nurses	 1.Investigator volunteer bias that may limit generalizability of the program 2.Intervention involved substantial in- person contact time between patients and study personnel

Study and country	Study design	Participants and sample size	Framework	Key component of the Intervention	Outcomes	Professionals	Limitations
Mons et al. 2013 Germany General practice setting	RCT IG, CG	Diabetic patients with poor glycaemic control at baseline 204	Unknown	Monthly supportive telephone-based counselling sessions over 12 months including monitoring of patients' health status, medication adherence, lifestyle, support of self-care and GP referral when needed.	Reduction in SBP: IG: -5.2; CG: 2.3 (P<0.05)	Practice nurses and GPs	Contamination bias due to individual randomization rather than cluster randomization
Paula et al. 2015 Brazil Outpatient clinics at hospital	RCT IG, CG	Outpatients with diabetes and hypertension 40	Unknown	Dietary Approaches to Stop Hypertension (DASH) diet eating plan and physical activity over 4 weeks	Reduction in SBP: IG: -17.6; CG: -6.3 (P<0.05) Reduction in DBP: IG: -17.6; CG: -6.3 (P<0.05)	Research dietitians and physical educators	Short follow-up period
Scain et al. 2009 Brazil Outpatient	RCT IG, CG	Patients with type 2 diabetes, not on insulin therapy	Unknown	8-hour structured group education program over 4 weeks (delivered in 4 sessions, for 4 weeks, by a trained	Reduction in SBP: IG: -10.2; CG: -4.6 Between group difference not	Trained nurse educators	Nil

Study and country	Study design	Participants and sample size	Framework	Key component of the Intervention	Outcomes	Professionals	Limitations
clinics at hospital		104		nurse educator) including lifestyle and health knowledge about diseases, complications, symptoms	significant		
Simpson et al. 2011 Canada Primary care clinics	RCT IG, CG	Patientswith diabetes and uncontrolled BP 153	Unknown	 1.Medication adjustment by pharmacist over 12 months through discussion with primary care physician; 2.Follow-up with patients to address medication related barriers (side effects, adverse events and adherence issues) 	Reduction in SBP: IG: -13.9; CG: -6.7 achievement of a clinically important reduction in blood pressure, defined as a 10% decrease in SBP at 1 year: 50% in IG (P<0.001); 28% in CG (P<0.001); OR: 2.5, (P=0.007)	Pharmacists with bachelor's degree in pharmacy, certified diabetes educator, and had practiced in community pharmacies for over 5 years.	Short-term intervention CG contaminated by IG high drop-out rate (14%)
Wakefield et al. 2011	RCT IG*2	Community- based patients with both diabetes and	Unknown	1.Nurse- managed home telehealth intervention over 6 months	1.For SBP, the high- intensity subjects had a significant decrease in SBP compared with the other groups	Nurses and physicians	Subjects had relatively good baseline control for A1c and SBP; minorities and

Study and country	Study design	Participants and sample size	Framework	Key component of the Intervention	Outcomes	Professionals	Limitations
USA Primary care clinics	CG	hypertension 302		2.Close surveillance support, and communication with nurse, lifestyle, medication education, medication adherence, follow- up	at 6 months and this pattern was maintained at 12 months. 2.BP reduction at 12 months: IG (high intensity): -4.9;IG (low intensity):0.76;CG:3.3		women were underrepresented
Willard- Grace et al. 2015 USA Primary care clinics	RCT IG CG	Adults who has either uncontrolled diabetes, or uncontrolled hypertension or uncontrolled hyperlipidaemia	Unknown	12 months in-clinic health coaching (review care plan, follow up between visits in person at least once every 3 months and by telephone at least once a month; lifestyle, health education, medication adherence, action plan)	Proportion in achieving SBP goal (IG:23.8% VS CG:28.9%) (P=0.46)	Trained medical assistants	Limited generalizability due to only 3 coaches delivered interventions Attrition bias Control group influenced by interventions
Wong et al. 2005	RCT	Patients with diabetes who needed	Unknown	A follow-up programme which included a weekly or	A shorter hospital stays (IG vs CG: 2.2	Nurses	Short follow-up (24 weeks)

Study and country	Study design	Participants and sample size	Framework	Key component of the Intervention	Outcomes	Professionals	Limitations
Hongkong Community	IG, CG	glycaemic monitoring and fit for discharge 101		biweekly telephone call from a nurse	vs 5.9) (P<0.001) A higher blood monitoring adherence at 24 weeks (IG vs CG: 5.3 vs 3.5) (P<0.001) A higher exercise adherence score at 24 weeks (IG vs CG:5.5 vs 3.2) (P<0.001)		
Wong et al. 2014 Hongkong Community	RCT IG1(home visits with calls) IG2 (calls only) CG	Discharged patients with chronic conditions 610	Unknown	Pre-discharge assessment and 4- week post- discharge follow-up involving two home visits (Weeks 1 and 3) and two phone calls (Weeks 2 and 4).	Lower readmission rates after 12 weeks (IG1 vs CG: 21.4% vs 25.7%)	Nurse case managers	Sampling bias Lack of cost- effectiveness analysis
	1	<u> </u>	F	RCTs in a Chinese	context	1	<u> </u>

Study and country	Study design	Participants and sample size	Framework	Key component of the Intervention	Outcomes	Professionals	Limitations
Xia et al. 2014 China Community	RCT IG, CG	Patients with hypertension and diabetes 860	Unknown	 Individualised health education on lifestyle and medication adherence through home visiting Regular follow up to monitor BP and lifestyle 	Reduction in SBP between groups: -4.81(P<0.05)	GPs and community nurses	Blinding bias
Xiao et al. 2009 China Community	RCT IG, CG	Patients with diabetes 132	Unknown	1.Individualised discharge education at hospital2. Fortnightly follow- up after discharge over 3 months	Proportion in uncontrolled BP: 31.3% (before intervention) VS 1.4% (after intervention (IG) (P<0.001)	Community nurses	Blinding bias
Yu et al. 2014 China Community	RCT IG, CG	Older patients with hypertension and diabetes 150	Unknown	Education on disease, lifestyle modification, develop action plan for physical activity	Reduction in SBP between groups: -11.85 (P<0.05)	Community nurses	Blinding bias

Appendix 6 Summary of detailed intervention strategies: intervention items and health professional groups who delivered the intervention items

Intervention items	Detailed contents	Health professional groups delivered the intervention
Lifestyle modification	Nurses conducted lifestyle modification and counselling including increasing physical activity and a customized walking program; smoking cessation; and a place to record questions for future visits.	Nurse
	Physician wrote a step count prescription at each visit to improve physical activity.	Physician
	Conducted health education including (1) reviewing BP as a risk factor, (2) discussing the causes of high BP, (3) describing the importance and consequences of high BP, (4) explaining the effect of diabetes on high BP, and (5) focusing on the lifestyle strategies the patient could undertake to improve BP.	Pharmacist
	The dietitian will establish diet plan for patients.	Dietitian
Close monitoring/ surveillance of conditions (i.e.	When patients are discharged from hospital, they will be referred to the community health centres.	Nurse
regular follow-up visits)	Discharge summary and pharmacotherapy history sent to the community nurse by the in-charge nurse on discharge.	
	Clinical outcomes were recorded and formatted as monthly report by the community nurse, and sent to specialist for review by Email.	
	Patients visited the community nurse and GPs in community health centres every month.	
	Fortnightly phone call to monitor patient's progress towards the setting goals, medication adherence and encourage to self- monitoring of BP, blood glucose.	
	Fortnightly phone call to monitor their conditions, progress and adverse events.	Nurse case manager

Intervention items	Detailed contents	Health professional groups delivered the intervention
	Followed up with patients between visits in person and by telephone.	Medical assistants
Treatment adherence (medication and behaviour)	The importance of dietary adherence was emphasized as an adjunct to pharmacotherapy.	Nurse
	Community nurse assessed whether the patient's medication-related needs being met and whether any medication therapy problems presented	-
	Problems of non-adherence to medication, possible medication side effects, BP results and any other significant clinical events occurring will be assessed by the community nurse and discussed with the patient.	
Medication review, adjustment and intensification	Nurse practitioner implemented medication titration and prescription.	Nurse practitioner
	Pharmacist formulated guideline-concordant recommendations to optimize medication management of blood pressure and other cardiovascular risk factors. These recommendations were discussed with the primary care physician who was responsible for authorizing medication changes.	Pharmacist
	The study case managers also made adjustments to the patients' medications.	Nurse case manager
	When necessary, the GP discussed with the specialist via email/telephone to adjust medication and therapeutic agents.	GP
Health education on diseases	Community nurses reinforced health education; improved prevention or treatment of existing geriatric conditions; improved patient's self-management ability.	Nurse
	Provided medication education by pharmacist.	Pharmacist

Intervention items	Detailed contents	Health professional groups delivered the intervention
Timely referral for further treatment (BP assessment/discuss with primary physician for medication)	Urgent symptoms were communicated to the specialist immediately for additional orders by GP through telephone.	Nurse
Improve motivation in self- care	The community nurse used motivational interviewing to facilitate the patient to adhere to medication at the monthly visits	Nurse
Partnership in goal setting and action plan	Community nurses guided patients to record their health goals, potential barriers, strategies to deal with difficult situations, ways to reward oneself; and identification of support people to help facilitate meeting goals. Develop individualized low-fat, low-sodium eating plans.	Nurse
	Established personal action plans, lifestyle modification goals, the progress towards the goals and adherence to medication.	Pharmacist
	established lifestyle modification goals (including goals for weight loss, dietary changes, physical activity, and smoking cessation, as appropriate) and developed personal action plans.	Nurse case manager

Appendix 7 Questionnaire for round 1 of the Delphi study

Questionnaire for round 1 of the Delphi study

Thank you for your willingness to participate in this study. The aim of this first round of survey is to seek your comments on the questions listed below. Could you please provide your answers in the space provided?

Once again, I really appreciate your support for this project.

PART A: Professional background

Please tick a box that applies to you

- 1. Your gender: Male \Box Female \Box
- 2. Your age _____ years
- 3. Your profession:

Specialist in hospital□

General practitioner in community health centre \Box

Specialized nurse in hospital \Box

Nurse in community health centre \Box

Dietitian 🗆

Pharmacist

4. The highest level of education you achieved

Diploma 🗆

Bachelor \Box

Master

PhD 🗆

5. Your current position and job title: For example associate chief physician, head of endocrine department

- 6. How many years have you been in the current position? ______years
- 7. How many years have you worked in your profession? ______years
- 8. What is your specialty in your profession?
- 9. How many years have you worked in the specialty area? ______years

10. What is the level of health care facilities you are working in based on the Government's current classifications of health care facilities?

Community health service centre \Box

Secondary healthcare organization \Box

Tertiary healthcare organization \Box

11. Are there other details about your practice or professional background you would like me to know? (Please write your answer in the space provided or attach separate documents if needed)

Part B: Content development of the intervention protocol

The intervention in this study will target diabetic patients with uncontrolled hypertension and are hospitalized for treatment for diabetics, hypertension and associated complications. Interventions will start from hospital (stage 1) and continue to in the community settings after discharge (stage 2). The Interventions will last 6 months. Health professionals from both hospital and community health centres will work in a collaborative way to implement the interventions.

The evidence-based intervention protocol described below was developed based on systematic review, meta- analysis, WHO guidelines and high-quality randomised controlled trials (RCTs) published by peer reviewed and international journals which had been approved to be effective in controlling blood pressure for diabetic patients in previous studies. In this part, you will be asked to make comments on the feasibility of this intervention protocol if it is implemented in hospitals and community health service centres (CHSCs) in Jiangxi Province. Please provide your

answer by giving a tick sign (\checkmark) in the agreement space and make further comments when disagree.

Stage 1: In the hospital

Main interventions	Detail of interventions		ee, disagree or unsure that the following mplemented in local hospital settings)
1.Health education	1. Patient will be provided with two face-to-face health education sessions (20 min. for each session) (health behaviour education and disease- associated education) by his/her in-charge nurse using a standardised guide and booklets provided by the researcher.	Agree	Unsure Disagree (If unsure or disagree, please answer the questions below) 1) What are your concerns or the barriers to implement the intervention? 2) What's your recommendation to overcome the barriers?
2.Lifestyle modifications – goals & action plan	2. Patients (or his/her caregivers) will establish lifestyle modification goals and develop personal action plans in working with the in-charge nurse.	Agree 🗆	Unsure Disagree (If unsure or disagree, please answer the questions below) 1) What are your concerns or the barriers to implement the intervention? 2) What's your recommendation to overcome the barriers?
	3. A user-friendly "Intervention diary-Patient version" will be provided to the patient by in-charge nurse to document personal action plans, lifestyle modification goals, the progress towards the goals and adherence to medication.	Agree 🗆	Unsure Disagree (If unsure or disagree, please answer the questions below) 1) What are your concerns or the barriers to implement the intervention? 2) What's your recommendation to overcome the barriers?

3. Medication education	4. Patients will be provided medication education by pharmacist. It includes: understanding the importance of complying with medication, how to identify and manage side effects, drug-drug interactions (including with traditional Chinese medicine TCM) and contradictions to other drugs or TCM.	Agree 🗆	Unsure Disagree (If unsure or disagree, please answer the questions below) 1) What are your concerns or the barriers to implement the intervention? 2) What's your recommendation to overcome the barriers?
4. Development of medication plan	5 Prior to discharge, an individualized medication treatment plan will be developed for each patient by the specialist. These will be documented in the "Intervention diary- Patient version" and the "Intervention record- Community nurse and GP version". (Level 1)	Agree 🗆	Unsure Disagree (If unsure or disagree, please answer the questions below) 1) What are your concerns or the barriers to implement the intervention? 2) What's your recommendation to overcome the barriers?
5. Diet management	6. The dietitian will establish diet plan for patients based on a dietary guideline (Dietary Approaches to Stop Hypertension (DASH) eating plan).	Agree 🗆	Unsure Disagree (If unsure or disagree, please answer the questions below) 1) What are your concerns or the barriers to implement the intervention? 2) What's your recommendation to overcome the barriers?
6.Discharge planning	7. When patients are discharged from hospital, they will be referred to the nearest Community Health Centres.	Agree 🗆	Unsure Disagree (If unsure or disagree, please answer the questions below) 1) What are your concerns or the barriers to implement the intervention? 2) What's your recommendation to overcome the barriers?

8. Discharge summary and pharmacotherapy history will be sent to the community nurse by the in-charge nurse on discharge.	Agree 🗆	Unsure Disagree (If unsure or disagree, please answer the questions below) 1) What are your concerns or the barriers to implement the intervention? 2) What's your recommendation to overcome the barriers?
9. An "Intervention record- Community nurse and GP version" will be sent to the community nurse and GP by the in-charge nurse to record required post-discharge interventions and outcomes.	Agree □	Unsure □ Disagree □ (If unsure or disagree, please answer the questions below) 1) What are your concerns or the barriers to implement the intervention? 2) What's your recommendation to overcome the barriers?

Stage 2:6 months follow up visits in the community health centres

Main interventions	Detail of interventions	Agreements (Agree, disagree or unsure that the following contents can be implemented in local community settings)
1. Fortnightly phone call	10. The community nurse will provide fortnightly phone call to monitor patient's progress towards the setting goals, medication adherence and encourage to self- monitoring of BP, blood glucose.	Agree Unsure Disagree (If unsure or disagree, please answer the questions below) 1) What are your concerns or the barriers to implement the intervention?
	11. The time and date for the phone support will be documented in the "Intervention diary- Patient	Agree Unsure Disagree If unsure or disagree, please answer the questions below)

	version" by the patient and the "Intervention record- Community nurse and GP version" by the community nurse.		 1) What are your concerns or the barriers to implement the intervention? 2) What's your recommendation to overcome the barriers?
2.Monthly clinic visit	12. Patients will visit the community nurse and GPs in CHSC every month.	Agree 🗆	Unsure Disagree (If unsure or disagree, please answer the questions below) 1) What are your concerns or the barriers to implement the intervention? 2) What's your recommendation to overcome the barriers?
	13. The time and date for the monthly review by community nurse will be documented in the "Intervention diary- Patient version" by the patient and the "Intervention record- community nurse and GP version" by the community nurse.	Agree 🗆	Unsure Disagree (If unsure or disagree, please answer the questions below) 1) What are your concerns or the barriers to implement the intervention? 2) What's your recommendation to overcome the barriers?
2.1Health education	14. Based on the patient's needs, the community nurses will reinforce health education; improve prevention or treatment of existing geriatric conditions; improve patient's self-management ability.	Agree 🗆	Unsure Disagree (If unsure or disagree, please answer the questions below) 1) What are your concerns or the barriers to implement the intervention? 2) What's your recommendation to overcome the barriers?
2.2 Adherence to health behaviour	15. The community nurse will review and assess patient's adherence to diet and lifestyle recommendations and current medication therapy,	Agree 🗆	Unsure Disagree (If unsure or disagree, please answer the questions below) 1) What are your concerns or the barriers to

	solve psychosocial barriers to self-care.		implement the intervention?
2.3 Medication adherence and medication intensification	16. The community nurse will use motivational interviewing to facilitate the patient to adhere to medication at the monthly visits.	Agree 🗆	Unsure Disagree (If unsure or disagree, please answer the questions below) 1) What are your concerns or the barriers to implement the intervention? 2) What's your recommendation to overcome the barriers?
	17. Problems of non-adherence to medication, possible medication side effects, BP results and any other significant clinical events occurring will be assessed by the community nurse and discussed with the patient.	Agree 🗆	Unsure Disagree If unsure or disagree, please answer the questions below) 1) What are your concerns or the barriers to implement the intervention? 2) What's your recommendation to overcome the barriers?
	18. At each visit, the community nurse will assess whether the patient's medication-related needs being met and whether any medication therapy problems presented.	Agree 🗆	Unsure Disagree (If unsure or disagree, please answer the questions below) 1) What are your concerns or the barriers to implement the intervention? 2) What's your recommendation to overcome the barriers?
	19. At each visit, the patient will be informed and reminded the categories, dosage and frequency of medication required to be taken prior to the next visit by the community nurse.	Agree 🗆	Unsure Disagree (If unsure or disagree, please answer the questions below) 1) What are your concerns or the barriers to implement the intervention?

