





ORIGINAL PAPER

A cluster-randomized study on the Risk Assessment and Management Program for home blood pressure monitoring in an older population with inadequate health literacy

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Abstract

The Risk Assessment and Management Program (RAMP) has successfully demonstrated a reduction of blood pressure (BP) and cardiovascular (CVD) risk of patients with hypertension. This study aimed to compare the blood pressure control rate of participants after attended RAMP group, with those attended RAMP individual from usual care. A prospective open cluster-randomized controlled trial was performed in five public primary care clinics. Patients with uncontrolled hypertension were recruited. RAMP group consisted of multi-disciplinary group education on knowledge of hypertension, lifestyle modification, and hands-on home blood pressure monitoring (HBPM) training. Each participant was given a branchial HBPM device. An individual face-to-face nurse follow-up was arranged 6 weeks later. Participants' office BP and clinical parameters were assessed at 6, 12, and 18 months. Three RAMP group and two RAMP-individual clusters recruited 152 and 139 participants, respectively. The mean age was 67.0 (SD 9.9) year. After 18 months of treatment, there was a significantly higher BP control rate in the RAMP-group participants than the RAMP-individual participants (78.9% vs 36.5%, $P < .001$). The systolic BP was reduced by 19.7 mm Hg (95% CI -22.03, -17.40, $P < .001$) and diastolic BP by 8.1 mm Hg (95% CI -9.66, -6.61, $P < .001$) in RAMP group while the RAMP individual demonstrated 9.3 mm Hg (95% CI -12.1, -6.4, $P < .001$) reduction in systolic BP without any significant difference in diastolic BP. The RAMP-group participants' body weight (BW) and body mass index(BMI) had no significant changes, while the RAMP-individual participants had a significant increase in BW and BMI. No adverse effect was reported.

Trial registration: ClinicalTrials.gov ID: NCT02551393

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1 | INTRODUCTION

Control of blood pressure (BP) below treatment target was shown to be effective in reducing the incidents of stroke and ischemic heart disease¹; nevertheless, many patients with hypertension had uncontrolled BP in different parts of the world, such as USA, Europe, Asia, Australia, and China.²⁻⁶ The factors for poor BP control include patients' social condition, poverty, or their reluctance to behavioral changes according to health care workers' recommendations.⁷ A variety of interventions were designed to empower patients' ability to identify risks, modify lifestyle, comply with drug therapy, and self-monitor of BP.⁸ Several meta-analyses have demonstrated that home blood pressure monitoring (HBPM) combined with home BP reading transmission, intensified patient education and drug titration as promising non-pharmacological interventions to reduce patients' BP.⁹⁻¹¹ International authority such as the European Society of Hypertension, the American College of Cardiology and the Australian Expert Consensus Statement have recommended the use of HBPM, particularly in patients with proven or suspected discrepancies in office and home BP.¹²⁻¹⁴

Implementation of HBPM into daily practice is not simple and straightforward. Existing studies illustrated some of the potential pitfalls during HBPM measurements, such as poor technique, poor compliance to measurement schedule, and inaccurate HBPM records.^{15,16} Various interventions had included HBPM education program as part of the management for uncontrolled hypertension.¹⁷ In Hong Kong, the public primary care service providers, the general outpatient clinics (GOPCs) have launched a structured, protocol-driven multi-disciplinary (doctors, nurses, allied health professionals) management program: Risk Assessment and Management Programme—Hypertension: RAMP-HT since October 2011. According to Yu et al.'s¹⁸ cohort study, patients had a statistically significant increase in BP control rate after RAMP-HT. As clinicians working in GOPCs, the authors noticed patients' difficulties in performing HBPM after RAMP-HT, particularly in applying brachial cuffs, following measurement schedule and recording their BP accurately. In response to the limited randomized controlled trial about the implementation of HBPM programs for the elderly from lower socioeconomic classes, we introduced RAMP group as a new element to RAMP-HT.¹⁹ We aimed to assess the difference in patient outcomes between the RAMP group and the conventional RAMP-HT (RAMP individual). Our hypotheses were after patients with uncontrolled hypertension attended RAMP group instead of RAMP individual:

1. There is an increase in BP control rate.
2. There is a reduction in both systolic BP (SBP) and diastolic BP (DBP) readings.
3. There is an improvement in other physical parameters, such as a reduction in body weight and BMI, and biochemical markers.

