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# Development and evaluation of a nurse-led hypertension management model: A randomized controlled trial

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ABSTRACT

*Background:* The hypertension prevalence rate is increasing but the control rate is unsatisfactory. Nurse-led healthcare may be an effective way to improve outcomes for hypertensive patients but more evidence is required especially at the community level.

*Objective:* This study aims to establish a nurse-led hypertension management model and to test its effectiveness at the community level.

*Design:* A single-blind, randomized controlled trial was performed in an urban community healthcare center in China. Hypertensive patients with uncontrolled blood pressure (systolic blood pressure ≥140 mmHg and/or diastolic blood pressure ≥90 mmHg) were randomly allocated into two groups: the study group (n = 67) and the control group (n = 67). The nurse-led hypertension management model included four components (delivery system design, decision support, clinical information system and self-management support). Patients in the control group received usual care. Patients in the study group received a 12-week period of hypertension management. The patient outcomes, which involved blood pressure, self-care behaviors, self-efficacy, quality of life and satisfaction, were assessed at three time points: the baseline, immediately after the intervention and 4 weeks after the intervention.

*Results:* After the intervention, the blood pressure of patients in the study group decreased significantly compared to those in the control group, and the mean reduction of systolic/diastolic blood pressure in the study and control groups was 14.37/7.43 mmHg and 5.10/2.69 mmHg, respectively ($p < 0.01$). In addition, patients in the study group had significantly greater improvement in self-care behaviors than those in the control group ($p < 0.01$). The study group had a higher level of satisfaction with hypertensive care than the control group ($p < 0.01$). No statistically significant difference in self-efficacy and quality of life was detected between the two groups after the intervention.

*Conclusions:* The nurse-led hypertension management model is feasible and effective in improving the outcomes of patients with uncontrolled blood pressure at the community level.

**What is already known about the topic?**

- Community-based hypertension management can help promote healthy lifestyles and potentially save medical costs.
- Nurses are key providers of community-based hypertension education.

**What this paper adds**

- This study provides evidence that nurse-led hypertension management is effective in enhancing individuals healthy lifestyle and maintaining normal blood pressure readings at the community level.
- China has a high prevalence rate of hypertension, and this study has developed a nurse-led community-based hypertension management model that contributes to hypertension management in the community.

## 1. Introduction

### 1.1. Background

Hypertension is a major risk factor for cardiovascular and other chronic diseases. In China, the hypertension prevalence rate was 30% in 2010 (Wang et al., 2014). The prevalence rate increased by about 10%

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in China from 2002 to 2010 (Gao et al., 2013; Li et al., 2005; Wang et al., 2014). However, only 8%–10% patients in China successfully control their blood pressure (BP), which is defined as an average SBP < 140 mmHg and an average DBP < 90 mmHg (Liu & Writing Group of 2010; Chinese Guidelines for the Management of Hypertension, 2011), which is much fewer than in high-income countries (37%–65%) (McAlister et al., 2011; Nwankwo et al., 2013). Doctors play a prominent role in hypertension management. Nurses are also important healthcare providers and have been proved as effective as doctors in improving the outcomes of hypertensive patients (Horrocks et al., 2002; Keleher et al., 2009; Laurant et al., 2005). Carter et al. (Carter et al., 2009) performed a meta-analysis of nurse-led healthcare management and found a 4.8 mmHg reduction in systolic blood pressure (SBP) in hypertensive patients, while other researchers (Clark et al., 2010; Glynn et al., 2010) called for further evaluation of this efficacy.

Generally, hypertensive patients in China receive health care in hospitals or clinics. However, the limited medical resources are not sufficient to meet the great demand. Community-based hypertension management, with its characteristic of highly efficient utilization of medical resources, is recommended by WHO (2002). In China, hypertension management at the community level is a recent development, but studies show that it has achieved preliminary success (Chen et al., 2014; Liang et al., 2014). However, none of these studies included a control group. Other studies (Gao et al., 2015; Lu et al., 2012; Ma et al., 2014) have adopted community-based interventions to investigate the effects of hypertension management via randomized controlled trials (RCT). However, some experimental designs are of poor quality. For example, the generation of the randomized sequence was inadequate in most of the studies (Lu et al., 2012). In addition, due to the lack of standard operational protocols, the practice of hypertension management in China varies widely. Thus, further studies are warranted to verify the results. Additionally, for healthcare providers in hypertension management in community health centers, more studies have focused on doctors and fewer on nurses (Gao et al., 2015; Lu et al., 2012). It is not known whether an approach involving nurses at the community level would be applicable and effective for hypertension management.

This study aimed to develop a nurse-led hypertension management model and to test its efficiency on hypertension patients with comparison to the usual care in community health centers. The BP reduction, self-care behaviors, self-efficacy, quality of life (QoL) and satisfaction of patients were systematically analyzed.

### 1.2. Conceptual framework of nurse-led hypertension management model and its features

The nurse-led hypertension management model was developed from the Chronic Care Model (Wagner, 1998; Wagner et al., 2001) and the Four-C Model (Wong et al., 2005). Four components in the Chronic Care Model, including delivery system design, decision support, clinical information system and self-management support were adopted in the nurse-led hypertension management model. The Four-C model (comprehensiveness, collaboration, coordination and continuity) (Wong et al., 2005, 2010), reflecting the strength of nursing intervention in hypertension management, was also employed in the nurse-led hypertension management model. It is of note that the nurse-led hypertension management model emphasized patients' self-management even after intervention.