			2) What's your recommendation to overcome the barriers?
2.4 Adjustment of medication treatment	20. BP, blood glucose, HbA1c, full lipid profile will be measured and assessed by the community nurse.	Agree 🗆	Unsure Disagree (If unsure or disagree, please answer the questions below) 1) What are your concerns or the barriers to implement the intervention? 2) What's your recommendation to overcome the barriers?
	21. The GP will be given a treatment guideline that has been agreed by experts in China to review and revise patients' individual treatment plan that is originally developed by the specialist. When necessary, the GP will discuss with the specialist via email/telephone to adjust medication and therapeutic agents.	Agree 🗆	Unsure Disagree (If unsure or disagree, please answer the questions below) 1) What are your concerns or the barriers to implement the intervention? 2) What's your recommendation to overcome the barriers?
	22. All decisions made in medication changes will be documented in the "Intervention diary-patient version" and in the "Intervention record-community nurse and GP version".	Agree 🗆	Unsure Disagree (If unsure or disagree, please answer the questions below) 1) What are your concerns or the barriers to implement the intervention? 2) What's your recommendation to overcome the barriers?
	23. BP, glucose readings and other clinical outcomes will be recorded and formatted as monthly report by the community nurse, and then sent to specialist for review by Email.	Agree 🗆	Unsure Disagree (If unsure or disagree, please answer the questions below) 1) What are your concerns or the barriers to implement the intervention?

		2) What's your recommendation to overcome the barriers?
24. Urgent symptoms will be communicated to the specialist immediately for additional orders by GP through telephone.	Agree 🗆	Unsure Disagree (If unsure or disagree, please answer the questions below) 1) What are your concerns or the barriers to implement the intervention? 2) What's your recommendation to overcome the barriers?

Appendix 8: Email text sent to potential participants

As the researcher and researcher's supervisor don't have the Email address of potential participants, the liaison person will forward the researcher's email below to the potential participants.

Subject: Invitation to a two-round survey on hypertension management for patients with diabetes

Dear colleagues,

I am forwarding the invitation to a two-round survey from Mr Qiang Tu, a PhD student from Flinders University in Australia to you. Please find the letter of support from the Department of Scientific Research Management of Health and Family Planning Commission of Jiangxi Province, letter of introduction to Mr Qiang Tu and his study provided by his supervisor, Associate Professor Lily Xiao at Flinders University in Australia, Information sheet, and questionnaire in the attachment. If you agree

to participate in the survey, please complete the questionnaire attached and return it to Mr Qiang Tu via his email address: tu0023@flinders.edu.au. If you do not wish to participate in the survey, please disregard this email.

Best regards

Liaison person's name

Subject: Invitation to a two-round survey on hypertension management for patients with diabetes

Dear potential participants,

My name is Qiang Tu who is a PhD student in the School of Nursing and Midwifery at Flinders University. I am undertaking a research to obtain health professionals' opinions on the applicability of a nurse-coordinated evidencebased hypertension management program for people with diabetes into care services in Nanchang, China, which will lead to the production of my PhD thesis and possible publication. The findings of the study will further improve the program design that is suitable for the Chinese healthcare context. I would like to invite you to assist with this project by completing a questionnaire which covers certain aspects of this topic. Around two hours on two occasions would be required. The research project has been granted permission by the Department of Scientific Research Management of Health and Family Planning Commission of Jiangxi Province, and approved by the Flinders University Social and Behavioural Ethics Committee. I have attached the letter of support from the Department of Scientific Research Management of Health and Family Planning Commission of Jiangxi Province, letter of introduction, information sheet, questionnaire and all other documents in the attachment for you to view. Please read the letter of introduction and information sheet before you make a decision to fill out the questionnaire.

Be assured that any information provided will be treated in the strictest confidence. The participant identity will be protected by not asking participants' name in the questionnaire survey and by not mentioning the names of health care facility in the resulting thesis, reports or other publications. Participant identities may be identifiable due to the small population pool within hospitals/health service centres. Participating in this study is entirely voluntary and you are free to withdraw from the study at any time without any repercussions on your employment status. All the data will be stored on

the Flinders University computer server with password protection.

If you are agree to participate, please complete the attached questionnaire then return it to me directly via this email address: tu0023 @flinders.edu.au. If you do not wish to participate in the survey, you do not need to do anything.

Thank you for your attention and assistance.

Yours sincerely

Qiang Tu

Appendix 9: Ethics approval for Delphi study

Monday, December 17, 2018 at 3:15:54 PM Australian Central Daylight Time

Subject: 7109 SBREC final approval notice (5 February 2016)

Date: Friday, 5 February 2016 at 11:33:00 am Australian Central Daylight Time

From: Human Research Ethics

To: Qiang Tu, Lily Xiao, Jeff Fuller, huiyun.du@flinders.edu.au, Shahid Ullah Priority: High

Dear Qiang,

The Chair of the <u>Social and Behavioural Research Ethics Committee (SBREC)</u> at Flinders University considered your response to conditional approval out of session and your project has now been granted final ethics approval. This means that you now have approval to commence your research. Your ethics final approval notice can be found below.

FINAL APPROVAL NOTICE

Project No.:	7109		
Project Title:		on the applicability of a nurse-coordina anagement program for people with d	
Principal Resear	cher: Mr Qia	g Tu	
Email:	<u>tu0023</u>	<u>)flinders.edu.au</u>	
Approval Date:	5 February 20	6 Ethics Approval Expiry Date:	1 April 2017

The above proposed project has been **approved** on the basis of the information contained in the application, its attachments and the information subsequently provided.

RESPONSIBILITIES OF RESEARCHERS AND SUPERVISORS

1. Participant Documentation

Please note that it is the responsibility of researchers and supervisors, in the case of student projects, to ensure that:

- all participant documents are checked for spelling, grammatical, numbering and formatting errors. The Committee does not accept any responsibility for the above mentioned errors.
- the Flinders University logo is included on all participant documentation (e.g., letters of Introduction, information Sheets, consent forms, debriefing information and questionnaires – with the exception of purchased research tools) and the current Flinders University letterhead is included in the header of all letters of introduction. The Flinders University international logo/letterhead should be used and documentation should contain international dialling codes for all telephone and fax numbers listed for all research to be conducted overseas.

Page 1 of 3

Appendix 10: Ethics approval for cluster randomised controlled trial

Office for Research

Flinders Medical Centre Ward 6C, Room 6A219 Flinders Drive, Bedford Park SA 5042 Tel: (08) 8204 6453 E: Health.SALHNOfficeforResearch@sa.gov.au



Government of South Australia

SA Health Southern Adelaide Local Health Network

Final approval for ethics application

You are reminded that this letter constitutes ethical approval only. Ethics approval is one aspect of the research governance process.

You must not commence this research project at any SA Health sites listed in the application until a Site Specific Assessment (SSA), or Access Request for data or tissue form has been authorised by the Chief Executive or delegate of each site.

30 November 2016

A/Professor Lily Xiao School of Nursing and Midwifery Flinders University BEDFORD PARK SA 5042

Dear A/Professor Xiao

The Southern Adelaide Clinical Human Research Ethics Committee (SAC HREC EC00188) have reviewed and provided ethical approval for this application which appears to meet the requirements of the *National Statement on Ethical Conduct in Human Research*.

Application Number: OFR # 345.16 - HREC/16/SAC/308

Title: Hypertension management program for community-dwelling older people with diabetes in Nanchang, China: a cluster randomised controlled trial

Chief investigator: A/Professor Lily Xiao

Approval Period: 30 November 2016 to 30 November 2019

The below documents have been reviewed and approved:

- General Research Application v.1.0 dated 26 August 2016
- PICF Intervention Group v1.0 13 dated August 2016
- PICF Usual Care Group PICF Intervention Group v1.0 13 dated August 2016
- Intervention Protocol v1.0 dated 16 August 2016
- Health Knowledge Questionnaire v1.0 dated 16 August 2016
- Intervention Diary Patient v1.0 dated 16 August 2016
- Intervention Record Community Nurse & GP v1.0 dated 16 August 2016
- Recruitment Posters & Response Slips v1.0 dated 16 August 2016
 Email Text Health Professionals Pilot v1.0 dated 16 August 2016
- Letter of Introduction v1.0 dated 25 August 2016.pdf
- Letter of Introduction v1.0 dated 25 August 2010.pdf

The following documents have been noted:

- SBREC Approval dated 5 February 2016
- Fulmer Spices Comprehensive Assessment Tool Older Adults v1.0 dated 16 August 2016
- Usual Care Table v1.0 dated 16 August 2016
- Chinese Versions
 - Chinese version Appendices
 - Chinese version Hypertension Knowledge Level Scale (HK-LS)

Appendix 11: Letter of support

Letter of support from Department of Scientific Research Management at Health and Family Planning Commission of Jiangxi Province, China

(Original document)

江西省卫生和计划生育委员会处(室)便函

批准函

2015年,我国正式发布了《全国医疗卫生服务体系规划纲要 (2015-2020)》,强调医院与社区卫生服务中心建立协作关系,提 高社区卫生服务中心对慢性病的预防和管理,以减少医院照护负担和 国家医疗负担。涂强是澳大利亚弗林德斯大学医学、护理与健康科学 学院的博士生,他的"基于循证医学的二型糖尿病患者高血压管理" 项目研究符合规划纲要的政策要求。

我们支持涂强在以下医院和社区卫生服务中心(医院:江西省人 民医院、南昌市第一医院、南昌大学第四附属医院、南昌三三四医院; 社区卫生服务中心:百花洲社区卫生服务中心、墩子塘社区卫生服务 中心、滕王阁社区卫生服务中心、十字街社区卫生服务中心、丁公路 社区卫生服务中心、系马桩社区卫生服务中心)开展题目为:基于循 证医学的二型糖尿病患者高血压管理项目在南昌实行的实用性问卷 调查,以及该管理项目的效果评价:随机对照试验等。该课题不需要 进行伦理申请。

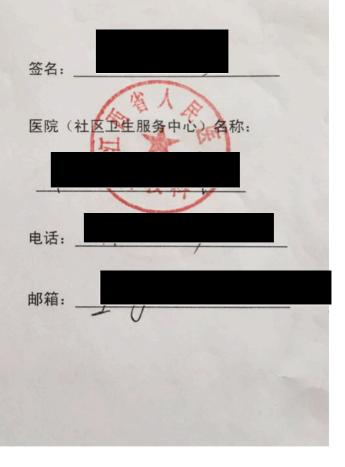


Letter of support from participating hospitals and community health centres

(Original document)

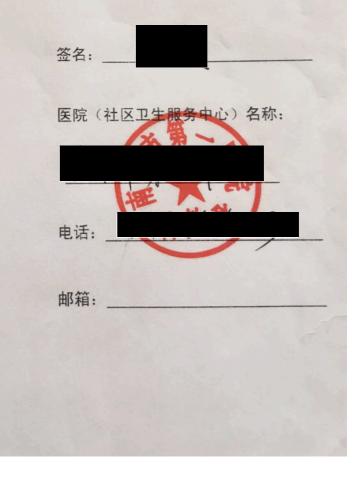
Letter of Support from People's Hospital of Jiangxi Province

2015年,我国正式发布了《全国医疗卫生服务体系规划纲要(2015-2020)》, 强调医院与社区卫生服务中心建立协作关系,提高社区卫生服务中心对慢性病的预防 和管理,以减少医院照护负担和国家医疗负担。涂强是澳大利亚弗林德斯大学医学、 护理与健康科学学院的博士生,他的"加强医院与社区的协作,提高对患有二型糖尿 病的老年患者的高血压控制"项目研究符合规划纲要的政策要求。



Letter of Support from First Affiliated Hospital of Nanchang University

2015年,我国正式发布了《全国医疗卫生服务体系规划纲要(2015-2020)》, 强调医院与社区卫生服务中心建立协作关系,提高社区卫生服务中心对慢性病的预防 和管理,以减少医院照护负担和国家医疗负担。涂强是澳大利亚弗林德斯大学医学、 护理与健康科学学院的博士生,他的"加强医院与社区的协作,提高对患有二型糖尿 病的老年患者的高血压控制"项目研究符合规划纲要的政策要求。



Letter of Support from Nanchang University Fourth Affiliated Hospital

2015年,我国正式发布了《全国医疗卫生服务体系规划纲要(2015-2020)》, 强调医院与社区卫生服务中心建立协作关系,提高社区卫生服务中心对慢性病的预防 和管理,以减少医院照护负担和国家医疗负担。涂强是澳大利亚弗林德斯大学医学、 护理与健康科学学院的博士生,他的"加强医院与社区的协作,提高对患有二型糖尿 病的老年患者的高血压控制"项目研究符合规划纲要的政策要求。

签名: _			
医院(礼	社区卫生服务	中心名称	F:
电话:	THE T	です。	8
邮箱:			

Letter of Support from Nanchang Sansansi Hospital

2015年,我国正式发布了《全国医疗卫生服务体系规划纲要(2015-2020)》, 强调医院与社区卫生服务中心建立协作关系,提高社区卫生服务中心对慢性病的预防 和管理,以减少医院照护负担和国家医疗负担。涂强是澳大利亚弗林德斯大学医学、 护理与健康科学学院的博士生,他的"加强医院与社区的协作,提高对患有二型糖尿 病的老年患者的高血压控制"项目研究符合规划纲要的政策要求。

签名:		
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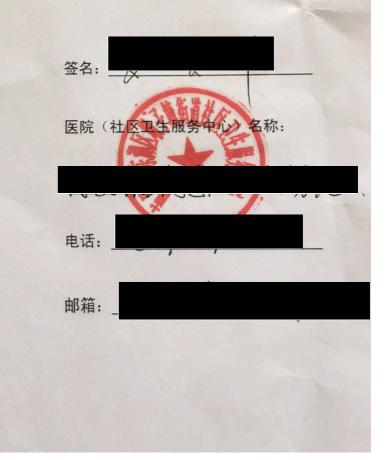
Letter of Support from Baihuazhou community health centre

2015年,我国正式发布了《全国医疗卫生服务体系规划纲要(2015-2020)》, 强调医院与社区卫生服务中心建立协作关系,提高社区卫生服务中心对慢性病的预防 和管理,以减少医院照护负担和国家医疗负担。涂强是澳大利亚弗林德斯大学医学、 护理与健康科学学院的博士生,他的"加强医院与社区的协作,提高对患有二型糖尿 病的老年患者的高血压控制"项目研究符合规划纲要的政策要求。



Letter of Support from Dunzitang community health centre

2015年,我国正式发布了《全国医疗卫生服务体系规划纲要(2015-2020)》, 强调医院与社区卫生服务中心建立协作关系,提高社区卫生服务中心对慢性病的预防 和管理,以减少医院照护负担和国家医疗负担。涂强是澳大利亚弗林德斯大学医学、 护理与健康科学学院的博士生,他的"加强医院与社区的协作,提高对患有二型糖尿 病的老年患者的高血压控制"项目研究符合规划纲要的政策要求。



Letter of Support from Tengwangge community health centre

2015年,我国正式发布了《全国医疗卫生服务体系规划纲要(2015-2020)》, 强调医院与社区卫生服务中心建立协作关系,提高社区卫生服务中心对慢性病的预防 和管理,以减少医院照护负担和国家医疗负担。涂强是澳大利亚弗林德斯大学医学、 护理与健康科学学院的博士生,他的"加强医院与社区的协作,提高对患有二型糖尿 病的老年患者的高血压控制"项目研究符合规划纲要的政策要求。

签名:	1 H H H M
医院(社区	卫生服务中心)名称:
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电话:	,
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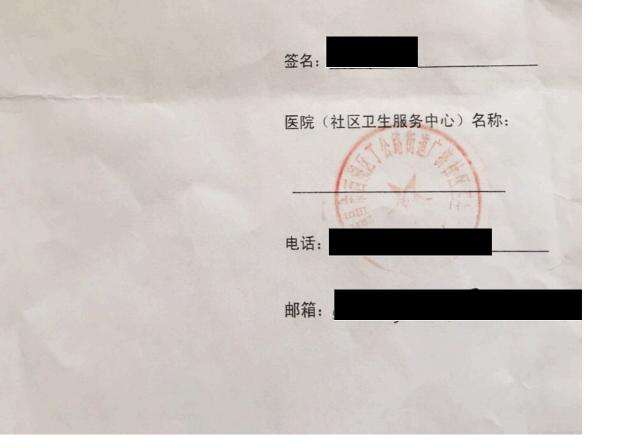
Letter of Support from Shizijie community health centre

2015年,我国正式发布了《全国医疗卫生服务体系规划纲要(2015-2020)》, 强调医院与社区卫生服务中心建立协作关系,提高社区卫生服务中心对慢性病的预防 和管理,以减少医院照护负担和国家医疗负担。涂强是澳大利亚弗林德斯大学医学、 护理与健康科学学院的博士生,他的"加强医院与社区的协作,提高对患有二型糖尿 病的老年患者的高血压控制"项目研究符合规划纲要的政策要求。