2 | METHODS

This study was approved by the Hong Kong Hospital Authority, Kowloon West Cluster Clinical Research Ethics Committee,

reference number: KW/EX-15-115(88-14). Written informed consents were obtained before the patients participated in the study.

2.1 | Setting

The five study clinics are government-funded community outpatient clinics in Kwai Chung and Tsing Yi District of the Hong Kong Special Administrative Region, China. They mainly served older age Hong Kong citizens from a lower socioeconomic class. There was a total of more than 30 000 patients with hypertension registered at these clinics. They attended once every 2-3 months for follow-up of hypertension and other comorbidities. Approximately 30% of them had uncontrolled hypertension according to the local statistics. Therefore, we estimated the target population of uncontrolled hypertensive patients to be around 9000.

2.2 | Study design

This study was a cluster-randomized controlled trial (cRCT) at practice level recruiting primary care patients with uncontrolled hypertension. The study design complied with the guidelines in the Consort 2010 statement: extension to cluster-randomized trials.²⁰ cRCT was applied because interventions (education groups and nurse follow-up) were delivered in each cluster (clinic) to their registered patients. Each patient with hypertension follow-up in one clinic inside their community.²¹ Participants were recruited from five outpatient clinics from April to July 2016. The five clinics were randomly assigned to intervention or control arm (3:2) by an independent statistician using random numbers table generated in SPSS version 25. All participants of this study were invited to attend the RAMP according to the department protocol. The interventions were groups of 10-20 participants in educational seminars. The health care workers (doctors and nurses) in RAMP individual were blinded to the intervention group content during the study period.

Inclusion criteria for clusters were more than three family physicians per clinic and the number of patients prescribed with anti-hypertensive drugs ≥ 6000 in the past 12 months, according to the computerized patient record. Patients were eligible if they had physician-diagnosed hypertension for more than 6 months. Their clinic SBP was more than 140 mm Hg (for those aged <80) and more than 150 mm Hg (for those aged ≥ 80) or DBP more than 90 mm Hg in their most recent two clinic visits. Higher cutoff for uncontrolled hypertension was adopted for older adults (age ≥ 80) according to the recommendation of treatment initiation in the Eighth Joint National Committee (JNC8) guideline and the National Institute for Health and Clinical Excellence (NICE) 2014 guideline.^{22,23} Patients who were mentally or physically unfit for HBPM, with a diagnosis of pregnancy, atrial fibrillation, or secondary hypertension were excluded from this study.

Clinic nurses identified potential participants from the computerized patient records after their registration for health care services.

After a minimum of 5-minute rest in a sitting position, they routinely measured blood pressure by an automated oscillometric blood pressure monitor (Omron HEM-907 device: passed International Protocol of the European Society of Hypertension for elderly).²⁴ Clinic nurses then confirmed their office BP by repeated measurement. We took the mean of the second and third office readings as intake BP. Next, research helpers explained the study to the patients. Patients then signed the written informed consent.

2.3 | Sample size estimation

Local statistics showed that the number of eligible patients was similar among different clinics. Sample size calculation was based on the expected mean difference in BP at 18 months after baseline.²⁵ Accounting for the clustering effect by practice, the intraclass correlation (ICC) in the primary care setting was taken as .01, which was a median estimate reported in the previous study.²⁶ In order to have 80% power and 5% false-positive error to detect a difference in blood pressure of 3 mm Hg with assumed standard deviation of 5 mm Hg, 216 participants were obtained by sampling five general outpatient clinics randomly. Assuming the attrition rate of 20% for 18-month follow-up, we need to recruit 45 participants in each group per clinic at baseline, in a total of 270 participants.

2.4 | Randomization and masking

Blinding of the intervention was not feasible for patients or providers. Each patient could only register to one clinic for chronic disease follow-up. Therefore, cluster randomization using different clinics as different experimental units was feasible. It could minimize contamination of treatment effect between patients in the intervention clusters and the control clusters. An independent biostatistician randomly allocated eligible clinic to intervention or control cluster using simple randomization by coin-flipping. Allocation took place after participant recruitment.