#### 1.2.1. Delivery system design

The team consisted of four trained nurses, one general practitioner, one researcher, and two coordinators. Nurses were in charge of home visits, telephone follow-ups and referral initiation when necessary. The general practitioner was responsible for providing pharmacological treatment for referred patients. The researcher was in charge of support for the nurses' decision-making and assessment of the quality of care delivered. The coordinators did not directly conduct interventions on patients but were responsible for time and resource allocation to allow the interventions to run smoothly.

#### 1.2.2. Decision support

A 36-h pre-intervention training program was conducted in this study to enhance the nurses' decision-making (Zhu et al., 2014). The training contents included knowledge and skills for nurse-led hypertension management.

#### 1.2.3. Clinical information system

The Chinese version of the Omaha System (Martin, 2005; Wong, 2012) was adopted for patients' information collection. The Omaha System records patients' current health problems and intervention strategies, as well as evaluating their knowledge, their behavior, and the status of their health problem. The Omaha System has been reported to be reliable and feasible (Wong, 2012).

#### 1.2.4. Self-management support

Self-management refers to the self-care behaviors. The trained nurse was asked to i) help patients to understand the importance of self-management; ii) encourage patients to discuss health conditions and set mutual goals; iii) help patients to make plans and perform self-monitoring; iv) provide relevant information and resources for self-management; and v) provide booklets (Zhu et al., 2014) with intelligible text and pictures to enable patients to enhance their knowledge of self-management.

## 2. Methods

### 2.1. Design

The study was a two-group parallel block RCT with a single-blind design. The calculation of the study sample size was based on a change in SBP. We assumed that $\alpha = 0.05$ and power = 0.8. The effect size was 0.59, obtained from Chiu and Wong's study (Chiu and Wong, 2010), which involved intervention strategies similar to those in the current study. The calculated sample size was 92. A total of 115 participants would allow for a 20% dropout rate. The study was conducted during August 2012 and September 2013 in a community health center in Guangzhou, China. Totally, 134 eligible residents were recruited. A total of 15 (11.2%) participants dropped out of the study (Fig. 1). By using intention-to-treat analysis, those who dropped out were also included in the data analysis. Their characteristics are shown in Table 1. Participants were randomly allocated into the study group (nurse-led hypertension management model) or the control (usual care) group at a ratio of 1:1 (Fig. 1). As shown in Table 1, the two groups had equivalent socio-demographic and clinical features. Ethical approval was obtained from The Hong Kong Polytechnic University (Project ID: HSEARS20120809001). Prior to the recruitment, written informed consent was obtained from each participant.

### 2.2. Inclusion and exclusion criteria

Inclusion criteria: participants with a diagnosis of hypertension; with uncontrolled BP (SBP ≥ 140 mmHg and/or DBP ≥ 90 mmHg at the last two clinic visits and at recruitment); ≥18 years old; within the service network of the community health center. Exclusion criteria: participants who had a diagnosis of secondary hypertension; took medicine that could increase BP; could not communicate or be contacted by phone; had a diagnosis of terminal illness; had co-morbidity in contradiction with the programmed intervention; were pregnant, breastfeeding or planning pregnancy.