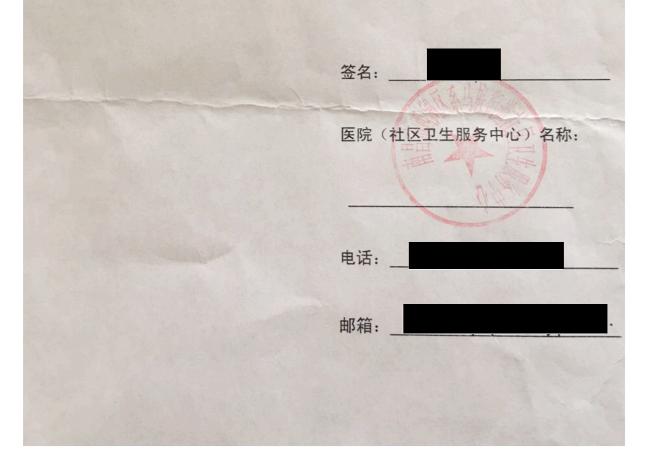
Letter of Support from Dinggonglu community health centre

2015年,我国正式发布了《全国医疗卫生服务体系规划纲要(2015-2020)》, 强调医院与社区卫生服务中心建立协作关系,提高社区卫生服务中心对慢性病的预防 和管理,以减少医院照护负担和国家医疗负担。涂强是澳大利亚弗林德斯大学医学、 护理与健康科学学院的博士生,他的"加强医院与社区的协作,提高对患有二型糖尿 病的老年患者的高血压控制"项目研究符合规划纲要的政策要求。



Letter of Support from Ximazhuang community health centre

2015年,我国正式发布了《全国医疗卫生服务体系规划纲要(2015-2020)》, 强调医院与社区卫生服务中心建立协作关系,提高社区卫生服务中心对慢性病的预防 和管理,以减少医院照护负担和国家医疗负担。涂强是澳大利亚弗林德斯大学医学、 护理与健康科学学院的博士生,他的"加强医院与社区的协作,提高对患有二型糖尿 病的老年患者的高血压控制"项目研究符合规划纲要的政策要求。



Letter of Support from the Department of Scientific Research Management of Health and Family Planning Commission of Jiangxi Province

(English Translation)

In 2015, Chinese government issued an "Outline for the Planning of the National Medical and Health Service System (2015-2020)" that emphasizes on building collaboration between hospitals and community health service centres in order to improve prevention and management of chronic disease in primary care settings, reduce hospital care burden and national medical cost burden. Mr Qiang Tu is a PhD student in the School of Nursing and Midwifery at Flinders University. The evidence- based hypertension management program for diabetic patients proposed by Mr Qiang Tu is inline with the "Outline for the Planning of the National Medical and Health Service System (2015-2020)" and supports the implementation of the Planning.

We permit and support Mr Qiang Tu to conduct the study named "Hypertension management program for community-dwelling older people with diabetes in Nanchang, China: A cluster randomized controlled trial" in the following hospitals and community health service centres (Hospitals: People's Hospital of Jiangxi Province, The First Affiliated Hospital of Nanchang University; Nanchang University Fourth Affiliated Hospital, Nanchang Sansansi Hospital; Community health service centres (CHSCs): CHSC at Baihuazhou street, CHSC at Dunzitang street, CHSC at Tengwangge street, CHSC at Shizhi street, CHSC at Dinggong street, CHSC at Ximazhuang Street). Ethics applications are not required for the studies.

> Department of Scientific Research Management of Health and Family Planning Commission of Jiangxi Province (Seal)

> > Date: January 4, 2016

Letter of support from participating hospitals and community health service centres

Letter of Support from People's Hospital of Jiangxi Province

(English Translation)

In 2015 Chinese government issued an "Outline for the Planning of the National Medical and Health Service System (2015-2020)" that emphasizes on building collaboration between hospitals and community health service centres in order to improve prevention and management of chronic disease in primary care settings, reduce hospital care burden and national medical cost burden. Mr Qiang Tu is a PhD student in the School of Nursing and Midwifery at Flinders University. The evidence- based hypertension management program for diabetic patients proposed by Mr Qiang Tu is in line with the "Outline for the Planning of the National Medical and Health Service System (2015-2020)" and supports the implementation of the Planning.

We permit and support Mr Qiang Tu to conduct the study entitled "Hypertension management program for community-dwelling older people with diabetes in Nanchang, China: A cluster randomized controlled trial" in our hospital.

Signature: Qingli Li

Phone: +86 791 86895513

Email:

People's Hospital of Jiangxi Province (seal)

Letter of Support from First Affiliated Hospital of Nanchang University

(English Translation)

In 2015 Chinese government issued an "Outline for the Planning of the National Medical and Health Service System (2015-2020)" that emphasizes on building collaboration between hospitals and community health service centres in order to improve prevention and management of chronic disease in primary care settings, reduce hospital care burden and national medical cost burden. Mr Qiang Tu is a PhD student in the School of Nursing and Midwifery at Flinders University. The evidence- based hypertension management program for diabetic patients proposed by Mr Qiang Tu is in line with the "Outline for the Planning of the National Medical and Health Service System (2015-2020)" and supports the implementation of the Planning.

We permit and support Mr Qiang Tu to conduct the study entitled "Hypertension management program for community-dwelling older people with diabetes in Nanchang, China: A cluster randomized controlled trial" in our hospital.

Signature: Xia Qian

Phone:

First Affiliated Hospital of Nanchang University (seal)

Letter of Support from Nanchang University Fourth Affiliated Hospital

(English Translation)

In 2015 Chinese government issued an "Outline for the Planning of the National Medical and Health Service System (2015-2020)" that emphasizes on building collaboration between hospitals and community health service centres in order to improve prevention and management of chronic disease in primary care settings, reduce hospital care burden and national medical cost burden. Mr Qiang Tu is a PhD student in the School of Nursing and Midwifery at Flinders University. The evidence- based hypertension management program for diabetic patients proposed by Mr Qiang Tu is in line with the "Outline for the Planning of the National Medical and Health Service System (2015-2020)" and supports the implementation of the Planning.

We permit and support Mr Qiang Tu to conduct the study entitled "Hypertension management program for community-dwelling older people with diabetes in Nanchang, China: A cluster randomized controlled trial" in our hospital.

Signature: Mi Chen

Phone:

Nanchang University Fourth Affiliated Hospital (seal)

Letter of Support from Nanchang Sansansi Hospital (English Translation)

In 2015 Chinese government issued an "Outline for the Planning of the National Medical and Health Service System (2015-2020)" that emphasizes on building collaboration between hospitals and community health service centres in order to improve prevention and management of chronic disease in primary care settings, reduce hospital care burden and national medical cost burden. Mr Qiang Tu is a PhD student in the School of Nursing and Midwifery at Flinders University. The evidence- based hypertension management program for diabetic patients proposed by Mr Qiang Tu is in line with the "Outline for the Planning of the National Medical and Health Service System (2015-2020)" and supports the implementation of the Planning.

We permit and support Mr Qiang Tu to conduct the study entitled "Hypertension management program for community-dwelling older people with diabetes in Nanchang, China: A cluster randomized controlled trial" in our hospital.

Signature: Shicai Wen

Phone:

Nanchang Sansansi Hospital (seal)

Letter of Support from Baihuazhou community health centre

(English Translation)

In 2015 Chinese government issued an "Outline for the Planning of the National Medical and Health Service System (2015-2020)" that emphasizes on building collaboration between hospitals and community health service centres in order to improve prevention and management of chronic disease in primary care settings, reduce hospital care burden and national medical cost burden. Mr Qiang Tu is a PhD student in the School of Nursing and Midwifery at Flinders University. The evidence- based hypertension management program for diabetic patients proposed by Mr Qiang Tu is in line with the "Outline for the Planning of the National Medical and Health Service System (2015-2020)" and supports the implementation of the Planning.

We permit and support Mr Qiang Tu to conduct the study entitled "Hypertension management program for community-dwelling older people with diabetes in Nanchang, China: A cluster randomized controlled trial" in our community health service centre.

Signature: Junfang Dai		
Phone:		
Email:		

Baihuazhou Community Health Service Centre (seal)

Letter of Support from Dunzitang community health centre

(English Translation)

In 2015 Chinese government issued an "Outline for the Planning of the National Medical and Health Service System (2015-2020)" that emphasizes on building collaboration between hospitals and community health service centres in order to improve prevention and management of chronic disease in primary care settings, reduce hospital care burden and national medical cost burden. Mr Qiang Tu is a PhD student in the School of Nursing and Midwifery at Flinders University. The evidence- based hypertension management program for diabetic patients proposed by Mr Qiang Tu is in line with the "Outline for the Planning of the National Medical and Health Service System (2015-2020)" and supports the implementation of the Planning.

We permit and support Mr Qiang Tu to conduct the study entitled "Hypertension management program for community-dwelling older people with diabetes in Nanchang, China: A cluster randomized controlled trial" in our community health service centre.

Signature: Huihua Luo

Phone:

Dunzitang Community Health Service Centre (seal)

Letter of Support from Tengwangge community health centre

(English Translation)

In 2015 Chinese government issued an "Outline for the Planning of the National Medical and Health Service System (2015-2020)" that emphasizes on building collaboration between hospitals and community health service centres in order to improve prevention and management of chronic disease in primary care settings, reduce hospital care burden and national medical cost burden. Mr Qiang Tu is a PhD student in the School of Nursing and Midwifery at Flinders University. The evidence- based hypertension management program for diabetic patients proposed by Mr Qiang Tu is in line with the "Outline for the Planning of the National Medical and Health Service System (2015-2020)" and supports the implementation of the Planning.

We permit and support Mr Qiang Tu to conduct the study entitled "Hypertension management program for community-dwelling older people with diabetes in Nanchang, China: A cluster randomized controlled trial" in our community health service centre.

Signature: Qingping Li

Phone:

Tengwangge Community Health Service Centre (seal)

Letter of Support from Shizijie community health centre

(English Translation)

In 2015 Chinese government issued an "Outline for the Planning of the National Medical and Health Service System (2015-2020)" that emphasizes on building collaboration between hospitals and community health service centres in order to improve prevention and management of chronic disease in primary care settings, reduce hospital care burden and national medical cost burden. Mr Qiang Tu is a PhD student in the School of Nursing and Midwifery at Flinders University. The evidence- based hypertension management program for diabetic patients proposed by Mr Qiang Tu is in line with the "Outline for the Planning of the National Medical and Health Service System (2015-2020)" and supports the implementation of the Planning.

We permit and support Mr Qiang Tu to conduct the study entitled "Hypertension management program for community-dwelling older people with diabetes in Nanchang, China: A cluster randomized controlled trial" in our community health service centre.

Signature: Yuerong Zhu

Phone:

Shizijie Community Health Service Centre (seal)

Letter of Support from Dinggonglu community health centre

(English Translation)

In 2015 Chinese government issued an "Outline for the Planning of the National Medical and Health Service System (2015-2020)" thatemphasizes on building collaboration between hospitals and community health service centres in order to improve prevention and management of chronic disease in primary care settings, reduce hospital care burden and national medical cost burden. Mr Qiang Tu is a PhD student in the School of Nursing and Midwifery at Flinders University. The evidence- based hypertension management program for diabetic patients proposed by Mr Qiang Tu is in line with the "Outline for the Planning of the National Medical and Health Service System (2015-2020)" and supports the implementation of the Planning.

We permit and support Mr Qiang Tu to conduct the study entitled "Hypertension management program for community-dwelling older people with diabetes in Nanchang, China: A cluster randomized controlled trial" in our community health service centre.

Signature:	Weihong	Zhang

Phone: +

Email:

Dinggonglu Community Health Service Centre (seal)

Letter of Support from Ximazhuang community health centre

(English Translation)

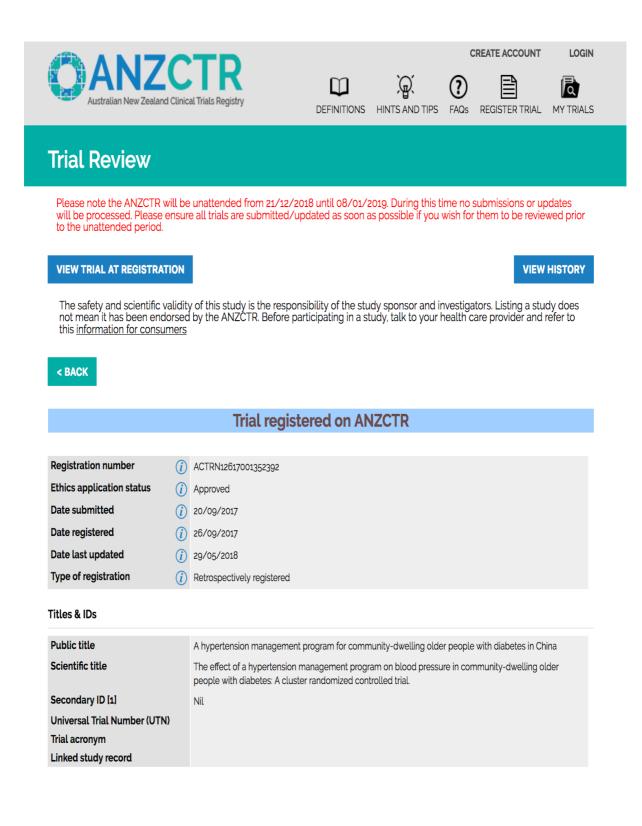
In 2015 Chinese government issued an "Outline for the Planning of the National Medical and Health Service System (2015-2020)" that emphasizes on building collaboration between hospitals and community health service centres in order to improve prevention and management of chronic disease in primary care settings, reduce hospital care burden and national medical cost burden. Mr Qiang Tu is a PhD student in the School of Nursing and Midwifery at Flinders University. The evidence- based hypertension management program for diabetic patients proposed by Mr Qiang Tu is inline with the "Outline for the Planning of the National Medical and Health Service System (2015-2020)" and supports the implementation of the Planning.

We permit and support Mr Qiang Tu to conduct the study entitled "Hypertension management program for community-dwelling older people with diabetes in Nanchang, China: A cluster randomized controlled trial" in our community health service centre.

Signature: Lilan Hu	
Phone:	
Email:	

Ximazhuang Community Health Service Centre (seal)

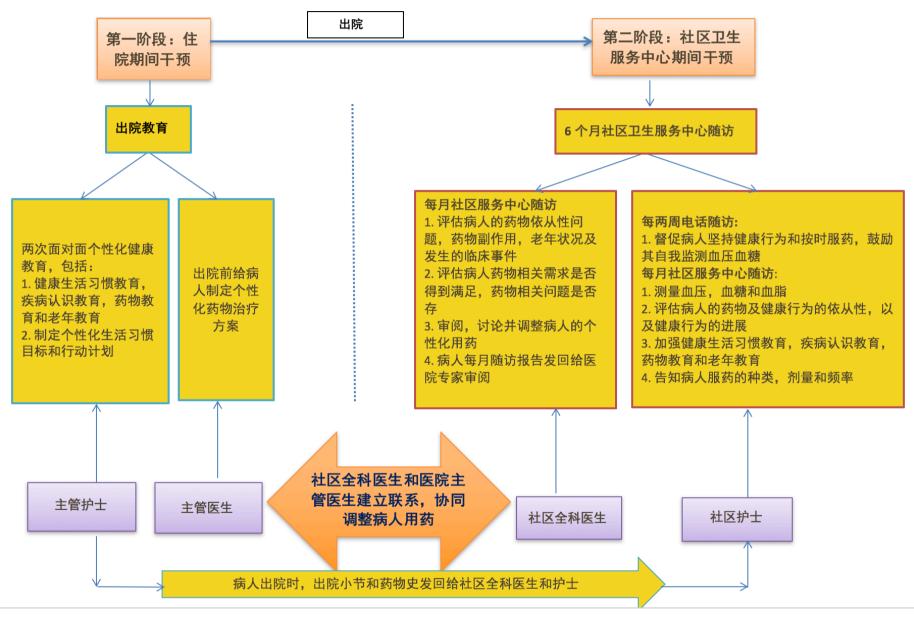
Appendix 12 Registration in ANZCTR



Appendix13 Guide to the implementation of hypertension management program for health professionals (Original document)

医务人员对老年糖尿病高血压患者的管理实施指南

此研究项目的干预措施是针对于糖尿病并发高血压的老年住院病人。干预措施包含两阶段:第一阶段为病人住院期间干预。第二阶段 为病人出院后在社区卫生服务中心接受的 6 个月的干预。来自于社区卫生服务中心和医院的医务人员将合作完成此干预项目。干预 项目具体细节请参考下图:



第一阶段:病人出院前主管护士和主管医生干预实施指南

主管护士将与医务人员共同实施以下出院教育:

- 给病人进行两次面对面的健康教育(每次 20-30 分钟),包括:健康生活习惯教育,疾病认识教育,药物教育和老年教育。教育内容将依照 研究者制定的标准化指南和教育手册进行。老年教育的内容将根据"常见老年综合征筛查表"的筛查结果进行。
- 和病人共同建立健康生活习惯目标以及制定病人的个人行动计划。提供给病人一份"干预日志-病人版",帮助病人记录个人健康行动目标、计划及进展,服药方案,不良事件,意外入院和紧急医疗服务的使用情况。
- 3. 和病人共同讨论并制定饮食计划。饮食计划将被记录在"干预日至-病人版"。
- 4. 出院时,把病人转回给社区卫生服务中心护士进行出院后随访管理。
- 5. 病人出院时,把病人的出院小节,药物史和"干预记录-社区护士和全科医生版"发给社区全科医生和护士记录随访干预

主管护士照护清单

条目	注释
1.向病人介绍糖尿病高血压管理的自我照护手册	
2.使用自我照护手册向病人进行两次出院前教育	
3.向病人介绍"干预日志-病人版"	
4.使用"干预日志-病人版"帮助病人制定个人健康行动目标和方案	

5.教会病人正确地自我血压和血糖监测	
6.教会病人正确地胰岛素注射以及服药依从性	
7.向病人解释高血压糖尿病以及药物相关的不良事件	
8.向病人解释并记录老年综合征,进行老年综合征预方和管理教育	
9.向病人解释社区的随访照护服务	
10.与社区医务人员进行联系,帮助病人约定出院后在社区服务中心的随访照护服务	
11.向病人提供出院小结以及转诊所需的相关文件	

主管医生将与医务人员共同实施以下出院教育:

1. 给病人制定个性化药物治疗方案,帮助病人出院后的药物管理。药物治疗方案将被记录在"干预日至-病人版"。

第二阶段:病人出院后社区护士和全科医生干预实施指南

社区护士将与医务人员共同实施以下随访照护服务:

1. 每两周对病人进行电话随访,监测病人的病情进展,督促病人坚持健康行为和按时服药,鼓励病人自我监测血压血糖.