2.5 | Control clusters (RAMP individual, usual care)

The Hong Kong Hospital Authority has aligned the hypertension management protocols in all public primary care clinics since 2011. Patients with hypertension were invited to attend the Risk Assessment and Management Programme (RAMP) annually.^{27,28} Generally, clinic nurses provided face-to-face individual counseling. They were trained to provide risk assessment, lifestyle modification counseling, and multi-disciplinary care allied health services referral (such as physiotherapist, dietitian and occupational therapist) according to a protocol for patients with different levels of risk of complications. Patients were referred to specialist family physicians if they had persistent uncontrolled BP clinical parameters. Patients were instructed to bring back their HBPM device for checking of

HBPM techniques. The professional-patient contact time varies from 20 minutes (1 session) to several hours (multiple follow-ups). The contact time depends on the patients' CVD risk factors and their participation. Large cohort studies have shown significant improvement in outcomes of patients attending RAMP.^{18,29}

2.6 | Intervention clusters (RAMP group)

In addition to RAMP individual, which only provides weekdays 9 AM to 5 PM services, the RAMP group offered group education program after office hour (6 PM to 10 PM). The topics were carefully curated according to the current best evidence, which consisted of self-care management, health care professionals, and patients' feedback.^{30,31} Educational materials such as presentations, patients' logbooks, and education leaflets were specially designed for older patients. All the contents were written simply and succinctly without jargon. Words with a font size of at least 14 points, maximized use of diagrams and pictures and hands-on practice, were used as appropriate. All groups were conducted in local Chinese dialect (Cantonese). Apart from the speaker (author MD), there were 2-3 health care workers assisting demonstration and HBPM hands-on training during group education. Firstly, our second author MD would give a 30-minute education talk, focusing on lifestyle modifications for hypertension such as risk factors avoidance, regular at least medium-intensity aerobic physical activities.³² Next, participants had 15-30 minutes to discuss among themselves on how to implement changes in their daily life. Then, a 5-minute self-explanatory video for steps of HBPM was shown. Subsequently, each participant borrowed a validated HBPM device until the next follow-up. Author ML or IH, who were our clinic nurse managers, then led a 20-minute interactive demonstration, focusing on the selection and the use of branchial cuffs and HBPM devices. They demonstrated an appropriate record of HBPM readings. Later, small groups of 3-4 participants were led by one of the authors or clinic nurses. Steps of HBPM were reinforced by supervised measurement until all participants could complete the HBPM procedures. At the end of the session, each participant would receive a 6-week appointment of RAMP nurse clinic. They were advised to bring back their medications and HBPM device to check their HBPM and drug adherence.

During the RAMP nurse clinic, author ML, IH, or other trained registered nurses assessed participants' BP, BMI, HBPM technique, and records. They interviewed participants about their lifestyle, HBPM practice, and knowledge using a structured questionnaire. Feedback and support were given based on individual patients' health problems. They were encouraged to purchase HBPM devices and continue HBPM. They were referred to the social welfare department for financial assistance if necessary.

2.7 | Outcomes assessment

Since the baseline health literacy level in RAMP group and RAMP individual was different, we adjusted the outcomes into adequate

and inadequate health literacy level. Controlled hypertension was defined as achieving the treatment target (<140/90 mm Hg). The primary outcome of this trial was the differences in BP control rate between RAMP group and RAMP individual at 6, 12, and 18 months. The secondary outcomes were the mean differences of SBP, DBP, body mass index, fasting blood sugar level, and low-density lipoprotein between baseline and follow-up. The predictors for satisfactory BP control at 18 months were also examined.

2.8 | Data collection

The trained research helpers collected basic socioeconomic factors by structured questionnaires. Participants' body mass index and waist circumference were measured. All biochemical laboratory tests and anti-hypertensive drugs prescribed within 3 months were recorded. Laboratory tests were arranged at 6, 12, and 18 months post-intervention. All trained research helpers were blinded to the study objectives and group allocation. Due to the nature of the study, the authors could not be blinded to the group allocation.