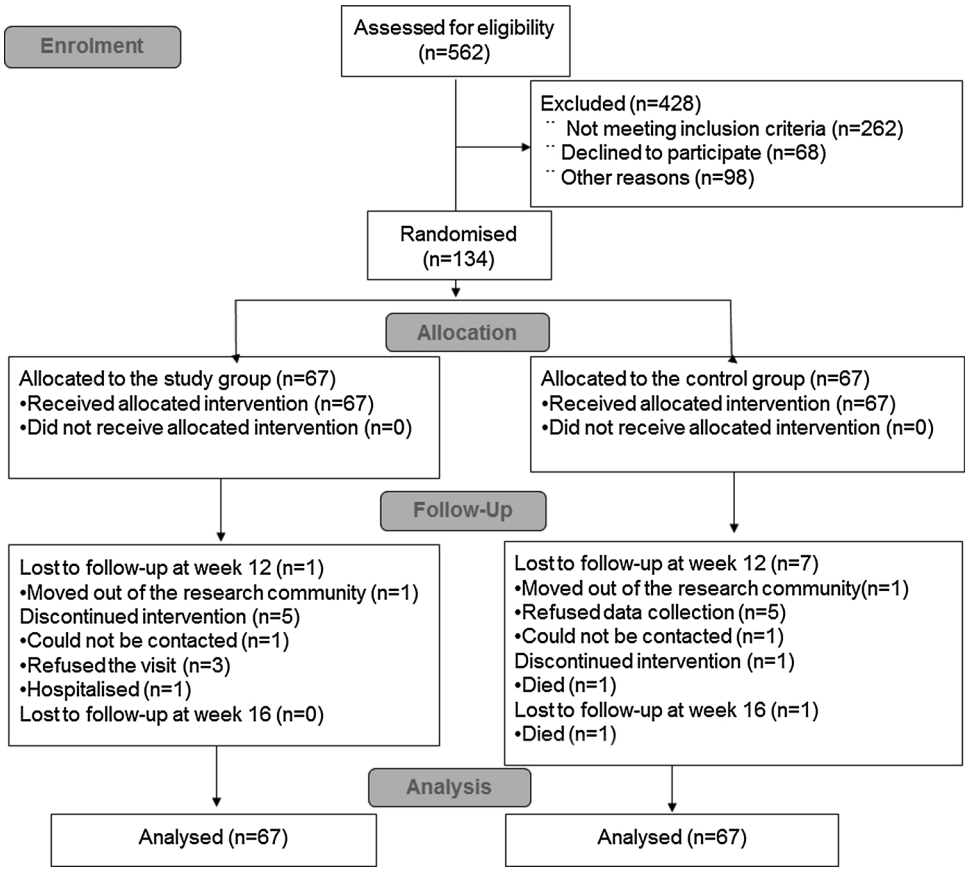


**Fig. 1.** Flow diagram of the nurse-led hypertension management model.

### 2.3. Intervention

The intervention in the study was protocol-dependent. The protocol involved home visits, telephone follow-ups and referrals. The national guidelines for hypertension management (Liu & Writing Group of 2010; Chinese Guidelines for the Management of Hypertension, 2011), previous studies (Chiu and Wong, 2010; Pezzin et al., 2010; Zhu et al., 2014), and expert consultation were referenced in the protocol development.

#### 2.3.1. Home visit

The trained nurse, guided by the Omaha System (Martin, 2005), conducted a 60-min home visit to patients within three days after recruitment. The patient's knowledge and behavior were assessed, as well as the status of their identified health problems. According to the results, the trained nurses performed relevant interventions that included teaching/guidance/counseling, treatment and procedures, and case management (Martin, 2005). Self-management, such as salt intake control, regular engagement in physical activities, home BP monitoring management, and medicine storage, were also included. To emphasize the importance of self-management, a mutually agreed goal and self-care behavioral contract were made after sufficient negotiation. During the home visit, the trained nurse would arrange for the general practitioner (a member of the research team) to the visit community health center if the patient met the referral criteria.

#### 2.3.2. Telephone follow-up

After the home visit, follow-up via telephone calls was conducted biweekly by a trained nurse. During the follow-up, the trained nurse monitored the previous health problems and current condition of patients, as well as modifications in their knowledge, behavior, and status. The previously signed self-care behavioral contract was also reviewed, and further modification was discussed. It was recommended that the patient participate in a face-to-face follow-up in a community health center, and if the patient met the referral criteria, a referral would be initiated. Each follow-up call, 10 min on average, was conducted strictly according to the procedure, and was recorded and saved.

#### 2.3.3. Referral

When the patient reported an increased BP, a trained nurse would assess their adherence, and/or any current illnesses or living circumstances that may affect their BP. If home BP monitoring was consistent with the guidance, it was suggested that the patient have a face-to-face interview with a trained nurse in a community health center. If the patient had symptoms that required medication adjustment or a further health check (SBP ≥ 180 mmHg or DBP ≥ 110 mmHg), referral to the general practitioner was needed, and relevant information including BP, a self-report and, if necessary, a medication list, pharmacy refill information, and medication adjustments were also transferred to the general practitioner.

### 2.4. Control

Each participant received a free annual health check, health education leaflets, and a follow-up with pharmacological treatment. The follow-ups were arranged by general practitioners if necessary. The trained nurses conducted home visits or telephone follow-ups for patients when needed after the study period.

### 2.5. Outcome measures

Outcome measures included BP, self-care behaviors, self-efficacy, QoL and satisfaction. Three time points were set to collect patients' data: T0 indicated after recruitment, T1 indicated immediately after the intervention (12 weeks post-recruitment) and T2 indicated four weeks after the intervention (16 weeks post-recruitment). Satisfaction