- a. 询问病人的病情进展以及解答病人的疾病咨询
- b. 加强病人的药物依从性,提醒病人做到按时服药
- c. 鼓励病人自我照护,增强他们的自信心
- d. 提醒病人下次随访的时间
- 2. 每月社区卫生服务中心随访
 - a. 测量病人血压,血糖和血脂。
 - b. 审阅评估病人的药物及健康行为的依从性,以及健康行为的进展。
 - c. 加强健康生活习惯教育,疾病认识教育,药物教育和老年综合征预方和管理的教育。
 - d. 告知病人服药的种类,剂量和频率。

社区护士照护清单

条目	注释
2.使用"干预记录-社区护士和全科医生版"记录每次给病人提供的照护服务	
3.提高病人的高血压糖尿病健康知识和治疗依从性通过相应的指南	
4.教会病人正确地自我血压和血糖监测	

5.教会病人正确地胰岛素注射以及服药依从性	
6.向病人解释高血压糖尿病以及药物相关的不良事件	
7.向病人解释并记录老年综合征,并记录	
8.病人如需转回医院,及时与医院医务人员取得联系帮助病人转诊	

社区全科医生将与医务人员共同实施以下随访照护服务

- 1. 评估病人的治疗结果,药物依从性问题,药物副作用,老年综合征及其他的临床症状和体征。
- 2. 评估病人药物治疗相关需求是否得到满足,药物相关问题是否存。
- 审阅,讨论并调整病人的个性化用药。必要时,和医院专家取得联系共同讨论病人的药物调整。鼓励病人记录药物调整在"干预日志-病人版"。
- 4. 将病人每月随访报告发回给医院专家审阅。

高血压知识指南

序号	题目	对	不对	不知道
1	舒张压(低压)增高表明血压增高			
2	舒张压(低压)增高或者收缩压(高压)增高均表明血压增高			
3	治疗高血压的药物必须每天都服用			
4	高血压患者只有在感觉不舒服的时候才必须服药			
5	高血压患者必须终身服药			
6	高血压患者在感觉良好的时候还需要服用降压药			
7	如果药物治疗能控制血压的增高,就没有必要改变生活方式			
8	血压增高是衰老的结果,所以治疗高血压是没有必要的			
9	如果高血压患者改变他们的生活方式,就不需要进行治疗			
10	只要规律服药,高血压患者就可以吃咸的食物			
11	高血压患者可以喝酒精类饮料			
12	高血压患者不能抽烟			
13	高血压患者必须经常吃水果和蔬菜			
14	对于高血压患者,油煎是最好的饮食烹饪方法			
15	对于高血压患者,煮或者烤是最好的饮食烹饪方法			
16	高血压患者最好食用白肉(如鸡肉,鸭肉,鱼肉)			
17	高血压患者最好食用红肉 (如猪肉,牛肉,羊肉)			
18	如果不治疗的话,高血压可能会导致早逝			
19	如果不治疗的话,高血压可能会导致心脏疾病,如心脏病发作			
20	如果不治疗的话,高血压可能会导致中风			
21	如果不治疗的话,高血压可能会导致肾功能衰竭			
22	如果不治疗的话,高血压可能导致视觉障碍			

糖尿病知识指南

序号	题目	对	不对	不知道
1	食用过多糖及其它甜食可导致糖尿病。			
2	糖尿病通常是由于体内缺乏足够的胰岛素而引起。			
3	糖尿病是由于肾脏不能将糖从尿中排出而引起。			
4	肾脏分泌胰岛素			
5	糖尿病在不治疗的情况下血液里糖的成分会增加。			
6	如果我有糖尿病,我的孩会有很大可能患糖尿病。			
7	糖尿病可以治愈。			
8	空腹血糖 11.5 是指血糖 太高。			
9	检查糖尿病的最佳方式是检查尿糖。			
10	日常锻炼可以增加体内对胰岛素或其它糖尿病药物的需求量。			
11	糖尿病分为两型: 型糖尿病 (胰岛素依赖型)及 型糖尿病 (非			
	胰岛素依赖型)。			
12	胰岛素的作用是由于食用过多食物而引起的。			
13	药物比适当饮食和锻炼更能控制我的糖尿病。			
14	糖尿病通常导致循环不良。			
15	当糖尿病病人皮肤有破损及擦伤时,伤口愈合缓慢。			
16	糖尿病病人在剪指甲时要特别小心。			
17	糖尿病病人应该用碘酒和酒精擦伤口。			
18	我怎麽做饭与我吃什麽食物一样重要。			
19	糖尿病可以损坏我的肾脏。			
20	糖尿病可以导致手,手指和脚失去感觉。			
21	发抖和出汗是血糖高的症状。			
22	小便次数多及口渴是血糖低的症状。			
23	穿紧弹性袜或紧袜子对糖尿病病人没有坏处。			
24	糖尿病饮食主要包括特殊食物。			

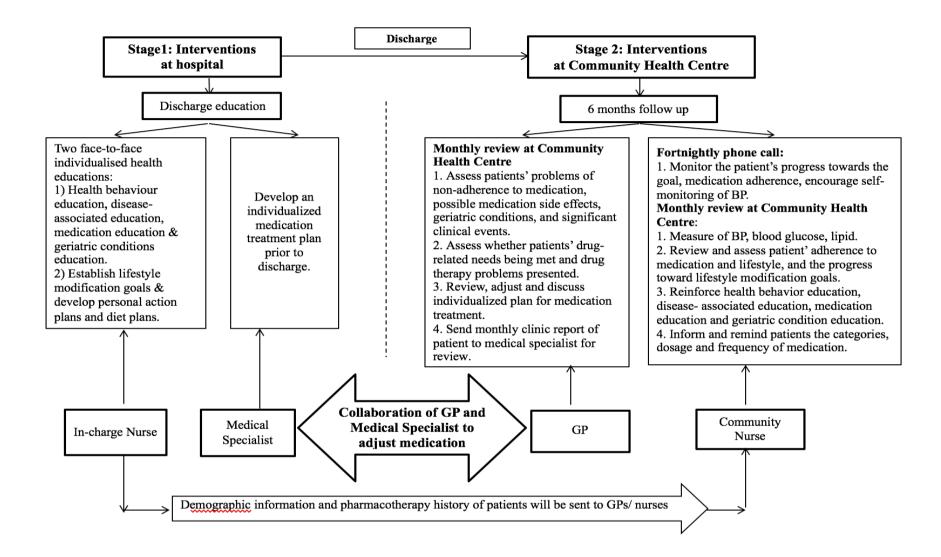
治疗依从性指南

条目	完全做到	基本做到	偶尔做到	根本未做到
1. 您能按医生要求的次数服药吗?				
2. 您能按医生要求的量服药吗?				
3. 您能按医生要求的时间服药吗?				
4. 您能按医生的要求长期服药从不间断吗?				
5. 您能按医生的要求服药从不擅自增加或减少药品品种吗?				
6. 无论是否出现高血压的症状,您能坚持服药吗?				
7. 您能做到不忘记服药吗?				
8. 当您自觉症状改善时,能做到不擅自停药吗?				
9. 当您自觉症状严重时,能做到不擅自停药吗?				
10. 您能遵守低盐饮食的要求吗?				
11. 您能增加低脂肪饮食的要求吗?				
12. 您能增加低胆固醇饮食的要求吗?				
13. 您能减少糖类和甜食的摄入吗?				
14. 您能增加粗粮的摄入吗?				
15. 您能增加新鲜蔬菜的摄入吗?				
16. 您能增加新鲜水果的摄入吗?				
17. 您能增加豆制品的摄入吗?				
18. 您能增加低脂奶制品的摄入吗?				
19. 您能减少咖啡的摄入吗?				
20. 您能做到限制饮酒吗?				
21. 您能戒烟吗?				
22. 您能坚持每周运动 5 次或 5 次以上吗?				
23. 您能每次运动三十分钟以上吗?				
24. 您能控制饮食量吗?				
25. 您能控制体重吗?				
26. 您每天留给自己一些时间放松吗?				
27. 您采用一些方法减轻压力吗?				
28. 您遇到意外事件时,能控制自己的情绪吗?				

Guide to the implementation of hypertension management program for health professionals

(English translation)

The hypertension management program is specifically developed for older people with multimorbidity of hypertension and diabetes who are ready to be discharged from an acute care hospital to their homes and require care services in the community. The interventions comprise two stages. In stage 1, the in-charge nurse will work in collaboration with the patient's medical specialist to implement an individualised discharge planning prior to discharge from hospital. In stage 2, the community nurse and General Practitioner (GP) in the Community Health Centres will work in collaboration to implement a 6-month follow-up intervention after the patient is discharged from hospital. The outline of the 2-stage intervention is illustrated in the figure and the details are described in the following sections.



Guide to the stage 1: individualised discharge planning

The in-charge nurse will implement the following care services in collaboration with other health professionals:

- The in-charge nurse will provide the patient with two face-to-face individualized health educations. Each session will take 20-30 minutes. Health education sessions will include health behaviour education, disease-associated education, medication-associated education and education on geriatrics conditions. The education on geriatrics conditions will be based on a geriatrics conditions screening using the evidence-based screening tool, "Fulmer Spices Comprehensive Assessment Tool for Older Adults".
- 2. The in-charge nurse will support the patient to establish lifestyle modification goals, develop personal action plans and enable patients to use "Intervention diary-patient version" in the hypertension management program. to document their lifestyle modification goals, personal action plans, progress towards the goals, medication adherence, adverse events and unplanned hospital admission/ the use of emergency care service.
- 3. The in-charge nurse will discuss and support the patient to establish diet plan and document their diet plan in the "intervention diarypatient version".
- 4. The in-charge nurse will refer patients to Community Health Centre for a 6-month follow-up.
- 5. The in-charge nurse will send discharge summary, pharmacotherapy history and 'Intervention record- community nurse and GP version' to community nurses to record interventions and outcomes.

Checklist for the in-charge nurse

Items	Notes
1.Introduce the 'Self-care Booklet for older people with hypertension and diabetes' to the patient	
2.Use the 'Self-care Booklet for older people with hypertension and diabetes' as an education tool for health education	

in two separate sessions prior to discharge	
3.Introduce the 'Intervention Diary-Patient Version' to the patient	
4.Use the 'Intervention Diary-Patient Version' as a tool to support patients to develop health behaviour goals and a plan to achieve the goals	
5. Check whether or not the patient is able to monitor BP and bool glucose correctly and act accordingly	
6.Demonstrate medication use including insulin inject and explain the need to adhere medication treatment	
7.Explain adverse events associated with medication treatment, hypertension and diabetes	
8.Explain geriatric conditions, prevention and management of these conditions	
9.Explain the follow-up care services in the Community Health Centres	
10.Communicate with the coordinator at the Community Health Centre to make the first appointment for patients in the follow-up care	
11.Provide patients with referral letter and documents for the follow-up care at the Community Health Centre	

The Medical specialist will implement the following care services in collaboration with other health professionals:

1. Provide the patient with individualised medication treatment plan before the patient is discharged. Individualized medication treatment will be recorded in "intervention diary- patient version".

Guide to the stage 2 implemented by the nurse and the GP at the community health centres

The Community nurse will implement the following care services in collaboration with other health professionals:

Provide the patient with fortnightly phone call support to monitor their progress towards the self-care goals, medication adherence and encourage self-monitoring of BP.

- 1. Discuss with the patient about their health conditions and respond to any queries the patient have
- 2. Monitor patient's progress towards goal; remind patients of adherence to health lifestyle
- 3. Intensify patients' medication adherence; remind patients of taking medication on time
- 4. Encourage self-monitoring of BP and blood glucose and record their BP and glucose reading in the intervention diary
- 5. Encourage patients to establish confidence to manage their diseases
- 6. Remind patients of the next appointment at Community Health Centres

Provide the patient with monthly review at Community Health Centres as described in the following:

- 1. measure, review and assess patients' BP, HbA1c and lipid.
- 2. review and assess patients' adherence to medication treatment and lifestyle changes.
- 3. reinforce health behaviour education, disease-associated education, medication education and geriatrics conditions education.

Checklist for the community nurse

Items	Notes
1.Use the 'Self-care Booklet for older people with hypertension and diabetes' as an education tool for health education in the 6-	
month follow up	
2.Use 'Intervention Record-community nurse and GP version' to record the time and date of interventions you have provided for	
patients	
3. Motivate patients to learn and improve health knowledge and treatment adherence; use the hypertension knowledge checklist,	

diabetes knowledge checklist and treatment adherence checklist as tools to reinforce health education for the patient	
4. Check whether or not the patients are able to monitor BP and bool glucose correctly and act accordingly	
5.Demonstrate medication use including insulin inject and explain adherence if needed	
6.Explain adverse events associated with medication treatment, hypertension and diabetes	
7.Explain geriatric conditions, prevention and management of these conditions	
8.Communicate with in-charge nurse at hospital to referral patients from Community Health Centre to hospital if needed	

The GPs will implement the following care services in collaboration with other health professionals:

- 1. assess the patient's responses to medication treatment, possible medication side effects, geriatric conditions, clinical outcomes and significant clinical events
- 2. review, adjust and discuss individualised plan for medication treatment. The GP will also need to consult the patient's medical specialist to discuss the mediation adjustment when needed.
- 3. send the patient's monthly clinic report to the medical specialist to review.

Hypertension knowledge checklist

Item	Item	Correct	Incorrect	Don't know
number				
1	Increased diastolic blood pressure also indicates increased blood pressure			
2	High diastolic or systolic blood pressure indicates increased blood pressure.			
3	Drugs for increased blood pressure must be taken everyday.			
4	Individuals with increased blood pressure must take their medication only when they feel ill.			
5	Individuals with increased blood pressure must take their medication throughout their life.			
6	Individuals with increased blood pressure must take their medication in a manner that makes them feel good.			
7	If the medication for increased blood pressure can control blood pressure, there is no need to change lifestyles.			
8	Increased blood pressure is the result of aging, so treatment is unnecessary.			
9	If individuals with increased blood pressure change their lifestyles, there is no need for treatment.			
10	Individuals with increased blood pressure can eat salty foods as long as they take their drugs regularly.			
11	Individuals with increased blood pressure can drink alcoholic beverages.			
12	Individuals with increased blood pressure must not smoke.			
13	Individuals with increased blood pressure must eat fruits and vegetables frequently.			
14	For individuals with increased blood pressure, the best cooking method is frying.			
15	For individuals with increased blood pressure, the best cooking method is boiling or grilling.			
16	The best type of meat for individuals with increased blood pressure is white meat.			
17	The best type of meat for individuals with increased blood pressure is red meat.			
18	Increased blood pressure can cause premature death if left untreated.			
19	Increased blood pressure can cause heart diseases, such as heart attack, if left untreated			
20	Increased blood pressure can cause strokes, if left untreated.			
21	Increased blood pressure can cause kidney failure, if left untreated.			
22	Increased blood pressure can cause visual disturbances, if left untreated.			

Diabetes knowledge checklist

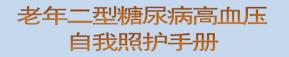
ltem	Item	Correct	Incorrect	Don't know
number				
1	Eating too much sugar and other sweet foods is a cause of diabetes.			
2	The usual cause of diabetes is lack of effective insulin in the body			
3	Diabetes is caused by failure of the kidneys to keep sugar out of the urine.			
4	Kidneys produce insulin.			
5	In untreated diabetes, the amount of sugar in the blood usually increases.			
6	If I am diabetic, my children have a higher chance of being diabetic.			
7	Diabetes can be cured.			
8	A fasting blood sugar level of 210 is too high.			
9	The best way to check my diabetes is by testing my urine.			
10 11	Regular exercise will increase the need for insulin or other diabetic medication.			
11	There are two main types of diabetes: Type 1 (insulin-dependent) and Type 2 (non-insulin-			
	dependent).			
12 13 14	An insulin reaction is caused by too much food.			
13	Medication is more important than diet and exercise to control my diabetes.			
14	Diabetes often causes poor circulation.			
15	Cuts and abrasions on diabetics heal more slowly			
16	Diabetics should take extra care when cutting their toenails.			
17	A person with diabetes should cleanse a cut with iodine and alcohol.			
18	The way I prepare my food is as important as the foods I eat.			
19	Diabetes can damage my kidneys.			
20	Diabetes can cause loss of feeling in my hands, fingers, and feet.			
21	Shaking and sweating are signs of high blood sugar.			
22	Frequent urination and thirst are signs of low blood sugar.			
22 23	Tight elastic hose or socks are not bad for diabetics.			
24	A diabetic diet consists mostly of special foods.			