2.8.1 | Validated 8-item Morisky Medication Adherence Scale (MMAS-8)³³

The MMAS-8 consists of eight self-reported items concerning common medication-taking behaviors leading to drug omission. There are seven yes/no questions, and the last one is a 5-point Likert-scale rating. It has been used widely in studies of different chronic illnesses, including hypertension. Participants scores eight (full mark) had good drug adherence. Participants scores 6-7 had moderate drug adherence, while those scores five or below had low drug adherence.

2.8.2 | Chinese Health Literacy Scale for Chronic Care (CHLSCC)

The CHLSCC is a locally validated tool to assess health literacy among Chinese patients with chronic illness. It displayed a good internal reliability (Cronbach's $\alpha = .91$).³⁴ It assesses remembering, understanding, applying, and analyzing ability. Participants scored 36 out of 48 or above indicated adequate health literacy; otherwise, they had inadequate health literacy.

2.9 | Statistical analysis

The analysis of both primary and secondary outcomes followed the CONSORT guidance on cluster-randomized trials.²⁰ The primary analysis included all randomized patients using the intention-to-treat (ITT) population unless patients passed away before the end of the study.³⁵ Mean values of all available values were imputed if there was missing data at 6, 12, and 18 months. Detail of missing values

of different study outcomes was reported in Appendix. The participants' descriptive statistics were reported as means and standard deviations (SD), or frequencies and percentages as appropriate. The primary outcome was the differences in the blood pressure control rate between the RAMP group and the RAMP individual. Given the baseline differences in RAMP group and RAMP individual, subgroup analysis of participants with adequate and inadequate health literacy was performed to investigate the true effect of interventions. A *P*-value <.05 was considered as significant.

The secondary outcome of the mean differences in BP levels at baseline, 6, 12, and 18 months post-intervention was evaluated using paired *t* tests in each study arm. The differences of mean SBP and DBP between intervention and control group were tested for significance using Student's *t* test for independent samples, which accounts for the intra-cluster correlation.

A multivariate logistic regression model was used to identify predictors on blood pressure control at follow-up. The adjusted odds ratio were calculated from the forward stepwise logistic regression model. The odds ratios were adjusted by age, sex, educational level, health literacy level, occupation, smoking and drinking history, hypertension grading during intake, presence of diabetes mellitus, and hyperlipidemia, drug compliance level during intake, and the factors of continuity of care at the end of 18 months. The variables with *P*-value less than .05 were entered and stayed in the regression model. All dropped-out or loss-to-follow-up participants were analyzed using the intention-to-treat principle. Participants who passed away regardless of the causes of deaths before the end of the study were excluded from the analysis. All analyses were performed using SPSS 25 (Copyright® IBM).

3 | RESULTS

Five clusters fulfilled the inclusion criteria and participated in the RCT. They had the same number of consultation rooms, doctors, and nurses. From local statistics in 2015 and 2016, there were more than 6000 patients regularly followed up at each clinic for hypertension. More than 1000 patients were diagnosed with uncontrolled hypertension according to their average of office BP readings in the last two visits. All clusters completed the study until the end of 18 months.

Figure 1 showed the modified CONSORT diagram of study workflow and participant recruitment. A total of 337 eligible patients were approached. Forty-six patients refused to participate. The response rate was 86.4%. In the three intervention clusters, 152 participants were successfully recruited. All of them (100%) attended the first educational groups. Only six participants withdrew the RAMP nurse clinic. They all agreed to continue doctors' follow-up in study clinics by clinicians and provided their outcome data in the electronic patient records. In the two control clusters, 139 participants were successfully recruited. Twelve of them refused to participate RAMP. Two of them were excluded from the analysis because they passed