**Table 1**
Socio-demographic and clinical characteristics of participants in two groups were shown.

| Characteristic | Total (n = 134) | Control group (n = 67) | Study group (n = 67) | t- test/χ2 test | *p*-value |
|---|---|---|---|---|---|
| Socio-demographic characteristics | | | | | |
| Age (years), mean (SD) | 69 (9.8) | 69 (10.2) | 69 (9.5) | −0.15 | 0.881[a] |
| Sex, n (%) | | | | | |
| Male | 66 (49.3) | 32 (47.8) | 34 (50.7) | 0.12 | 0.730[b] |
| Female | 68 (50.7) | 35 (52.2) | 33 (49.3) | | |
| Educational level, n (%) | | | | | |
| No formal education | 7 (5.2) | 5 (7.5) | 2 (3.0) | | 0.716[c] |
| Primary education | 29 (21.6) | 15 (22.4) | 14 (20.9) | | |
| Secondary education | 55 (41.0) | 27 (40.3) | 28 (41.8) | | |
| Tertiary education | 43 (32.1) | 20 (29.9) | 23 (34.3) | | |
| Living status, n (%) | | | | | |
| Living alone | 12 (9.0) | 6 (9.0) | 6 (9.0) | 0.00 | 1.000[b] |
| Living with others | 122 (91.0) | 61 (91.0) | 61 (91.0) | | |
| Marital status, n (%) | | | | | |
| Married | 110 (82.1) | 56 (83.6) | 54 (80.6) | 0.20 | 0.652[b] |
| Single/Divorced/Widowed | 24 (17.9) | 11 (16.4) | 13 (19.4) | | |
| Employment, n (%) | | | | | |
| Employed | 17 (12.7) | 9 (13.4) | 8 (11.9) | 0.07 | 0.795[b] |
| Unemployed/Retirement | 117 (87.3) | 58 (86.6) | 59 (88.1) | | |
| Income, n (%) | | | | | |
| More than expenses | 37 (27.6) | 19 (28.4) | 18 (26.9) | | 0.526[c] |
| Equal to expense | 90 (67.2) | 43 (64.2) | 47 (70.1) | | |
| Less than expenses | 7 (5.2) | 5 (7.5) | 2 (3.0) | | |
| Clinical characteristics | | | | | |
| Number of years with hypertension (years), mean (SD) | 11 (8.9) | 11 (8.2) | 12 (9.5) | −1.11 | 0.270[a] |
| Comorbidity, n (%)[d] | | | | | |
| Yes | 102 (76.1) | 49 (73.1) | 53 (79.1) | 0.66 | 0.418[b] |
| Diabetes (yes) | 32 (23.9) | 13 (19.4) | 19 (28.4) | 1.48 | 0.224[b] |
| Post-stroke (yes) | 12 (9.0) | 6 (9.0) | 6 (9.0) | 0.00 | 1.000[b] |
| Heart disease (yes) | 34 (25.4) | 15 (22.4) | 19 (28.4) | 0.63 | 0.427[b] |
| Use of anti-hypertensive drug, n (%) | | | | | |
| Number of anti-hypertensive drugs | | | | | |
| 0 | 12 (9.0) | 10 (14.9) | 2 (3.0) | | |
| 1 | 75 (56.0) | 35 (52.2) | 40 (59.7) | | |
| 2 | 38 (28.4) | 18 (26.9) | 20 (29.9) | | |
| ≥3 | 9 (6.7) | 4 (6.0) | 5 (7.5) | | |
| Class of anti-hypertensive drug[d] | | | | | |
| Use of Calcium channel blocker (yes) | 83 (68.0) | 37 (64.9) | 46 (70.8) | 0.48 | 0.489[b] |
| Use of Angiotensin Receptor Blocker (yes) | 42 (35.3) | 23 (40.4) | 19 (29.2) | 1.64 | 0.197[b] |
| Use of Angiotensin Converting Enzyme Inhibitor (yes) | 7 (5.7) | 3 (5.3) | 4 (6.2) | 0.05 | 0.833[b] |
| Use of Beta-adrenergic-blocker (yes) | 28 (23.5) | 10 (17.5) | 18 (27.7) | 1.77 | 0.184[b] |
| Use of thiazide-type diuretic (yes) | 2 (1.6) | 0 (0.0) | 2 (3.1) | | 0.496[c] |
| Use of compound anti-hypertensive drugs (yes) | 14 (11.8) | 7 (12.3) | 7 (10.8) | 0.07 | 0.794[b] |
| Body mass index ($kg*m^2$), mean (SD) | 24 (3.3) | 25 (3.4) | 24 (3.2) | 0.30 | 0.768[a] |
| Waist circumference (cm), mean (SD) | 87 (9.5) | 87 (10.0) | 86 (9.0) | 0.51 | 0.610[a] |

[a] Unpaired *t*-test.
[b] Person Chi-Square.
[c] Fisher's Exact Test.
[d] Participants can choose more than one option in these parameters.

measurement was performed at T0 and T1, and the others were conducted at T0, T1 and T2.

BP was measured twice using the same calibrated sphygmomanometer and stethoscope, and the measurement strictly followed the guidelines (Liu & Writing Group of 2010; Chinese Guidelines for the Management of Hypertension, 2011). The mean value was recorded.

The self-care behavior meant the patients' adherence to anti-hypertensive drugs (scores ranged from 0 to 3) and suggested non-pharmacological behaviors (scores ranged from 0 to 8). The adherence form was adopted in previous studies conducted in China (Wong et al., 2005; Zhu et al., 2014). A higher score meant better adherence. The assessment of adherence to anti-hypertensive drugs depended on time, frequency, and dose. Suggested non-pharmacological behaviors, including smoking cessation, alcohol restriction, salt restriction, regular physical activity, and home BP monitoring were evaluated for the last 4 weeks.

Self-efficacy was measured using the Chinese version of the Short-Form Chronic Disease Self-Efficacy Scale (Chow and Wong, 2014), which included a rating of the patient's confidence in general disease and symptom management. The scale for each item ranged from 1 (not at all confident) to 10 (totally confident).