Treatment adherence checklist

Item	All of the time	Most of the time	Some of the time	Never
1. Would you comply with the total times of prescribed medications?				
2. Would you comply with the total number of pills consumed daily?				
3. Would you comply with the required time to take prescribed medications every day?				
4. Would you never stop taking prescribed medication?				
5. Would you never increase or decrease tablets by yourself?				
6. Would you adhere to take prescribed medications, whether in hypertension symptoms or not?				
7. Would you never forget to take prescribed medications?				
8. Would you never stop taking prescribed medications when you feel better?				
9. Would you never stop taking prescribed medications when you feel badly?				
10. Would you comply with low salt diet?				
11. Would you comply with low fat diet?				
12. Would you comply with low cholesterol diet?				
13. Would you reduce intake of sugar and sweets?				
14. Would you eat more roughages?				
15. Would you increase intake of fresh vegetables?				
16. Would you increase intake of fresh fruits?				
17. Would you eat more bean products?				
18. Would you increase intake of low fat dairy products?				
19. Would you reduce intake of coffee?				
20. Would you give up drinking?				
21. Would you give up smoking?				
22. Would you exercise for 5 times and above per week?				
23. Would you exercise more than 30 minutes per time?				
24. Would you limit the total diet?				
25. Would you control weight?				
26. Would you leave some time to relax every day?				
27. Would you adopt methods to relieve stress?				
28. Would you get a hold of yourself when facing with any incidents?				

Appendix 14 Self-care Booklet for older people with hypertension and type 2 diabetes

(Original document)





作者: 澳大利亚弗林德斯大学 博士生涂强

糖尿病高血压的疾病认识

尿病合并高血压定义

临床上许多高血压病人,经常伴有糖尿病;而糖尿病 也较多地伴有高血压;两者被俗称"姊妹病"。糖尿病高 血压两种疾病无论是病因、互相影响还是危害上都存 在共通性,因此常常合并发作,形成糖尿病高血压。

临示病高血压发病病因

糖尿病和高血压享有共同的发病原因和危险因素。两 者可能存在共同的遗传基因。糖尿病对具有升压作用 的血管紧张素(一种身体激素)敏感,糖尿病易引起肾功 能损害,而糖尿病肾功能损害可致血压升高。另外, 糖尿病人血糖高,血粘度高,血管壁受损、血管阻力 变大都是易引起高血压的危险因素。

由于二者都和血脂高、缺乏健康生活习惯和缺乏运动 有关系,因此无论是糖尿病合并高血压患者还是单纯 的糖尿病、高血压患者,甚至健康人群,都应该养成 良好的生活习惯、适量运动、控制体重,从根本上改 善和预防糖尿病高血压。糖尿病高血压的病人一定要 控制血压,即使血压仅下降很少,都能有效预防严重 并发症的发生。

糖尿病高血压的联系

糖尿病患者高血压的患病率为非糖尿病患者的两倍, 且糖尿病患者高血压患病率的高峰比正常人提早 10 年 出现,约 50%-75%糖尿病患者合并高血压,而伴有高 血压者更易发生心肌梗塞、脑血管意外及末梢大血管 病,并加速视网膜病变及肾脏病变的发生和发展。 糖尿病患者可使血压升高,并引起严重并发症。另一 方面,高血压又可加重糖尿病引起的损害,包括它对 小血管和肾脏的影响,形成恶性循环。

唐尿病合并高血压的筛查与诊断

糖尿病患者合并高血压的诊断界值低于非糖尿病者。 收缩压≥130 mm Hg 或舒张压≥80 mm Hg 需择日复测血压,若复测收缩压仍≥130 mm Hg 或舒张 压≥80 mm Hg,可确诊为糖尿病合并高血压。

血压变化对糖尿病影响

- 维持正常血压:有利于减少糖尿病并发症的发生,并降低病死率。高血压是2型糖尿病患者发生大血管和微血管病变的独立危险因素,所以降压治疗与降糖治疗同等重要,不能忽视降压治疗。
- 血压升高:高血压可使糖尿病患者心脑血管病 变风险提高2倍;高血压促进糖尿病肾病和视 网膜病变的发生发展。

正常血糖血压的范围

	血压的分级	
类别	收缩压 (mmHg)	舒张压 (mmHg)
理想血压	〈120	〈80
正常高值	120-139	80-89
1 级高血压(轻 度)	140-159	90-99
2 级高血压(中 度)	160-179	100-109
3 级高血压(重 度)	≥180	≥110
单纯收缩期高 血压	≥140	〈90

血糖的控制标准

	控制目标
空腹	<7.2 mmol/L
餐后两小时	<10.0 mmol/L
HbA1 <u>c(</u> %)	<7%
空腹:停止含热量食物	8 小时以上。
餐后两小时:从讲食第-	- 口开始计算两小时之后。

糖尿病高血压症状

糖尿病本身症状不典型或具有多饮,多尿,多食,乏 力,困倦,消瘦等特征性改变以及糖尿病合并其他并 发症的相应表现。高血压本身早期可无症状或有头痛, 头晕,视物模糊,眼花,食欲不振,耳鸣,失眠等。 糖尿病并发高血压患者的症状为两者之一或两者皆具。 伴有自主神经病变的糖尿病患者易出现卧位血压正常 或升高拌直立体位的血压降低。

糖尿病高血压的病情危害

 危害一:冠心病和高血压心脏病 糖尿病合并高血压的患者,冠心病和高血压心脏病 的发病率和死亡率较高,临床表现为心律失常、心肌肥大、 劳损或心脏扩大,常因并发心力衰竭、心肌梗死、心源性休 克而死亡。

 危害二:脑血管意外 糖尿病合并高血压的患者,容易发生脑血管意外, 其中更容易发生脑血栓和脑卒中。

• 危害三:肾功能衰竭

高血压会加快糖尿病肾病的发生发展,而糖尿病肾 病的进展加速,又会引起血压的进一步升高,形成恶性循环。 因此,糖尿病合并高血压的患者更容易发生肾功能衰竭。

• 危害四:周围动脉硬化及坏疽

高血压能够导致动脉硬化,即动脉壁增厚变硬、缺乏 弹性、动脉内径变小,造成局部供血不足,这会引起或加重 糖尿病患者的大血管和微血管并发症,加重糖尿病病情的发 生与发展。

 危害五:视网膜眼底病变 糖尿病高血压对视网膜的危害情况:高血压使视网 膜动脉硬化,随着病情的发展,视网膜可出现出血、渗出、 水肿,严重时出现视神经乳头水肿。可引起病人的视觉障碍, 如视物不清,视物变形或变小等。糖尿病眼底病变与高血压 和动脉硬化的眼底病变往往并存,常导致失明。

糖尿病高血压的危害是致命的。糖尿病患者容易发生血管病变,能促进或加重高血压的发生和发展。高血

压能加重糖尿病患者的大血管和微血管并发症,加重 糖尿病病情的发生与发展。因此,糖尿病合并高血压 后,既要控制血糖,也要控制血压,降血糖与降血压 治疗同时进行才能降低并发症发生率和死亡率。

糖尿病高血压的危险因果



- 缺乏体育锻炼
- 高盐饮食
- 吸烟
- 过量饮酒
- 精神紧张
- 血脂异常,糖调节异常

糖尿病高血压的治疗与管理

为什么要自我管理糖尿病高血压?

治疗糖尿病高血压除了靠医生还需加强自我管理

- 糖尿病高血压一旦发病终身存在,治疗也将持续终身
- 治疗糖尿病高血压需药物和生活方式双管齐下
- 降压降糖药物种类繁多,使用哪种药物因人而异,
- 要不断视治疗反应调整治疗方案,这需病人积极与 医生配合

控制高血压的关键是病人要对自己的高血压进行管理。

管理哪些事情?

- 了解并管理自己的降压降糖目标
 - 2

- 自我监测血糖血压并作好记录
- 定期复诊
- 管理自己的药物
- 管理自己的生活方式

多长时间测一次血压?

- 高血压患者最好每月由医务人员测一次血压
- 自己在家可随时监测血压,并作好监测结果记录
- 血压正常者也应定期测血压

定則短访

 定期随访的目的是评估治疗效果,观察危险因 素和临床情况的变化。



随访时配合医生护士进行相关检查

 随访时医生护士可能会要求您进行化验检查, 以进一步了解病情,此时,要积极与医务人员 配合。

管理自己的药物

当拿到医生给您开的药后,了解以下情况并记录下来

- 药物的名字
- 一天吃几片
- 一天吃几次
- 什么时候吃
- 常见的副作用

了级计答理自



管理自己的生活方式 您将需要遵从医务人员给您制定的生活习惯。请 参考以下健康生活方式。



少吃高鹽 不吸菸或戒菸 節制飲酒 壓力紓解 高鈉食物

- 对饮食的管理 低盐低脂饮食,食盐摄入量每日不超过 5g,蔬菜 摄入量每日多于 400g(可参考手册末页饮食指南) 对运动的管理
- 每天保持 30 分钟体育锻炼,例如:太极。避免在 高温环境下在室外做剧烈运动。作好有关的运动计 划, 按计划完成并作好记录
- 制定作息时间,按时作息,使生活规律
- 体重减轻
- 戒烟戒酒
- 保持乐观积极心态,缓解精神压力
- 配合社区义务人员做好高血压分级管理,定期 随访

了解释压药物的使用原则

- 从小剂量开始,逐步调整至有效剂量。这样可 以保证以最小的剂量获得最佳的疗效,可使不 良反应隆至最小。
- 要在 24 小时将血压平稳控制在正常范围,防 止血压忽高忽低。
- 用低剂量单药治疗疗效不满意时可采用 2 种或 多种降压药物联合治疗。

为什么要强调 24 小时平稳控制血压?

24 小时平稳控制血压,可防止血压波动导致的不良事 件

- 血压存在昼夜节律变化,夜间血压较低,清晨 血压会突然升高。
- 24 小时平稳控制血压,可防止晨间(4-10 点) 血压波动造成的猝死, 卒中或心脏病发作。



为什么建议联合使用降压药? 联合使用降压药,可更好保护心脑肾等重要器官

为了更好保护心脑肾等重要器官,需要更大程度降

- 低血压。要做到这一点,单药治疗常力不能及
- 降压药联合使用,其降压作用有协调或至少相加的 作用,可更大程度降低血压

联合用药可减少药物的不良反应

- 单药治疗常需要较大剂量,易出现不良反应
- 联合用药时,每种药物剂量不大,药物的不良反应 可以相互抵清或至少不重叠相加。

血压降不下来怎么办?

服用降压药后血压没有降下来,不要随便换药或加量。 此时需要检查自己是否有以下不良生活方式

- 仍有高盐饮食 •
- 吸烟

- 缺乏运动
- 心理压力过大
- 生活不规律、失眠

通过改变不良生活方式血压仍不能降下来,要和医生 沟诵寻求解决办法

血压正常后可以停药吗?

血压正常后不要随意停药

血压降至正常,不等于高血压已治愈,如果自 行停药,血压还会再次升高,还要再使用药物降压。 这样服药断断续续,不仅达不到治疗效果,而且由于 血压经常波动,会引起心脑肾严重的并发症,如脑出 血等。

- 正确的做法是:要及时和医生沟通,在医生指 导下减少药物种类和剂量,达到药物维持量。
- 长期坚持维持量治疗

降压药要规律服用

规律服用降压药可保护心脑肾等重要脏器

- 服药不规律会导致血压时高时低,长期血压波动会 诱发中风,心肌梗死等心脑血管急症
- 规律服用降压药可使血压长期,平稳维持在正常水 平,有利于保护心脑肾等重要脏器

服用降压药的最佳时间

- 早上6点起床后服用,这样有效控制清晨血压的急。 剧上升,避免急性脑出血
- 尤其注意不要在睡前服用降压药,这样会 使夜间血压变得更低,容易出现脑血栓。

快會指示

食物结

兼昭医冬人吊的快会指清 26 1。 通過通知下

大食信息。	_		
构	份数	(次/	每分规相

	天)	
谷类	6-8	28 克谷类食品,半碗米饭 或面食
蔬菜	4–5	1 份生鲜叶类菠菜,半份 生或熟蔬菜,半份蔬菜叶
水果	4–5	1 份中等大小的水果,1/4

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	份水果干,半碗新鲜,冷
	冻或罐头水果, 半杯果汁
2-3	1 杯牛奶或酸奶,43g 奶 酪
《 6	烹制瘦肉,禽肉或鱼肉 28g,1 只鸡蛋
4-5次/周	坚果,籽类食品各 43g,1 勺花生酱,43
	g, 半份豆类食品
2–3	1 勺植物黄油,菜油,蛋 黄酱或沙拉酱
《5 次 / 周	1 勺糖,果冻或果酱,半 杯沙冰,1 杯柠檬汽水
	《6 4-5 次 / 周 2-3

饮食中脂肪,蛋白质和碳水化合物分别占总热量的 27%,18% 和 55%。

如何测量血压?

- 开始测量血压时,使用合适尺寸的血压袖带。袖带 的气囊应环绕上臂的 80%。
- 将袖带平展地缚于上臂,其下缘距肘窝约 2-3CM, 不可过紧。
- 听诊器胸件置于袖带下肘窝处肱动脉上,轻按使听 诊器和皮肤全面接触,不能压得太重。
- 4. 迅速将袖袋充气至 180mmHg。以中等速度(3mm/秒) 从袖袋释放空气。
- 5. 用听诊器听,同时观察血压计。第一个敲击声是受 试者的收缩压。当敲击声消失时,即为舒张压(如 120/80)。
- 6. 记录两臂的压力并注意差异;同时记录受试者的体位(仰卧位)、使用哪只手臂、袖带大小(小袖带、标准袖带或大袖带)。
- 7. 如果受试者血压升高,再测两次血压,间隔几分钟。 血压在 180/120mmHg 或以上需要立即注意。

如何测量血糖?

- 1. 洗手后, 保持手部干燥。
- 2. 在手干燥的情况下拿取试纸,并将试纸放入血糖仪中。

3. 将采血笔丛指尖内外侧采血。
 4. 将试纸贴触血液,并等待结果。
 5. 您的血糖水平将显示在血糖仪上。

如何注射胰岛素?

- 1. 注射前洗手。
- 2. 安装胰岛素注射笔用针头。
- 3. 排净胰岛素笔芯中的空气。
- 4. 预混胰岛素需充分混匀。
- 5. 检查注射部位和消毒。常见注射部位包括大腿,腹 部,臀部和三头肌。
- 6. 将针头注入皮下,并保持注射笔垂直。
- 7. 缓慢进行皮下注射。
- 8. 注射完毕以后,针头滞留至少10秒后再拔出。
- 注射完成后立即将针头取下,丢弃在加盖的硬壳容器中。

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Self-care Booklet for older people with multimorbidity of hypertension and type 2 diabetes

(English Translation)

Self-care booklet for older people with multimorbidity of hypertension and type 2 diabetes



Qiang Tu PhD candidate Flinders University

WHAT DO I NEED TO KNOWABOUTDIABETESHYPERTENSION?

Coexistence of type 2 diabetes and hypertension

People with type 2 diabetes (diabetes in this booklet) often have hypertension. Diabetes and hypertension are commonly known as 'sister <u>diseases'</u>. Hypertension affects approximately 75 per cent of people living with diabetes.

Shared risk factors of diabetes and hypertension

Both diabetes and hypertension are associated with modifiable lifestyle risk factors and have genetic- and family-related factors. Both diabetes and hypertension are associated with unhealthy lifestyles and lack of physical exercise. Therefore, people with both diabetes and hypertension need to establish healthy lifestyles, engage in moderate exercise and weight control to prevent complications associated with diabetes and hypertension.

Relationship between diabetes and hypertension

The chance of individuals with diabetes having hypertension is twice as high as the general

population. People with hypertension are more likely to develop heart diseases, eye impairment, and kidney failure. High blood pressure can worsen the damage caused by diabetes, including its effects on small blood vessels and kidneys.

Diagnostic criteria for the coexistence of diabetes and hypertension

The diagnosis for people with the coexistence of diabetes and hypertension is lower than for nondiabetics. People with systolic blood pressure of \geq 130 mmHg or diastolic blood pressure of \geq 80 mmHg should be retested the second day. If the systolic blood pressure is still \geq 130 mmHg or diastolic blood pressure \geq 80 mmHg, it can be diagnosed as the multimorbidity of diabetes with hypertension.

Impact of Increased or decreased blood pressure among people with diabetas

Maintain normal blood pressure:

Normal blood pressure helps reduce the complications and mortality associated with hypertension and diabetes. Hypertension is an independent risk factor for vascular disease in people with type 2 diabetes. Treatment to maintain normal blood pressure is as important as treatment to maintain normal blood sugar. Therefore, adherence to treatment for hypertension cannot be ignored.

Increased blood pressure:

Hypertension can double the risk of cardiovascular and cerebrovascular disease in people with diabetes. Hypertension can also cause and worsen the development of diabetic kidney disease and diabetic eye disease.