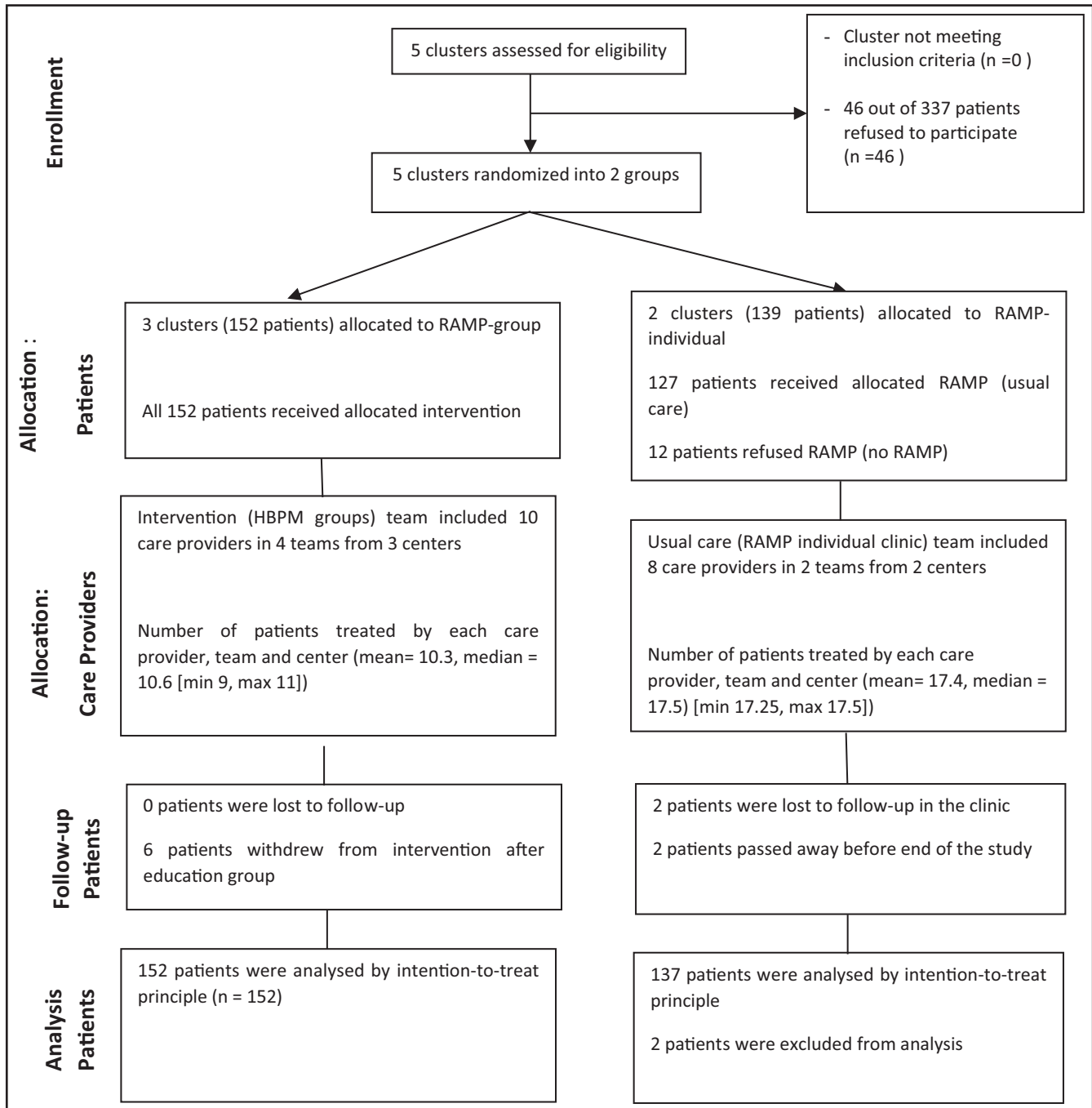


FIGURE 1 CONSORT diagram of the study

away before the end of the study. Two participants were lost to follow-up 6 weeks later.

Table 1 compared the clinical and personal characteristics of participants from RAMP group and RAMP individual. There was no statistically significant difference in their mean age, sex proportion, educational level, and employment status. They were in older age-group (overall mean age 67.0, SD 9.9) and predominantly women (60.5%). Their educational level was mostly low (61.5% attended primary school or below). Most were not full-time employed (78%). The participants in RAMP individual had lower baseline health literacy, longer duration of hypertension, lower incidence of stroke,

lower mean low-density lipoprotein level, and more proportion of participants on calcium channel blockers than those in RAMP group.