The Chinese version of the Short-Form Health Survey (Fang, 2000) was used to assess the QoL of the patient. It contained 36 items and eight domains: Physical Functioning, Role-Physical, Bodily Pain, General Health, Vitality, Social Functioning, Role-Emotional and Mental Health. The score for each domain ranged from 0 (worst possible health status) to 100 (best possible health status).

The satisfaction assessment (Zhu et al., 2014) contained 8 items, and the following aspects were evaluated: hypertension-related knowledge, self-care skill, counseling, and provision (Wong et al., 2005; Zhu et al., 2014). Each item contained six levels, from 0 (not applicable)

to 5 (very satisfactory).

### 2.6. Statistical analysis

Data was analyzed using the SPSS Statistics Version 20.0 (IBM Corp. Armonk, NY). The Chi-square test was used for categorical variables, while the unpaired *t*-test was used for continuous variables. The unpaired *t*-test was also used to analyze the outcomes of the two groups. Repeated measures ANOVA was carried out to evaluate the outcome over time, and one-way repeated measures ANOVA was performed if the difference was significant. For further analysis of the within-group differences at different time points, a Bonferroni post hoc test was performed (Portney and Watkins, 2009). The Mann-Whitney test was used to determine the difference between the two groups at each time point in self-care behavior and satisfaction. The Friedman test was used to examine self-care behavior modification over time in each group. When a significant difference was detected, the Wilcoxon signed-ranks and post hoc tests were further performed. $P < 0.05$ was considered as statistically significant.

## 3. Results

### 3.1. BP

Our results showed that SBP decreased significantly in patients of the study group (−14.37 mmHg) compared with those of the control group (−5.10 mmHg) between T0 and T1 ($P = 0.003$). Similarly, a more significant decline of DBP was found in patients in the study group (−7.43 mmHg) than in the control group (−2.69 mmHg) ($P = 0.002$). Overall, the SBP reduction was about 14.72 mmHg in the study group, which was much greater than that in the control group (9.22 mmHg) from T0 to T2. Similarly, the DBP decreased more in the study group (−7.43 mmHg) than in the control group (−5.14 mmHg). However, the differences between the two groups in SBP and DBP reduction were not statistically significant from T0 to T2 (Table 2).

A significant interaction (time × group) effect was observed in the mean value of SBP and DBP over time between the two groups ($P = 0.015$ and $P = 0.009$). The SBP and DBP decreased significantly with time, both in the control group and the study group ($P < 0.05$), but no statistically significant difference in SBP or DBP was found in the between-group effect (Table 3).

Therefore, both the nurse-led hypertension management model and usual care had positive effects on BP reduction, and this effect was significant at T1 in the study group than that in the control group. In addition, a sustained effect in BP reduction was shown in the study group.

**Table 2**
The mean reduction of blood pressure in two groups over time was shown.

| Outcome measures | T0 vs. T1 | T0 vs. T2 |
|---|---|---|
| Reduction of systolic blood pressure (mmHg), mean (SD) | | |
| Control group (n = 67) | −5.10 (15.17) | −9.22 (19.89) |
| Study group (n = 67) | −14.37 (20.06) | −14.72 (20.02) |
| t, *p*-value | 3.02, 0.003 | 1.60, 0.113 |
| Reduction of diastolic blood pressure (mmHg), mean (SD) | | |
| Control group (n = 67) | −2.69 (7.79) | −5.14 (9.65) |
| Study group (n = 67) | −7.43 (9.08) | −7.43 (9.07) |
| t, p-value | 3.20, 0.002 | 1.42, 0.159 |
| Reduction of systolic blood pressure achieved 5 mmHg or above, n (%) | | |
| Control group (n = 67) | 32 (47.8) | 38 (56.7) |
| Study group (n = 67) | 44 (65.7) | 44 (65.7) |
| $\chi^2$, *p*-value | 4.38, 0.036 | 1.31, 0.287 |
| Reduction of diastolic blood pressure achieved 2 mmHg or above, n (%) | | |
| Control group (n = 67) | 30 (44.8) | 38 (56.7) |
| Study group (n = 67) | 43 (64.2) | 43 (64.2) |
| $\chi^2$, p-value | 5.09, 0.024 | 0.78, 0.377 |

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

### 3.2. Self-care behaviors

As shown in Table 4, no significant difference was found in the score for adherence to anti-hypertensive drugs between the two groups at T0, T1, and T2. A significant increase in score for adherence to anti-hypertensive drugs was observed in the study group with time (T0 vs. T1, $P = 0.001$; T0 vs. T2, $P = 0.000$), but not in the control group. The score for adherence to non-pharmacological suggestions over time also increased in the study group (T0 vs. T1, $P = 0.001$; T0 vs. T2, $P = 0.000$) and the control group (T0 vs. T1, $P = 0.008$; T0 vs. T2, $P = 0.000$). However, the median score for adherence to non-pharmacological suggestions was significantly higher in the study group than in the control group at T1 ($P = 0.000$) and T2 ($P = 0.023$).

### 3.3. Self-efficacy

At T0, there were significant differences in self-efficacy between the study and control groups, which were measured at 5.94 and 6.71 respectively ($P = 0.015$). Thus, they were used as covariates in the statistical testing. Two-way repeated measures ANOVA was performed. There was no significant difference between the two groups in interaction effect (time × group), between-group effect or time effect.