Range of normal blood pressure and glucose

Classification of hypertension

Diagnostic category	Systolic (mmHg)	Diastolic (mmHg)
ldeal blood pressure	〈 120	〈 80
Normal high blood pressure	120–139	80–89
Grade 1 (mild) hypertension	140–159	90–99
Grade 2 (moderate) hypertension	160–179	100–109
Grade 3 (severe) hypertension	≥ 180	≥ 110
Isolated systolic hypertension	≥ 140	〈 90

Blood sugar goals for people with diabetes

	Controlled
Fasting blood glucose	< 7.2 mmol/L

Two-hour glucose	postprandial	< 10.0 mmol/L
HbA1c (%)		< 7%

Symptoms for coexistence of diabetes and hypertension

Many people with diabetes have no symptoms. Common symptoms are increased thirst, passing more urine, constant hunger, fatigue, drowsiness and weight loss. Many people with hypertension have no symptoms. Common symptoms include headache, dizziness, blurred vision, vertigo, loss of appetite, tinnitus and insomnia. People with coexistence of diabetes and hypertension have either or both symptoms. People with diabetes who have impairment of autonomic nerve system are prone to normal blood pressure in the supine position or a decrease in blood pressure in the straight steric position.

Complications of coexistence of diabetes and hypertension

 Coronary heart disease and hypertensive heart disease

People with the coexistence of diabetes and hypertension have a higher chance of coronary heart disease and hypertensive heart disease. Without appropriate treatment, the mortality rate due to heart disease is very high.

Cerebrovascular accident

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People with coexistence of diabetes and hypertension are more likely to develop cerebrovascular accidents including cerebral thrombosis and stroke.

Kidney failure

High blood pressure will damage kidneys and cause kidney failure. The progression of diabetic kidney disease will cause further increases in blood pressure. Therefore, people with both diabetes and hypertension are more likely to develop renal failure.

Peripheral arteriosclerosis and gangrene

Hypertension can lead to arteriosclerosis thickening and hardening of the arterial wall, lack of elasticity, and small internal diameter of the artery, resulting in insufficient local blood supply. Diabetic gangrene occurs when body tissue dies due to the loss of blood supply. Diabetic gangrene usually affects toes and fingers and causes a change in skin colour to red or black, numbness, swelling, pain, skin breakdown and infections.

Eye impairment

Both hypertension and diabetes damage the retina, the area at the black of your eye that receive light and sends an image to your brain. The damage can cause visual impairment such as unclear vision, deformation or smallness of the perceived object. The damage can lead to blindness. Lowering blood pressure and glucose simultaneously can reduce eye impairment.

Modifiable risk factors for the coexistence of diabetes and hypertension



- · Overweight and obese
- · Lack of physical exercise
- · High salt diet
- Smoking
- Excessive drinking
- Abnormal dyslipidemia, abnormal glucose regulation

MANAGEMENT OF DIABETES AND HYPERTENSION

Why diabetes and hypertension require selfcare? In addition to relying on treatment from health professionals, it is necessary to perform selfcare. Self-care is the key to controlling high blood pressure and high blood sugar.

- Diabetes and hypertension are lifelong conditions that require lifelong treatment and management.
- Treating diabetes and hypertension requires both medication and lifestyle changes
- There are many categories of medication treatment. Medications that are prescribed vary from person to person. It is necessary to constantly adjust the treatment plan according to the treatment response. This requires you to actively consult with health professionals.

What do I need to do?

- Understand these diseases and develop selfcare goals
- Self-monitor blood sugar and blood pressure and record in the diary
- Regularly follow-up at community health centre
- Comply with medication treatment
- · Comply with healthy lifestyles

How often to measure blood pressure?

- Have your blood pressure checked monthly by health professionals at community health centre.
- Monitor your blood pressure at home and record your results every day.

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 Even if you have normal blood pressure, you still need to measure blood pressure regularly.

Regular follow-up

The purpose of regular follow-up at the community health centre is to assess treatment outcomes and your health conditions.



Medication management

You will need to follow your doctor's instructions to manage your medication treatment at home. Please follow record these aspects regarding your medication treatment in your diary.

- · The name of the medications
- Frequency of taking medications
- Dosages of taking medications
- Time of taking medications
- · Common side effects of medications



Lifestvie modifications

You will need to follow the lifestyle modification goals you have set out with your medical doctor and nurse. The commonly recommended healthy lifestyles are:



- Low-salt and low-fat diet Reduced intake of salt < 5 g per day and at least 400 g of vegetables per day (refer to the Diet Guide at the end of the manual)
- Physical activity

Flexibility training and balance training as agreed with your doctor and nurse such as Tai Chi 30 minutes a day. You will need to avoid exercising outdoors on very hot days. You will need to avoid physical exercise your medical doctor and nurse have not recommended to you. You will need to record your physical in your diary.

- Set a regular schedule to achieve a better work–life balance
- Reduce weight
- Quit smoking and drinking
- Maintain an optimistic and positive attitude and relieve stress
- Work with community health professionals to manage high blood pressure through regular follow-ups

Understanding the principles of using antihypertensive medications

- Start with a small dose and gradually adjust to an effective dose. This ensures optimal results at the lowest dose and minimises adverse effects.
- Keep blood pressure in a normal range for 24 hours to prevent blood pressure from rising and falling.
- Combination therapy with two or more antihypertensive drugs can be used when the efficacy of low-dose monotherapy is not satisfactory.

Smoothing 24-h blood pressure control

Smoothing 24-h blood pressure control can prevent adverse events caused by blood pressure fluctuations.

- There is a circadian rhythm in blood pressure, with low blood pressure at night, and a sudden increase in blood pressure in the morning.
- Smooth 24-h blood pressure control can prevent sudden death, stroke or heart attack caused by blood pressure fluctuations in the morning (4–10 am).



Why do you need to use combined antihypertensive medications?

Combined use of antihypertensive medications can better protect against the infection of important organs such as heart, brain and kidney.

 To better protect the function of important organs such as the heart, brain and kidney, it is necessary to lower blood pressure to a greater extent. A single medication usually cannot achieve this treatment goal.

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 Combined use of antihypertensive medications can lower blood pressure to a greater extent due to the combined antihypertensive effect.

Combination therapy can reduce adverse drug reactions

- Single medication often necessitates larger doses, which increases the likelihood of adverse reactions
- When medications are combined, each dose is not <u>large</u> and the adverse effects of the drug can be reduced or at least not overlapped.

What if the blood pressure does not drop?

If your blood pressure does not reduce after taking antihypertensive medications, please do not change the type or dosage of medications. You will need to check if you have the following unhealthy lifestyle factors.

- · High-salt diet
- Smoking
- Lack of exercise
- Excessive psychological stress
- Lack of daily routine and insomnia

You will need to seek help from your doctor if your blood pressure is still high after you have achieved these healthy lifestyles.

Can I stop taking medications when blood pressure is normal?

- Do not stop taking medicine after normal blood pressure. Blood pressure dropping to normal does not mean high blood pressure has been cured. If you stop the medications immediately, blood pressure will rise again and you will need to retake medications. Taking medication intermittently, not only failing to achieve the therapeutic effect, can cause serious complications of the heart and brain due to frequent fluctuations in blood pressure.
- The correct approach is to communicate with your doctor in a timely manner and reduce the type and dose of the drug under the guidance of your doctor.
- Long-term adherence to the dosage of medications suggested by your doctor.

Antihypertensive medication should be taken requiarly

Regular use of antihypertensive medication can protect important organs such as the heart, brain and kidney

- Irregular medication can lead to high and low blood pressure, and long-term blood pressure fluctuations can induce stroke, myocardial infarction and other cardiovascular and cerebrovascular emergency.
- Regular use of antihypertensive medication can maintain blood pressure at a normal level for a long time, which is

beneficial to protect important organs such as heart, brain and kidney.

The best time to take antihypertensive medications

- Take these medications after waking in the morning. This effectively controls the sharp rise in blood pressure in the morning to help avoid acute cerebral hemorrhage.
- Be especially careful not to take antihypertensive medication before going to bed. It makes the blood pressure at night lower and increases the likelihood of cerebral thrombosis.

<u>Diet plan</u>

Food group	Servings per day	1 serving is equal to:
Grains	6-8	 1 slice bread, or <u>1 ounce</u> dry cereal, or 1/2 cup cooked rice, pasta, cereal
Vegetables	4-5	 1 cup raw leafy vegetables, or ½ cup cut up raw or cooked vegetables
Fruits	4-5	 1 medium piece of fruit, or ¼ cup dried fruit, or ½ cup fresh, frozen or canned fruit
Fat-free or low-fat milk and milk	2-3	 1 cup milk or yogurt, or 1 ½ ounce cheese

Lean meats, poultry and fish	No more than 6	• <u>1_ounce</u> cooked meats, or poultry, or fish, or 1 egg
Nuts, seeds and legumes	4-5/ <u>wk</u>	 1/3 cup nuts, or 2 tbsp peanut butter, or 2 tbsp of seeds, or ½ cup cooked legumes
Fats and oils	2-3	 1 tsp soft margarine (non-hydrogenated), or 1 tsp vegetable oil, or 1 tbsp mayonnaise, or 2 tbsp salad dressing
Dessert	Less than 5 /wk	 1 tsp sugar, jelly or jam, half a cup of smoothie, 1 cup of lemonade
Note In the	table 1 our	in about 240ml 1 top in

products

Note: In the table, 1 cup is about 240ml, 1 tsp is about 15ml; fat, protein and carbohydrate in the diet account for 27%, 18% and 55% of the total calories, respectively

How to measure blood pressure?

- To begin blood pressure measurement, use a properly sized blood pressure cuff. The length of the cuff's bladder should be at least equal to 80% of the circumference of the upper arm.
- 2. Wrap the cuff around the upper arm with the cuff's lower edge one inch above the antecubital fossa.
- 3. Lightly press the stethoscope's bell over the brachial artery just below the cuff's edge.

- Rapidly inflate the cuff to 180mmHg. Release air from the cuff at a moderate rate (3mm/sec).
- 5. Listen with the stethoscope and simultaneously observe the sphygmomanometer. The first knocking sound (Korotkoff) is the subject's systolic pressure. When the knocking sound disappears, that is the diastolic pressure (such as 120/80).
- Record the pressure in both arms and note the difference; also record the subject's position (supine), which arm was used, and the cuff size (small, standard or large adult cuff).
- If the subject's pressure is elevated, measure blood pressure two additional times, waiting a few minutes between measurements. A blood pressure of 180/120mmHg or more requires immediate attention.

How to measure blood alucose?

- 1. Wash and dry your hands well.
- 2. Insert a test strip into your meter.
- 3. Prick the side of your fingertip with the needle (lancet) provided with your test kit. Gently squeeze or massage your finger until a drop of blood forms.
- 4. Touch and hold the edge of the test strip to the drop of blood.
- 5. The meter will display your blood glucose level on a screen after a few seconds

How to perform an insulin injection?

1. Wherever possible, wash your hands with soap and water before injecting.

- 2. Put a new needle onto your <u>pen, and</u> remove the caps of the pen needle.
- 3. Hold the pen upright and perform an 'air shot'. This requires dialling up at least 2 units and pressing the plunger to expel a test shot of insulin. This helps to clear any bubbles out of the needle. If you do not get a steady stream, repeat the air shot until you do get a steady stream of insulin coming out.
- 4. Dial up your dose.
- 5. Pick a soft fatty area to inject. Tops of thighs, belly, bum and triceps.
- 6. Put the needle in and keep the pen steady.
- 7. Push the plunger relatively slowly to inject the dose.
- After the dose has been injected, hold the needle in for a good 10 seconds to help insulin get delivered and prevent any of the dose escaping out.
- 9. Ensure that the used needle bin is deposited into a sharps bin.

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Appendix 15 Intervention Diary- patient version

Please tick \checkmark in the spaces of the items you have done prior to each visit

Code of patient: _____ Code of health facility: _____

	Discharge planning	Self-management record after discharge											
	Contents	1 st month DMY	2 nd month D_MY	3 rd month D_MY	4 th month D_MY	5 th month DMY	6 th month D_MY						
Healt	Diet	Completed If uncompleted, times of non-adherence to goals											
Health behaviour goal	Alcohol	Completed □ If uncompleted,times of non-adherence to goals											
	Physical exercise	Completed □ If uncompleted, times of non-adherence to goals											
and plan made on the	Smoking	Completed □ If uncompleted, times of non-adherence to goals											
	Positive emotions	Completed □ If uncompleted, times of non- adherence to goals											
	Geriatric conditions	Completed If uncompleted, times of non- adherence to goals											
discharge	Other	Completed If uncompleted,times of non-adherence to goals											
BP	reading of self-monitoring	1 st week 2 nd week 3 rd week 4 th week											

	1.Name of medication		no missed 🛛					
Me	Dosage	times/day						
dic	and Frequency	tablet/each	times of missed					
atio	Frequency	time	medication this month					
n	2.Name of	unio						
Medication use	medication		Reasons of medication non					
	Dosage	times/day	adherence					
and its	and Frequency	tablet/each						
	riequency	time						
adh	3.Name of							
ere	medication							
adherence	Dosage and	times/day						
œ	Frequency	tablet/each						
		time						
	falls and fall-related injuries \Box							
	pins and needles \Box							
	dizziness 🗆							
≥	headache							
Adverse events	sleep difficult	ties ⊔ egs or ankles □						
rse	chest distres							
ev	stomach disc							
ents	backache 🗆							
~	cough 🗆							
	dyspnoea 🗆							
	vomit 🗆	(f)						
Number	others (pleas	se specity)						
Numbers of unplanned hospital admission/ the use of emergency service after								
discharge								
	Date for th	e next visit	р м ү					
		G HOAL VIOIL	U'					
				•	•	•	•	

Appendix 16 Intervention record- community nurse and GP version

Please tick \checkmark in the spaces of the items you have done at each visit

				C									CD			
	Community nurse											GP				
	Fortnigh	tly phone call						Monthly cl	inic visit							
Date	Length of time	Monitor the patient's progress towards the goal, medication adherence, encourage BP self-monitoring	Length of time	Measure BP	Health education and establish lifestyle goal	Test health knowled ge	Adherence to lifestyle recommen dations	Medication adherence	Adverse events and unplanne d admissio n	Nurse Signature	Review and discuss individual treatment plan	Medicati on change (describe)	Discussi ons with specialist s (describe the outcomes)	Refer patient to specialist and its reason	GP Signature	
	1 st Phone call	Yes 🗆 No 🗆					Complied always Complied often	Complied always Complied often								
1 st month d/m/y	2 nd phone call	Yes 🗆 No 🗆					Complied sometimes Complied rarely Non-	Complied sometimes Complied rarely Non-			Issues identified: 					
	3 rd phone call	Yes 🗆 No 🗆					complied	complied								
2 nd month d/m/y	4 th phone call	Yes 🗆 No 🗆														

3 rd month d/m/y	5 th phone call 6 th phone call	Yes No Yes No	BP reading	Score:	Score:	Score:	Number :			
4 th month d/m/y	7 th phone call 8 th phone call	Yes No Yes No								
5 th month d/m/y	9 th phone call 10 th phone call	Yes No Yes No								
6 th month d/m/y	11 th phone call 12 th phone call	Yes No Yes No No	BP reading	Score:	Score:	Score:	Number 			

Appendix 17 Two-way referral letter between hospital and community health centre

Participant code:		Gender:	Birth date:		Admission number at hospital:			
Telephone r	number:		Home addre	Home address:				
	Ward at hospital:			Community health service centre:				
	Date of discharge from	n hospital :		Date of a	dmission to community health service centre:			
	daymonth	year		daymonthyear				
Discharge	Name of in-charge do	ctor:	Admission	Name of GP:				
	Telephone number: _			Telephone number:				
	Name of in-charge nu	rse:		Name of nurse:				
	Telephone number: _			Telephone number:				

Appendix 18 Usual care table to record adverse events and unplanned hospital admission/ the use of emergency care service

Code of patient:		Code of health facility:							
ltems		1 st month ^D MY	2 nd month	3 rd month	4 th month	5 th month	6 th month		
Adverse events	falls and fall-related injuries pins and needles dizziness headache sleep difficulties swelling of legs or ankles chest distress stomach disorder backache cough dyspnoea vomit	DMY	DMY	DMY	DMY	DMY	DMY		
	Others(please specify)								

Please tick \checkmark in the cells of adverse events you had

Appendix 19 Published abstract for Delphi study

12 th European Diabetes Congress September 15-17, 2016 Berlin, Germany										
Theme: New Therapeutic Mechanisms of Diabetes										
Organizing Committee	Submit Abstract	Register Now	Program Schedule	Reader Base						
Search		s	earch 1000+ Events							

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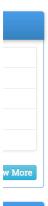


Flinders University, Australia

Title: Development of a hypertension management program for communitydwelling older people with diabetes in Nanchang, China: A Delphi study

Biography

Biography: Qiang Tu



Abstract

Background: Hypertension is poorly controlled in older people with diabetes. China has a large number of older populations living with diabetes and hypertension, and yet an underdeveloped primary care system to manage the conditions effectively. Research evidence on hypertension management for this population is limited.

Aims: To gain health professionals' consensus on the applicability of an evidence-based hypertension management program.

Methods: A comprehensive literature review was undertaken to develop an evidence-based hypertension management program for community-dwelling older people with diabetes. The program were stated in a questionnaire and distributed to health professionals in Nanchang who were specialized in the area of practice via Email. This Delphi study set out 75% and over agreement as the consensus rate.

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Appendix 20 Certificate of presentation of Delphi Study in the 12th European Diabetes Congress



Appendix 21 Published article for study protocol

Tu et al. Trials (2018) 19:385 https://doi.org/10.1186/s13063-018-2766-5

STUDY PROTOCOL

Trials

Open Access

CrossMark Hypertension management for communitydwelling older people with diabetes in Nanchang, China: study protocol for a cluster randomized controlled trial

Qiang Tu¹, Lily Dongxia Xiao^{1*}, Shahid Ullah², Jeffrey Fuller¹ and Huiyun Du¹

Abstract

Background: Although China has a large number of older people living with diabetes and hypertension, the primary care system is underdeveloped and so management of these conditions in community care settings is suboptimal. Studies have shown that the collaborative care model across care settings that address both pharmacology and nonpharmacology interventions can achieve hypertension control for older people with diabetes. Barriers to implementing and evaluating this model of care are widely recognized in low and middle-income countries including China.