3.1 | Primary outcome

Figure 2 showed the primary outcome of this study. All participants had uncontrolled BP at baseline. 51.3% of RAMP group achieved controlled BP, while only about one-fourth (25.5%) of RAMP individual had controlled BP at 6 months. The overall BP control rate was highest at 12 months. After 18 months, 78.9% of RAMP group

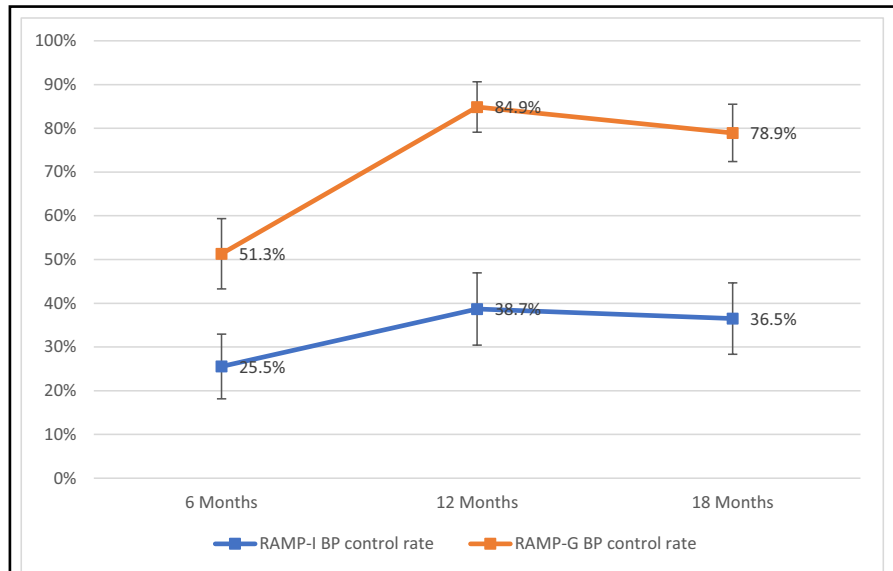
TABLE 1 Participants' sociodemographic and clinical parameters at baseline

Characteristics	RAMP individual (N = 137)	RAMP group (N = 152)	P-value ^a
Age (y; mean ± SD)	67.8 ± 10.2	66.1 ± 9.7	.156
Gender (%): Male	58 (42.3)	55 (36.2)	.285
Gender (%): Female	79 (57.7)	97 (63.8)	
Occupation (%): Not employed	105 (76.6)	120 (78.9)	.637
Occupation (%): Employed	32 (23.4)	32 (21.1)	
Primary school or below (%)	81 (59.1)	97 (63.8)	.413
Secondary school or above (%)	56 (40.9)	55 (36.2)	
Never smoke/ex-smoker (%)	130 (94.9)	147 (96.7)	.439
Current smoker (%)	7 (5.1)	5 (3.3)	
Never drink/ex-drinker (%)	127 (92.7)	140 (92.1)	.849
Current drinker (%)	10 (7.3)	12 (7.9)	
CHLSCC Chinese Health Literacy Scale for Chronic Care (Total 0-48)			
Mean ± SD, Median	28.23 ± 13.74	35.00 ± 12.76	<.001
Adequate health literacy (≥36) (%)	52 (38.0)	94 (61.8)	<.001
Inadequate health literacy (<36) (%)	85 (62.0)	58 (38.2)	
Clinic BP			
Systolic BP (mm Hg, mean ± SD)	152 ± 9.87	152.0 ± 10.4	.779
Diastolic BP (mm Hg, mean ± SD)	78.5 ± 10.7	80.76 ± 11.9	.088
Hypertension since diagnosis (years ± SD)	10.88 ± 9.28	8.43 ± 8.04	.017
Uncomplicated hypertension (%)	54 (39.4)	49 (32.2)	.203
Heart disease (%)	12 (8.8)	17 (11.2)	.493
Proteinuria (%)	17 (12.4)	13 (8.6)	.283
Stroke (%)	7 (4.6)	1 (0.7)	.045
Type of anti-hypertensive drugs (%)			
Angiotensin receptor blockers	21 (15.3)	24 (15.8)	.914
Angiotensin-converting enzyme inhibitors	37 (27.0)	32 (21.1)	.236
Calcium channel blockers	109 (79.6)	104 (68.4)	.032
Beta-blockers	51 (37.2)	51 (33.6)	.514
Alpha-blockers	12 (8.8)	19 (12.5)	.305
Diuretics	8 (5.8)	8 (5.3)	.831
Biochemical results			
Fasting blood sugar (mmol/L, mean ± SD)	6.16 ± 1.54	6.28 ± 1.40	.464
Low-density lipoprotein (mmol/L, mean ± SD)	3.08 ± 0.99	3.3 ± 0.95	.028
Anti-hypertensive (AHT) drugs			
Number of types	1.80 ± 0.83	1.66 ± 0.89	.155
Daily frequency	1.31 ± 0.49	1.27 ± 0.56	.557
8-item Morisky Medication Adherence Scale (MMAS-8) during intake			
MMAS-8 (mean ± SD)	6.95 ± 1.23	6.78 ± 1.43	.273
Good (%)	56 (40.9)	64 (42.1)	.148
Moderate (%)	61 (44.5)	54 (35.5)	
Low (%)	20 (14.6)	34 (22.4)	