### 3.4. Quality of life (QoL)

No interaction effect (time × group) or between-group effect was observed in QoL by two-way repeated measures ANOVA analysis. However, a significant within-group effect was seen in the study group in six aspects of QoL: Role Physical (T0 62.31, T1 74.25, T2 83.58, $P = 0.000$), Bodily Pain (T0 66.90, T1 73.52, T2 75.64, $P = 0.008$), General Health (T0 48.42, T1 51.16, T2 54.13, $P = 0.014$), Social Functioning (T0 80.78, T1 85.63, T2 89.37, $P = 0.001$), Role Emotional (T0 72.14, T1 78.11, T2 86.07, $P = 0.016$), and Mental Health (T0 75.94, T1 79.88, T2 81.43, $P = 0.009$) also showed time effects by one-way repeated measures ANOVA analysis. In addition, a significant improvement in these six aspects was observed in the study group from T0 to T2. In regard to the control group, a significant time-dependent improvement was shown in Role Physical (T0 70.90, T1 72.76, T2 82.46, $P = 0.006$), Role Emotional (T0 77.11, T1 85.57, T2 87.56, $P = 0.014$), and Mental Health (T0 78.69, T1 80.42, T2 82.03, $P = 0.035$) from T0 to T2, although only Role Physical and Role Emotional showed significant increases.

### 3.5. Patient satisfaction

After the intervention, satisfaction was collected for patients in both groups. Data revealed that the median value of patient satisfaction increased from 3 to 28 ($P = 0.000$) in the study group, while it was from 0 to 7 ($P = 0.000$) in the control group. A remarkably higher satisfaction value was seen in the study group than in the control group at T1 ($P = 0.000$) (Table 5).

## 4. Discussions

A nurse-led hypertension management model has been established in the present study, and this model can enhance the effects of traditional hypertension management at the community level. This model incorporated the roles of both nurses and general practitioners in non-pharmacological and pharmacological treatment. Importantly, the patient's role was emphasized. In addition, this model included the local healthcare organization, as well as the intact system of delivery, decision support, and clinical information system.

WHO (2013) advocates implementing non-communicable disease

**Table 3**
Comparison analysis of mean blood pressure between two groups at three time points.

| Outcome measure | (Time) | | | Time Within group | | Between group (Group) | | Time × Group | | $T_0$:$T_1$ | $T_1$: $T_2$ | $T_0$:$T_2$ |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | T0 | T1 | T2 | F | *p*-value | F | *p*-value | F | *p*-value | *p*-value | *p*-value | *p*-value |
| Systolic blood pressure (mmHg), mean (SD) | | | | 32.58 | 0.000[a] | 0.07 | 0.790[a] | 4.34 | 0.015[a] | | | |
| Control group (n = 67) | 149.65 (14.59) | 144.55 (19.10) | 140.43 (22.69) | 9.29 | 0.000[b] | | | | | 0.023[c] | 0.164[c] | 0.001[c] |
| Study group (n = 67) | 153.90 (16.74) | 139.53 (16.05) | 139.18 (17.66) | 26.36 | 0.000[b] | | | | | 0.000[c] | 1.000[c] | 0.000[c] |
| *t*, *p*-value | −1.57, 0.119[d] | 1.65, 0.102[d] | 0.36, 0.723[d] | | | | | | | | | |
| Diastolic blood pressure (mmHg), mean (SD) | | | | 39.21 | 0.000[a] | 2.92 | 0.090[a] | 4.87 | 0.009[a] | | | |
| Control group (n = 67) | 83.53 (11.45) | 80.84 (10.94) | 78.40 (13.28) | 13.00 | 0.000[b] | | | | | 0.019[c] | 0.019[c] | 0.000[c] |
| Study group (n = 67) | 82.63 (11.47) | 75.28 (13.02) | 75.20 (11.68) | 29.50 | 0.000[b] | | | | | 0.000[c] | 1.000[c] | 0.000[c] |
| *t*, *p*-value | 0.45, 0.652[d] | 2.68, 0.008[d] | 1.48, 0.143[d] | | | | | | | | | |