This study will therefore test the hypothesis that a hypertension management program built on collaboration between hospitals and community health service centers in China can improve blood pressure control in people aged 60 years and older with diabetes as compared to usual care.

Methods: A cluster randomized controlled trial will randomly allocate 10 wards from four hospitals in Nanchang to either an intervention group (N = 5) or a usual care group (N = 5). At least 27 participants will be recruited from each ward and the estimated sample size will be 135 patients in each group. The intervention includes individualized selfcare education prior to discharge and 6-month follow-up in community health service centers. Health professionals from both hospitals and community health service centers will be resourced to collaborate on the implementation of the postdischarge interventions that reinforce self-care. The primary outcome is systolic blood pressure at 6-month follow-up adjusted for baseline value. Secondary outcomes are self-care knowledge, treatment adherence, HbA1c and lipid levels, quality of life, the incidence of adverse events and the incidence of unplanned hospital readmission at 6-month follow-up adjusted for baseline value. A multilevel mixed-effect linear regression model will be used to compare the changes in health outcomes between the intervention and usual care groups.

Discussion: This study will determine whether collaborative care among health professionals between hospitals and community health service centers will improve hypertension management for older people with diabetes in the study sites. The program, if effective, will have an immediate application to hypertension management in the healthcare system in China.

Trial registration: Australia New Zealand Clinical Trials Registry, ACTRN12617001352392. Retrospectively registered on 26 September 2017

Keywords: Hypertension, Diabetes, Cluster randomized controlled trial, China, Collaborative care, Primary health system

* Correspondence: Illyxiao@flinders.edu.au ¹College of Nursing and Health Sciences, Flinders University, GPO Box 2100, Adelaide, SA 5001, Australia

Full list of author information is available at the end of the article



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Background

It is estimated that one third of adults (over 100 million) with type 2 diabetes around the world live in China [1]. One third of the Chinese population are expected to be aged 60 years and older (430 million people) by the year 2050 [2]. The continuous growth of the older population will inevitably increase the incidence of hypertension and diabetes in this population group, resulting in an increased burden on the healthcare system. Hypertension frequently coexists with diabetes. It is reported that 50-80% of patients with diabetes are affected by concurrent hypertension [3]. People with comorbidity of diabetes and hypertension are associated with two times higher risk of developing cardiovascular disease and 7.2 times higher mortality rate compared to those who have diabetes only [4, 5]. Clinical studies have indicated that cardiovascular events and hypertension-related mortality in patients with diabetes can be significantly reduced by optimal hypertension management [6, 7]. However, in China only 14.9% of patients with coexisting hypertension and diabetes have their blood pressure controlled and the disease burden on the health systems is widely reported [8]. Although a primary care approach to hypertension management is well recognized as the most cost-effective way to reduce the disease burden [9], there are no practice guidelines for hypertension management at the community level in China and evidence on how to support the development of this care approach is lacking. This study will add research evidence to the international community to inform practice by exploring a postdischarge intervention to improve hypertension management for older people with diabetes codelivered by health professionals working in hospital and primary care settings in Nanchang, China.

Factors associated with uncontrolled hypertension among older people with diabetes include patient factors (i.e., the lack of knowledge, skill and resources to perform self-care) and healthcare system factors (i.e., the lack of continuity of care and collaboration between different care providers) [2, 10, 11]. Poor communication and collaboration between hospitals and community health service centers exists in many low and middle-income countries which leads to fragmented healthcare delivery for discharged patients [12-14]. Although community health service centers have been established in China to strengthen primary care, collaboration between these centers and hospitals is underdeveloped. A study on healthcare referral services in four cities of China, including Nanchang, revealed that 57% of GPs never had communication with specialists [15]. A population-based study showed that only 34% of residents considered the use of community health service centers in Changsha, China [16]. The main factors contributing to the underutilization of primary care

appear to be the lack of effective mechanisms to enable referrals to GPs from hospital specialists, and the lack of communication and collaboration between hospital care and primary care providers [12, 15].

In this study context, after hospital discharge, patients who are not managed by GPs and community nurses usually seek treatments in hospitals only when their conditions get worse [13]. As limited time is available for each patient, the treatment at hospitals mainly focuses on medication, but without attention to nonpharmacological interventions, such as health education to improve patients' self-care capabilities. This acute and episodic treatment is not in line with contemporary self-care principles that encourage patients to actively engage in their chronic condition management through goal-setting and regular review [17]. Improvements in referral to and capacity-building of the primary care system will enable patients to use primary care as the main source of care to improve both pharmacological and nonpharmacological interventions.

A body of evidence shows that up to 50% of community-dwelling older people in the USA had one or more geriatric conditions such as incontinence, falls, malnutrition, cognitive impairment and pressure ulcers [18, 19]. These conditions compound the complexity of hypertension and diabetes, and contribute to adverse outcomes and hospital admission [20]. Community-dwelling older people who are susceptible to or have these geriatric conditions require primary care services to achieve a long-term control of these conditions, rather than relying on irregular outpatient clinic visits or admission to hospital.

Studies have demonstrated that close collaboration between hospitals and community health service centers can provide patients with continuous and integrated care delivery, which is recognized as an effective approach to improve quality of care, decrease healthcare utilization and reduce costs associated with hypertension treatment [12, 21, 22]. Randomized controlled trials in high-income countries with well-developed healthcare systems and health insurance schemes have demonstrated that multifactorial interventions delivered by a multidisciplinary team involving nurses and doctors had positive effects in hypertension management for older people with diabetes [23-25]. This management often incorporates the following components: health education at hospital and community healthcare settings, healthy lifestyles (i.e., weight loss, smoking cessation, salt and alcohol restriction, increased physical activity), medication adherence and intensification, timely medication adjustment and complication prevention, and continuous and rigorous follow-up visits in primary care [23, 26-29]. Reports of intervention programs including a combination of these components remain scarce in the low and middle-income countries with lower health resources in primary care such as China.

In this study, collaboration between hospitals and community health service centers will be developed to promote a primary care approach to managing hypertension for older people with type 2 diabetes. This collaboration will support the capacity-building of the primary care system in chronic disease management. We hypothesize that a hypertension management program built on collaborative care among health professionals within and between hospitals and community health service centers will improve blood pressure control among community-dwelling older people with diabetes in Nanchang, China.

Methods

Study design

A cluster randomized controlled trial will commence at hospitals via discharge and then continue at community health service centers for 6 months in Nanchang, the capital city of Jiangxi Province in China. This cluster design will minimize the risk of contamination between intervention and usual care groups and reflect the classification of public hospitals in China at three levels, namely community health service centers, secondary hospitals and tertiary hospitals [30]. Tertiary hospitals are the final referral hospitals and provide more comprehensive care services for patients compared with secondary hospitals. The Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) that provide an overview of the schedule of enrolment, interventions and assessments are presented in Fig. 1. The SPIRIT checklist is shown in Additional file 1. The timeline diagram is presented in Fig. 2.

Ethical approval and consent to participate

The study protocol was approved by the Southern Adelaide Clinical Human Research Ethics Committee in Australia (Approval Number: 345.16) and the Department of Scientific Research Management at the Health and Family Planning Commission of Jiangxi Province, China. All participants and health professionals delivering the interventions will be given written information so that they can provide informed consent. Each participant and participating health facility will be given a unique numerical code to ensure anonymity. Information provided by participants will be collected in a de-identifiable form and treated confidentially. Data collected through this study will be stored in a secure area in the University that the first author is enrolled in a PhD program. All study-related data will only be accessible to the researchers.

Eligibility: inclusion criteria and exclusion criteria

Hospitals are eligible for recruitment if they have cardiovascular wards and geriatric wards that predominantly provide care services for older people with hypertension. Participants from these wards are eligible for recruitment if: (1) they receive care for both type 2 diabetes and hypertension from one of the four hospitals selected for the study; (2) the reason for hospitalization is uncontrolled hypertension and/or associated complications; (3) they are diagnosed with coexisting type 2 diabetes and hypertension; (4) they are aged \geq 60 years; (5) they are fit for discharge justified by the specialist; (6) they are without cognitive impairment (assessed by the Mini-Mental State Examination); and (7) they reside in residential areas where the six community health service centers provide care services.

Participants will be excluded if they are: (1) diagnosed with type 1 diabetes; (2) unable to participate in the study because of severe organ damage, disability, cognitive impairment and other life-threatening disease; (3) unwilling to return to a community health service center for follow-up visits; and (4) living outside of these six communities.

Randomization

Participants will be recruited from hospitals and continue the trial at community health service centers. Randomization will be performed based on the ward clusters rather than participants. Health professionals involved in the study practice are in a single ward only, therefore the chance of contamination between intervention and usual care wards in the same hospital is very low. There are six secondary hospitals and five tertiary hospitals that provide in-patient care for patients with diabetes and hypertension in Nanchang. As part of the ethics application processes, researchers in the project sent out invitations to all of these 11 public hospitals in Nanchang and informed them that two secondary hospitals and two tertiary hospitals would be randomly selected. The number of hospitals to be included in the trial was estimated on the sample size calculation. In total, six secondary hospitals and five tertiary hospitals agreed to participate. To ensure the selected hospitals are representative of the hospitals in Nanchang, two hospitals will be randomly selected from each level. There are two eligible wards in each participating secondary hospitals and three eligible wards in each tertiary hospital. To ensure the selected wards are representative of the wards in each level of the selected hospitals, three wards from tertiary hospitals and two wards from secondary hospitals will be randomly assigned to either an intervention group or a usual care group. The group assignment will be undertaken by a PhD fellow who is not involved in the trial and is blind to the wards. Patients who meet the inclusion criteria in these participating wards will be invited to the trial. There are six community health service centers that provide chronic disease management for residents in

	STUDY PERIOD							
	Cluster enrolment -t4	Cluster allocation -t3	Participant enrolment -t2	Baseline data collection -t1	Group assignment disclosed	Post-enrolment		
TIMEPOINT						Prior to discharge t1	3 months after discharge t2	6 months after discharge t3
ENROLMENT:								
1.Cluster screening and identification	Х							
2.Cluster recruitment	X							
3.Cluster randomisation		X						
4.Eligibility screen of participants in each cluster			x					
5.Participant recruitment			X					
6. Informed consent of participants			x					
7.Baseline assessment of participants				x				
8.Informing participants of group assignment					х			
INTERVENTIONS:								1
1.Intervention at hospital						Х		
2.Intervention at community							X	X
USUAL CARE:								
Usual care						Х	Х	Х
ASSESSMENT :								
I.Blood pressure (Baseline: medical record; T2 and T3: Intervention record- community nurse and GP version)				x			х	Х
2.Hypertension and diabetes-related health knowledge (Hypertension Knowledge Level Scale (HK-LS) and Diabetes Knowledge Questionnaire (DKQ))			x			х	х	
3.Medication adherence and health lifestyle adherence (Treatment adherence questionnaire of patients with hypertension (TAQPH))				х			х	х
4.HbA1 and blood lipids (Baseline: medical record; T2 and T3: Intervention record- community nurse and GP version)				х			х	х
5.Quality of life (Hypertension scale of the system of Quality of Life Instruments for			x			x	x	
Chronic Diseases (QLICD-HY))				А				A .
6. Adverse events and complications (Interv	ention diary- J	atient version)				х	х
7. Unplanned hospital admission/the use	of emergency	care service	(Intervention				v	v
diary- patient version)							х	X

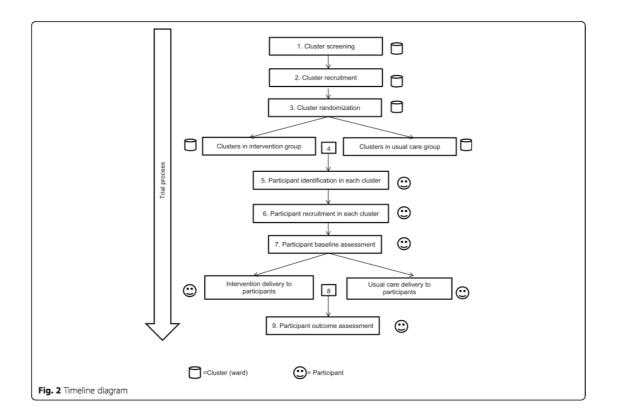
Nanchang. The invitations were sent to these community centers and all of them agreed to participate in the trial. A flow chart of the randomization is shown in Fig. 3.

Description of the interventions

The interventions were developed from a comprehensive literature review about effective hypertension management for older people with diabetes. The intervention will start from the hospital with individualized discharge education provided by the patient's in-charge nurse and the medical specialist (first stage of intervention). After patients are discharged, and in addition to the usual follow-up in the hospital outpatient clinic, they will be referred to the community health service centers to receive the follow-up intervention over 6 months provided by general practitioners (GPs) and community nurses (second stage of intervention). Health professionals from both hospital and community health service centers will be resourced to work in a collaborative way to implement the postdischarge interventions. A flow chart of the intervention protocol is shown in Fig. 4 and discussed in the following.

Stage 1: interventions at hospital

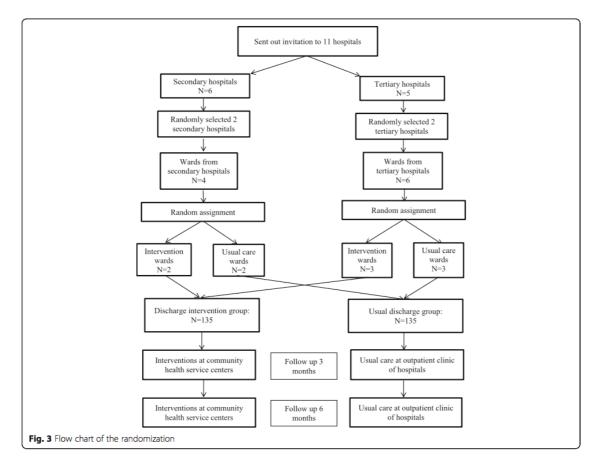
1.1.Individualized discharge education. Patients will be given two face-to-face individualized health education sessions specific to diabetic



patients with hypertension by the in-charge nurse. The health education includes health behavior education, disease-associated education and medication education with 15 min for each session. A geriatrics condition screening will also be undertaken using the widely recognized evidence-based screening tool "Fulmer SPICES Comprehensive Assessment Tool for Older Adults" [31]. Education on preventing and managing geriatric conditions will be provided by the in-charge nurse based on the findings from the screening.

- 1.2. Lifestyle modification goals: intervention diary—patient version.
 - 1.2.1. Patients will be asked to establish lifestyle modification goals and develop personal action plans with the in-charge nurse. Patients will be provided an "intervention diary—patient version" (Additional file 2) to document their lifestyle modification goals, personal action plans, progress toward the goals, medication adherence, adverse events and unplanned hospital admissions/use of emergency care services.

- 1.2.2. Patients will be asked to discuss and establish their diet plan with the in-charge nurse. The diet plan will be recorded in the "intervention diary—patient version".
- 1.3. Individualized medication treatment. Prior to discharge, patients will be given an individualized medication treatment plan by the medical specialist. Individualized medication treatment will be recorded in the "intervention diary—patient version".
- 1.4. Referral to the community health service center: intervention record—community nurse and GP version.
 - 1.4.1. When patients are discharged from hospital, they will be referred to a community health service center by the in-charge nurse for regular follow-up over 6 months. An "Intervention record—community nurse and GP version" (Additional file 3) will be sent to the community nurse by the in-charge nurse on discharge to record the required postdischarge interventions and outcomes.



- 1.4.2. In order to establish collaboration and maintain communication among the doctor and nurse at the hospital, the patient and the GP and nurse at the community health service center, a two-way referral letter has been developed (Additional file 4).
- 1.4.3. The in-charge nurse at the hospital will contact the GP and nurse in the community health service center through a telephone call and will fill in the two-way referral letter for patients.
- 1.4.4. The in-charge nurse will help patients to contact the nearby community health service center for the follow-up visit. Patients will be advised of the community health service center they have been referred to, and the name and contacts of the GP and nurse in the community health service center.
- 1.4.5. Data in relation to the patient's demographic information, pharmacotherapy history and other clinical information will be sent to the

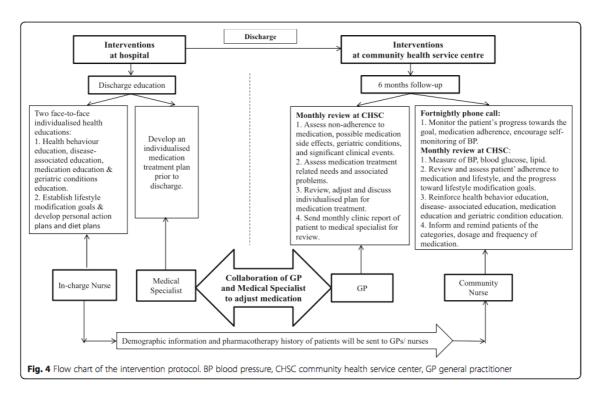
community nurse by the in-charge nurse on discharge.

- 1.4.6. Patients will take the referral letter and discharge abstract to the community health service center for the follow-up visit.
- 1.5. Monitoring.

The in-charge nurse at the hospital will keep track of the patient's referral progress through making telephone calls with the patients and community nurses to ensure patients are seen at the community health service center.

Stage 2: regular follow-up interventions over 6 months at community health service centers

- 2.1. Fortnightly telephone call. Patients will receive a fortnightly telephone call at home from the community nurse to monitor their progress toward setting goals and medication adherence.
- 2.2. Monthly community health service center visit.