Bold values denote statistical significance at the $P < .05$ level.

^a P-value of proportions by Pearson chi-square tests; continuous variables by Student's *t* tests.

FIGURE 2 The blood pressure control rate in RAMP group and RAMP individual at 6, 12, and 18 mo [Color figure can be viewed at wileyonlinelibrary.com]



BP = Blood Pressure; RAMP-G = RAMP-group; RAMP-I = RAMP-individual

	RAMP-individual BP control rate Percentage (95% C.I.)	RAMP-group BP control rate Percentage (95% C.I.)
6 Months	25.5% (18.2, 32.9)	51.3% (43.3, 59.4)
12 Months	38.7% (30.4, 46.9)	84.9% (79.1, 90.6)
18 Months	36.5% (28.3, 44.7)	78.9% (72.4, 85.5)

C.I. = confidence interval

attained controlled BP status, while there was only 36.5% RAMP individual achieved BP under control.

Figure 3 depicted a subgroup analysis of the participants with adequate and inadequate health literacy. It demonstrated consistent results favouring the BP control rate in RAMP group over RAMP individual regardless of the participants' health literacy. In RAMP individual, those with adequate health literacy had the lowest BP control rate (26.9%) at 18 months.

To assess predictors of uncontrolled BP, Table 2 illustrated the results of the stepwise logistic regression model of predictors for uncontrolled HT after 18 months. The final model adjusted for sex and low drug adherence. The results indicated that the RAMP group was 7.26 times more likely to have controlled BP in comparison with the RAMP individual ($P < .001$). Men (aOR = 0.45, $P < .001$) and those with low drug adherence (aOR 0.46, $P = .03$) were less likely to have controlled BP.

3.2 | Secondary outcomes

The decrease in SBP and DBP in RAMP group and RAMP individual was shown in Figure 4. There were significant decreases in systolic

BP of 19.7 mm Hg (95% CI -22.0, -17.4, $P < .001$) and diastolic BP 8.1 mm Hg (95% CI -9.7, -6.6, $P < .001$) after 18 months in IC. In CC, there was also a significant decline in SBP of 9.3 mm Hg (95% CI -12.1, -6.4, $P < .001$), but the DBP did not show any statistically significant difference between the two groups. Participants with adequate HL demonstrated a better reduction in SBP (-21.3 mm Hg, 95% CI -24.1, -18.5, $P < .001$) than those with inadequate HL (-17.2 mm Hg, 95% CI -21.2, -13.2, $P < .001$).

The mean difference of body weight (BW), BMI, fasting blood sugar level, and low-density lipoprotein level from baseline to 18 months in RAMP group and RAMP individual were displayed in Table 3. There was no statistically significant change of BW and BMI over time in RAMP group. On the contrary, there was a significant increase of BW by 0.67 kg and BMI by 0.27 kg/m² in RAMP individual. There was no significant change in fasting blood sugar from the baseline. Both RAMP group and RAMP individual demonstrated a significant reduction in LDL during the study period.