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

**Table 4**
Comparison analyses of median score of self-care behavior between two groups at three time points.

| Outcome measures | T0 | T1 | T2 | χ2 | *p*-value | T0:T1, T1:T2, T0:T2 *p*-value |
|---|---|---|---|---|---|---|
| Anti-hypertensive drug, median [IQR] | | | | | | |
| Control group (n = 57) | 3 [2–3] | 3 [2–3] | 3 [2–3] | 0.64 | 0.728[a] | |
| Study group (n = 65) | 3 [1–3] | 3 [2–3] | 3 [3–3] | 31.94 | 0.000[a] | 0.001, 0.017, 0.000 |
| Z, p-value | −1.92, 0.055[b] | −0.94, 0.347[b] | 1.72, 0.086[b] | | | |
| Non-pharmacological behavior, median [IQR] | | | | | | |
| Control group (n = 67) | 5 [5–6] | 6 [5–7] | 6 [5–7] | 16.76 | 0.000[a] | 0.008, 0.012, 0.000 |
| Study group (n = 67) | 5 [4–6] | 7 [6–8] | 7 [6–8] | 64.19 | 0.000[a] | 0.000, 0.036, 0.000 |
| Z, *p*-value | −0.90, 0.370[b] | −4.86, 0.000[b] | −2.28, 0.023[b] | | | |
| Home blood pressure monitoring, median [IQR] | | | | | | |
| Control group (n = 67) | 1 [1–2] | 1 [1 − 1] | 1 [1 − 1] | 3.00 | 0.223[a] | |
| Study group (n = 67) | 1 [1 − 1] | 2 [2 − 2] | 2 [1–2] | 43.10 | 0.000[a] | 0.000, 0.010, 0.001 |
| Z, p-value | −0.46, 0.649[b] | −6.54, 0.000[b] | −3.83, 0.000[b] | | | |
| Smoking cessation, median [IQR] | | | | | | |
| Control group (n = 67) | 1 [1 − 1] | 1 [1 − 1] | 1 [1 − 1] | | 1.000[a] | |
| Study group (n = 67) | 1 [1 − 1] | 1 [1 − 1] | 1 [1 − 1] | 0.67 | 0.717[a] | |
| Z, p-value | −1.21, 0.228[b] | −1.45, 0.146[b] | −1.21, 0.228[b] | | | |
| Alcohol restriction, median [IQR] | | | | | | |
| Control group (n = 67) | 1 [1 − 1] | 1 [1 − 1] | 1 [1 − 1] | 0.40 | 0.819[a] | |
| Study group (n = 67) | 1 [1 − 1] | 1 [1 − 1] | 1 [1 − 1] | 4.33 | 0.115[a] | |
| Z, p-value | −1.57, 0.117[b] | −1.53, 0.125[b] | −0.71, 0.481[b] | | | |
| Salt restriction, median [IQR] | | | | | | |
| Control group (n = 67) | 1 [1 − 1] | 1 [1–2] | 2 [1–2] | 15.73 | 0.000[a] | 0.024, 0.294, 0.001 |
| Study group (n = 67) | 1 [1–1] | 2 [1–2] | 2 [1–2] | 55.49 | 0.000[a] | 0.000, 0.268, 0.000 |
| Z, p-value | −0.83, 0.407[b] | −2.60, 0.009[b] | −0.62, 0.536[b] | | | |
| Physical activity, median [IQR] | | | | | | |
| Control group (n = 67) | 2 [1–2] | 2 [1–2] | 2 [2 − 2] | 12.68 | 0.002[a] | 0.045, 0.295, 0.031 |
| Study group (n = 67) | 2 [1–2] | 2 [1–2] | 2 [2 − 2] | 30.43 | 0.000[a] | 0.000, 0.470, 0.000 |
| Z, p-value | −0.66, 0.507[b] | −2.09, 0.037[b] | −0.44, 0.662[b] | | | |

[a] Friedman Test.
[b] Mann-Whitney *U* test, T0 = baseline, T1 = 12 weeks after recruitment, T2 = 16 weeks after recruitment.

**Table 5**
The median of patient satisfaction pre- and post-intervention in two groups.

| | T0 | T1 | *Z* | *p*-value |
|---|---|---|---|---|
| Patient satisfaction, median [IQR] | | | | |
| Control group (n = 67) | 0 [0–8] | 7 [0–20] | −3.56 | 0.039[a] |
| Study group (n = 67) | 3 [0–15] | 28 [16–33] | −6.49 | 0.000[a] |
| Z, *p*-value | −1.35, 0.176[b] | −5.47, 0.000[b] | | |

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

intervention via a primary healthcare approach. Experience from Japan ("Community-based efforts", 2013) and Canada (Kaczorowski et al., 2008) has demonstrated that the community-based intervention is an affordable and sustainable way to manage hypertension. The present study is a preliminary one on community-based hypertension management by strictly adopting an RCT design in China. The results showed improvement in the self-management of hypertension patients, especially in BP reduction, self-care behavior and patient satisfaction. The majority of participants in this study were elderly (mean age 69). The effects of the nurse-led hypertension management model demonstrate that it may be a promising method of BP control in an aging society.

Ma et al. (2014) found that patients in a nurse-led motivational

interview group had significantly reduced SBP/DBP levels compared with those in a usual care group after a six-month intervention. Chiu and Wong (2010) reported a similar intervention, in which experienced nurses provided face-to-face consultations with patients in a nurse-led hypertension clinic in Hong Kong, along with follow-up via telephone calls. Patients in the control group only received clinic consultations. After the intervention, the SBP and DBP was significantly reduced in the study group compared with those in the control group. We consistently demonstrated that nurse-led hypertension management was more effective than usual care in SBP/DBP reduction. A mean reduction of SBP was 14.4 mmHg from T0 to T1 in the study group. Patients in the study group also had a mean DBP reduction of 7.4 mmHg, while that in the control group was about 2.7 mmHg. Importantly, the positive effects of nurse-led hypertension management lasted for four weeks. Generally, a reduction of SBP by 5 mmHg or of DBP by 2 mmHg is considered as clinically significant (Verdecchia et al., 2010). Our data show that the number of participants whose SBP reduction was more than 5 mmHg at T1 was much higher in the study group than in the control group. As for DBP, about 64.2% participants in the study group achieved clinical reduction at T1, significantly higher than that in the control group. Thus, our results revealed that nurse-led hypertension management showed a clinically significant effect on reduction of SBP and DBP, and this positive effect sustained even after the intervention was completed.