Patients will be asked to visit the community nurse and GP at the community health service center every month for follow-up visits.

- 2.2.1. Patients will receive blood pressure measurement every month by the community nurse.
- 2.2.2. Patients will receive a review and assessment from the community nurse on their adherence to medication and lifestyle recommendations, and their progress toward lifestyle modification goals.
- 2.2.3. Patients will receive reinforced health education from the community nurse to improve their self-management ability and treatment adherence. Patient will be given health education on preventing or treating geriatric conditions based on the "Fulmer SPICES Comprehensive Assessment Tool for Older Adults".
- 2.2.4. Patients will receive an assessment from the GP on their clinical outcomes, problems of nonadherence to medication, medication side effects, drug therapy problems, drug-related needs and clinical events occurred.
- 2.2.5. Patients will be asked to discuss their individualized treatment plan and medication adjustment with the GP.

- 2.2.6. Patients will be asked to document their medication changes in the "intervention diary—patient version".
- 2.2.7. Patients will be reminded of the categories, dosage and frequency of medication required to be taken prior to the next visit by community nurse.
- 2.3. GP and medical specialist collaboration. The GP will discuss with the medical specialist at the hospital via email or telephone when necessary to adjust medication. BP, HbA1c and lipid readings will be recorded by the community nurses and formatted as a monthly report and then sent to medical specialists for review. Urgent symptoms will be communicated to the medical specialist immediately for additional orders by the GP.

Usual care

In the usual care group, patients will receive routine discharge education at hospital. After they are discharged, they will go to their usual outpatient clinic of the hospital to receive follow-up and outcome measures at 3 and 6 months. They will not be referred to the community health service center. They will be asked to record the number of adverse events and unplanned hospital admissions/use of emergency care services during 3-month and 6-month follow-up in a usual care table (Additional file 5). The researcher will

record the HbA1c and lipid levels close to the 3-month and 6-month follow-up from the patients' medical record.

Outcome measures

Primary outcome

The primary outcome is systolic blood pressure at 6-month follow-up adjusted for baseline value. At each measurement point, blood pressure will be measured three times at 5-min intervals on the participant's right arm in a sitting position. The average of the three blood pressure readings will be calculated as the final BP reading for each group at each time point, which minimizes measurement error.

Secondary outcomes

Secondary outcomes are the following outcomes at 6-month follow-up adjusted for baseline value: (1) hypertension and diabetes-related health knowledge score measured by a combination of the Hypertension Knowledge-Level Scale (HK-LS) [32] and the Diabetes Knowledge Questionnaire (DKQ) [33]; (2) medication adherence and health lifestyle adherence score measured by the Treatment Adherence Questionnaire of Patients with Hypertension (TAQPH) [34]; (3) HbA1c and lipid values; (4) quality of life score measured by the hypertension scale of the Quality of Life Instruments for Chronic Diseases (QLICD-HY) [35]; (5) the incidence of adverse events and complications associated with hypertension, diabetes, treatments and geriatric syndromes recorded by patients/or carers in the "intervention diary-patient version"; and (6) the incidence of unplanned hospital admissions/use of emergency care services due to uncontrolled hypertension, diabetes and geriatric syndromes recorded by patients or carers in the "intervention diary—patient version".

Through the study, we hope to identify the challenges that patients face in their hypertension management in the community healthcare settings and to evaluate how to overcome these challenges by improving the capacity of the primary care system. Hence, two open-ended questions will be included for patients upon study completion: (1) Are you satisfied with the follow-up provided by the GP and community nurse in the community health service center? (If not, please explain the reason); and (2) Did you encounter any difficulties of care in the community health service center after discharge? (If yes, please list the difficulties you encountered).

Sample size

The sample size calculation is based on the primary outcome and is estimated on the basis of an earlier randomized controlled trial study in relation to hypertension management for diabetic patients [36]. In this earlier study, the researchers found a 7.3 mmHg significant reduction in systolic blood pressure (SBP) with a standard deviation of 12.1 mmHg and an intraclass correlation coefficient (ICC) of 0.05 in the intervention group [36]. Since randomization in our study will be done by wards (clusters), the sample size has been adjusted to take into account the design effect. Our study is designed to have 80% power to detect a difference of 7.3 mmHg SBP between the group means when the standard deviation is 12.1 mmHg. This assumes that a sample size of five clusters per group with 25 participants per cluster will complete the study and the ICC is 0.05, giving a design effect of 1.48. The ICC also reflects the situation that the hospitals in the study are from the same city under the same hospital administration standard; therefore, each cluster is unlikely to differ from the others with respect to the variable of interest. Each cluster will be of equal size. Assuming an attrition rate of 10%, we would require 27 participants per cluster. In total, 10 clusters with 270 participants will be recruited.

Participant recruitment

Recruitment posters will be presented in the patient activity rooms in the participating wards. An information pack including an information sheet, consent form and other study-related documents (i.e., intervention diarypatient version; usual care table) will be displayed on a table placed under the poster for potential participants to view. Potential participants will be asked to return their decision on participation via a response slip to a drop box in each participating ward. On receiving the response slip, a research recruiter who is blinded to the group allocation and has no interest in the outcome of the study will contact the patients to confirm their eligibility to participate. One of the project team members, who will know the allocation, will provide detailed information related to the study and have the participants sign the consent form. Although the allocation will be known to the project team member, the risk of selection bias and influences on the measure of baseline outcome will be minimal because the participants will have been identified and recruited by the research recruiter rather than the project team member. Participants will be informed that refusal to participate in this study will not alter the caring relationship between them and the hospitals. Participants will be reminded that they can discontinue participation in the study at any time without any influences on their usual care.

Data collection

At baseline, the in-charge nurse will distribute the questionnaires to participants or their family caregiver. They will complete the questionnaires once the consent form is signed and before the individualized discharge education is provided. The patient's in-charge nurses at the hospital will provide assistance to participants should they have any questions about the questionnaire. Clinical outcomes (BP, HbA1c and lipid values) will be directly recorded from the health record of patients by a research assistant.

At 3-month and 6-month follow-up, community nurses will distribute the questionnaires to participants in the intervention group when they visit the community health service center. Community nurses will be available to assist patients should they have any questions about the questionnaire. In the usual care group, a nurse in the medical specialist clinics will distribute the questionnaire to participants when they visit the outpatient clinic at 3-month and 6-month follow-up. The nurse will be available to assist patients should they have any questions.

Completed questionnaires will be placed in a prepared sealable envelope to maintain confidentiality. The researcher will prepare a drop box in each ward, community health service center and outpatient clinic. Participants will return the sealed questionnaires to the drop box. The research assistants will collect completed questionnaires on a weekly basis.

Quality control procedures

Quality of data collection will be ensured during the whole study phases. Two 1-h workshops and ongoing support at each participating site will be provided to the health professionals to allow them to discuss, understand and follow the study protocol. Research assistants will be employed to distribute and collect the questionnaires. Consent forms, questionnaires and other data collection documents will be checked for completeness. Data at three time points (baseline, 3-month and 6-month follow-up) will be checked using the birth date of patients to ensure the data are matched correctly. The quality of the study will be overseen by the PhD supervision team and the representative of the Department of Scientific Research Management at Health and Family Planning Commission of Jiangxi Province, China. The data entered into SPSS will be checked to prevent input errors by the other two PhD fellows who are not involved in this study. The compliance of patients with the interventions will be optimized by a telephone call from the nurse at the community service center to remind them of the follow-up visits at the community health service center.

Blinding and allocation concealment

Participants will not know their group allocation during the recruitment and baseline data collection. The research recruiter who is blinded to the group allocation and has no interest in the study will assist the recruitment of participants. Allocation will be disclosed to participants after the baseline data collection. Due to the nature of the study interventions, health professionals who deliver the intervention will know the group allocation during the trial. However, the statistician involved in the data analysis is blinded to the group allocation.

Intervention fidelity

Intervention fidelity refers to the extent that proposed interventions are delivered as planned in the protocol. The items of interventions recorded by both patients and community health professionals include: (1) intervention diary—patient version; and (2) intervention record—community nurse and GP version. Compliance with required interventions will be matched using these two tools.

Dealing with contingencies

Possible contingencies are the following: (1) patients refuse to participate in the project; the strategy to deal with this will be to extend the recruitment period to gain sufficient sample size; and (2) unexpected tasks that health services need to deal with, such as outbreak of infectious disease; the strategy to deal with this will be to temporarily cease the trial and recommence when the health service returns to normal. The Department of Scientific Research Management at Health and Family Planning Commission of Jiangxi Province, China, will deal with the contingencies that may occur during the study.

Statistical methods

Statistical analysis will be performed using Statistical Package for Social Science (SPSS) version 23 and STATA software version 14. To test the effectiveness of the intervention on the primary and secondary outcomes, a multivariate multilevel mixed-effects linear regression model will be used to analyze outcomes. This is due to the hierarchical structure of the data and is based on the consideration of the correlations between participants' repeated measurements over time. Because the participants are nested within hospital wards, we will fit a three-level mixed model with random intercepts at both the cluster and the participant-within-cluster levels. Thus, models will account for the clustering in wards, participants within clusters and over time using the mixed command. Wards and participants within wards will be treated as random effects. The main effects will be group (intervention or comparison), time (baseline, 3 and 6 months) and group × time interaction. A small-sample correction to the restricted maximum likelihood estimator will be used to improve the inference for the fixed parameters and is available in STATA mixed command. Models will be adjusted by baseline value and confounders that include age, gender, body mass index (BMI), duration of hypertension, duration of diabetes, smoking status and education level [37, 38]. A univariate model will also be used for unadjusted estimates. The level of significance will be set at p < 0.05. Where appropriate, 95% confidence intervals (95% CIs) will be reported along with p values.

Data analysis will be performed according to the intention-to-treat principle. Participants who withdraw or do not complete the 6-month follow-up will be included in the analysis. A multiple imputation technique will be used for large missing data.

Discussion

The transition between hospital care and community care is a critical period in the care of elderly patients with diabetes and hypertension who often have complex medical problems. The incidence rate of adverse events after discharge and the readmission rate are high due to the inappropriate self-care behaviors of patients and lack of timely monitoring of patients' conditions by health professionals [11, 39]. It has been reported that within a week after hospital discharge, primary health care is required by 80% of patients [11]. Continuity of care through follow-up in primary care as the first contact for patients after discharge can bring positive outcomes for older patients [11, 26]. The transition from passive care to proactive and preventive care can be achieved through establishing a care continuum in the current health systems in China and other low and middle-income countries. Currently, most patients in China only visit doctors when the symptoms of diseases appear. Many complications do not show symptoms in the early stages when they are easier to treat and so the best treatment period may be delayed or missed. By establishing continuous care after discharge, disease-related complications can be prevented or detected earlier and so promptly treated in the primary care system.

As recommended by the World Health Organization [14], patients with chronic conditions require long-term, comprehensive and coordinated care after discharge that is easy to access and provided by the primary health system. A well-developed primary care system contributes to alleviating disparities in healthcare utilization [40]. In 2015, the Chinese government issued an "Outline for the Planning of the National Medical and Health Service System (2015-2020)" which emphasizes collaboration between hospitals and community health service centers. The purpose is to improve prevention and management of chronic disease in primary care settings, reduce hospital care burden and lower national medical costs. This study is in line with these national health reforms that transfer the focus of care from hospitals to community health settings. Interventions introduced in this trial will build capacity of the primary care system to provide accessible and quality care for elderly people with chronic conditions. Interventions in the trial will enable older people to easily access health care a short distance from their home instead of waiting in long queues at a hospital. Collaboration between hospitals and community health service centers can bridge the gap between service capacity of community health professionals and residents' demand for quality in healthcare.

Hypertension and diabetes management after discharge is a process that requires lifelong adjustments to nonpharmacological and pharmacological interventions due to the chronic nature of these conditions. Lack of adherence to pharmacological and nonpharmacological treatment has been identified as a key barrier to optimal hypertension control. Medication adherence is positively associated with hypertension control and reduction in the risk of complications [41]. However, only 20-60% patients in China comply with antihypertensive drugs [42]. Nearly half of patients with diabetes and hypertension are likely to discontinue their medication treatment in the first 6 months after discharge or when their symptoms diminish [2, 42]. Among the patients who adhere to medications, 50% of them take their medications in an incorrect way [2]. Therefore, long-term medication management is required.

As a chronic disease, hypertension requires life-long medication treatment. Older patients whose memory function decline are more likely to forget taking medications as prescribed and to experience side effects and adverse reactions. Inappropriate medication management can lead to repeat hospital admission. In a study involving 86 patients who were hospitalized, 49% of hospital admissions were due to medical error [11]. Therefore, it is important to prevent medication-related problems. In this study, health professionals at community health service centers will regularly monitor patients' medication compliance, deal with the side effects of medication and adjust medical therapies to achieve continuity in optimal medication management.

Therapeutic lifestyle changes (TLC) have demonstrated effectiveness in the control of hypertension and improved quality of life among older people [28]. However, a community-based cross-sectional study in Alexandria found that only one in 10 patients can follow the recommended lifestyle modifications such as dietary change, exercise adjustment and weight control [43]. Factors associated with poor self-management include a lack of understanding of the care plan and low confidence and motivation to make healthy choices. Health education can address these barriers by equipping patients with the motivation, self-care skills and knowledge to manage their chronic conditions. Considering the low level of health knowledge among older people, a sustainable and structured follow-up, including regular health education (involving positive behavior changes and

medication compliance), and professional health counseling are required for older patients who are discharged. In addition, the monthly monitoring of conditions for older people in community settings can ensure early detection of their functional decline, which prevents hospital readmission. A study in Canada found that hypertension-related hospital admissions of older patients was reduced by 9% during 10 weeks by implementing a community-based education program [42]. Therefore, a sustainable health system is built through promoting service improvements in primary care, such as intensive follow-up to support older patients to maintain their adherence to medical treatment and healthy lifestyle.

Previous hypertension management programs in China have been mostly hospital based or community based and only target either pharmacology or nonpharmacology interventions [8, 26]. This is first trial in China to build integrated care based on collaboration and coordination between hospitals and community health service centers to support older people to manage diabetes and hypertension at home using multifactorial interventions. In addition, this study synthesizes the latest evidence and includes the combination of effective intervention components on hypertension management for people with diabetes, which differs from the previous studies in China that only tested single intervention components [44, 45].

The program, if effective, will have an immediate application to hypertension management in the healthcare system in China. In addition, this study uses hypertension and diabetes as an entry point to improve chronic disease management in primary care. Success of this intervention program, that transfers patients from hospital to community health service centers, can also be applied to the management of other chronic diseases for hospitalized patients.

Limitations of this study are the following. First, the trial will be undertaken in 10 clusters only and hence sampling bias may occur, which means that the findings may not represent the population. Second, as an open-label study, the patients and health professionals will be aware of the groups they are assigned to and their allocated treatment during the trial. Patient bias may occur when they complete the self-reported questionnaires. Third, the duration of follow-up at the community health service center is relatively short (only 6 months). The long-term effects of this intervention program will need to be explored in a future study.

Trial status

At the time of submission of the manuscript, this trial is in progress and participants are being recruited. The study began in June 2017, and is expected to be complete by June 2018.

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Additional files

Additional file 1: SPIRIT checklist. (PDF 806 kb) Additional file 2: Intervention diary—patient version. (DOCX 27 kb) Additional file 3: Intervention record—community nurse and GP version. (DOCX 30 kb) Additional file 4: Two-way referral letter. (DOCX 21 kb) Additional file 5: Usual care table. (DOCX 19 kb)

Abbreviations

GP: General practitioner; HbA1C: Glycosylated hemoglobin

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Availability of data and materials

All datasets generated from this study will be available from the corresponding author on reasonable request. The investigators have full access to the data. The results of the study will be submitted for publication once the data collection and analysis are completed.

Risk to participants

As the program is a quality improvement of practice in nature and is required by hospital administration and regulation in China, there are no foreseen risks to participants. Proposed interventions will be included in daily practice and replace conventional practice which is less well organized and may take longer. For example, conventional patient education will be replaced with individualized patient education using an education guide developed by the researchers. The interventions will provide well-organized discharge education for patients.

Dissemination plan

All of the participants and health professionals will be informed of the final research results via a newsletter. Participants will not have any control in the immediate reporting and future use of data collected for the purposes of the research. No individual will be identifiable in the future publications and research report in order to protect participants' identities.

Authors' contributions

QT conceived the conceptual design of the study and drafted the manuscript. LDX conceived the conceptual design of the study and drafted and revised the manuscript. SU contributed to the sample size calculation, designed the statistical analysis and critically reviewed the manuscript. JF and HyD participated in designing the study and reviewing and revising the manuscript. All authors read and approved the final manuscript.

Ethics approval and consent to participate

The study protocol was approved by the Southern Adelaide Clinical Human Research Ethics Committee in Australia (Approval Number: 345.16) and the Department of Scientific Research Management at the Health and Family Planning Commission of Jiangxi Province, China. All participants and health professionals delivering the interventions will be given written information so that they can provide informed consent. Each participant and participating health facility will be given a unique numerical code to ensure anonymity. Information provided by participants will be collected in a deidentifiable form and treated confidentially. Data collected through this study will be stored in a secure area in the University that the first author is enrolled in a PhD program. All study-related data will only be accessible to the researchers.

Consent for publication Not applicable.

Competing interests

The authors declare that they have no competing interests.

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Author details

¹College of Nursing and Health Sciences, Flinders University, GPO Box 2100, Adelaide, SA 5001, Australia. ²South Australian Health and Medical Research Institute, Adelaide, SA, Australia.

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