The self-care behaviors of patients are important in hypertension management. Our results found that nurse-led hypertension management enhanced the self-care behaviors of patients more than usual care. More importantly, a sustained effect on self-care behavior was also seen four weeks after the intervention. Self-efficacy did not show a statistically significant difference between nurse-led hypertension management and usual care. This may be related to participants' lower education level in this study. A total of 68% of participants in this study had less than tertiary education. These less educated participants tended to report lower self-efficacy (Leganger and Karaft, 2003). The non-significant results in self-efficacy may also be related to the fact that the participants had a long history of hypertension (mean 11 years) and had not successfully controlled their BP before joining this study.

Young et al. (2010) demonstrated that a six-month lifestyle intervention program had a positive effect on QoL improvement, especially in General Health, Role-Emotional, Vitality, and Mental Health. Ma's study (Ma et al., 2014) reported that a six-month motivational interviewing intervention program significantly improved patients' QoL in Physical Functioning, General Health, Vitality and Mental Health. Unlike these studies, our study was insufficient to support the difference in QoL between the two groups, although there was an improvement tendency of Role-Physical, Bodily Pain, General Health, Social Functioning, Role-Emotional and Mental Health in terms of patients receiving nurse-led hypertension management. The main reason may be that the period of 12 weeks in this study may be too short for it to be possible to detect the difference. Another reason may be the comorbidity that may affect QoL (Poljičanin et al., 2010). In this study, 76.1% of participants had one or more comorbidity, which may have limited improvements in the QoL of hypertensive patients (Wang et al., 2017).

Satisfaction is the patient's perception of healthcare. Our data revealed higher satisfaction in patients with nurse-led hypertension management than in those receiving usual care. It had been reported that patients with chronic diseases had a higher level of satisfaction with nurse-led care than with doctor-led care in the primary care setting (Keleher et al., 2009; Laurant et al., 2005); our study was consistent with these findings. We also agree with the findings of the study by Chiu and Wong (2010), which demonstrated that nurse-led hypertension follow-ups resulted in a higher level of satisfaction. These positive results may be closely related to i) the longer period of medical consultations than usual (Bebb et al., 2007; Caldow et al., 2007); and ii) the patient-centered intervention, which improved the patients' sense of achievement resulting from the BP reduction. Here, we introduced nurse-led hypertension management, in which trained nurses comprehensively assessed the health condition of patients and conducted home visits to facilitate care. They also conducted follow-ups via phone calls, to maintain consistency in healthcare. Also, they coordinated with general practitioners as well as health resources, which not only reduced the overlapped treatments but also saved time. This advanced and active hypertension management achieved a significantly higher satisfaction level in patients in the community health center.

The present study had some limitations. Firstly, nurse-led hypertension management was only tested in a single community health center, leading to a lack of generalizability. Secondly, the center is a typical urban community health center in China. Therefore, it is not known whether nurse-led hypertension management is also suitable for rural healthcare settings. Thirdly, the research center is located in southern China, where the prevalence, treatment and control rates of hypertension are distinct from those in northern China (Ma et al., 2012; Meng et al., 2012). Fourthly, this study was single-blinded. Thus, the participants and healthcare providers may not have been completely blinded to the intervention strategies. Further studies are warranted to avoid these limitations.

The current study has implications for service, nursing and research. First, the model established in the study supports patients as informed, prepared and motivated partners in self-care behavior. Given the increasing prevalence of hypertension and limited healthcare resources, optimal BP control can best be achieved by promoting patients' ability to manage their own conditions. The model established in the study provides an efficient approach for managing a large volume of hypertensive patients in a community-level setting in which there is a shortage of doctors. The nurses can focus on the health promotion and maintenance aspects, while the doctors can support treatment that requires drugs and treatment of co-morbidities. The results of this study provided evidence of the importance and value of nurses in the health-promoting aspects. In the nurse-led hypertension management model, the training program provided a structured curriculum enabling nurses to enhance their decision-making abilities. Already, the main contents of the training curriculum have been used to train community nurses and general practitioners in the cities of Shenzhen, Guangzhou, and Hangzhou in mainland China. In addition, the nurse's traditional dependent role in hypertension management was expanded, and more independent roles, such as assessment and counseling, were essential to make the program a success. This model of nursing can be implemented for patients with other chronic conditions or diseases. In the research center, for instance, these trained community nurses have launched advanced healthcare services for the elderly.

## 5. Conclusions

Our study is the first report about the modified nurse-led intervention model, which incorporated several components of the healthcare system and had a significant improvement effect on the self-management of hypertension patients, especially shown in BP reduction, self-care behavior improvement and patient satisfaction.

## Conflicts of interest

None.

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## Ethical approval

Ethical approval was obtained from The Hong Kong Polytechnic University (Project ID: HSEARS20120809001).

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