3.3 | Safety outcome

There was no adverse incident reported.

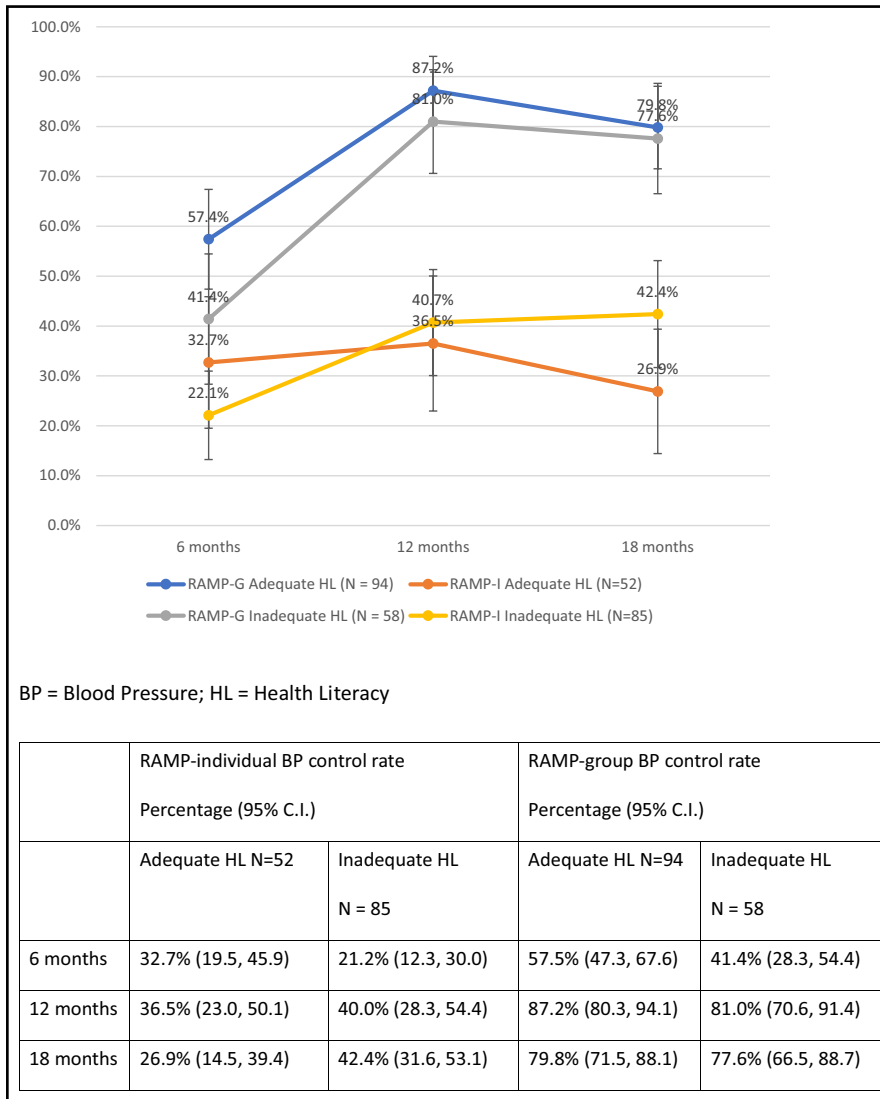


FIGURE 3 Subgroup analysis of BP control rate of participants with adequate and inadequate health literacy among RAMP group (RAMP-G) and RAMP individual (RAMP-I) [Color figure can be viewed at wileyonlinelibrary.com]

TABLE 2 Stepwise logistic regression model of predictors for uncontrolled HT at 18 mo post-intervention

Predictors	Reference group	Coefficient	P-value*	Adjusted Odds Ratio	95% CI of OR
Sex	Male	-0.81	<.001	0.45	0.26, 0.77
Drug adherence (intake)	Low	-0.77	.03	0.46	0.23, 0.93
Intervention group/control group	Intervention group	1.98	<.001	7.26	4.18, 12.62

Bold values denote statistical significance at the $P < .05$ level.

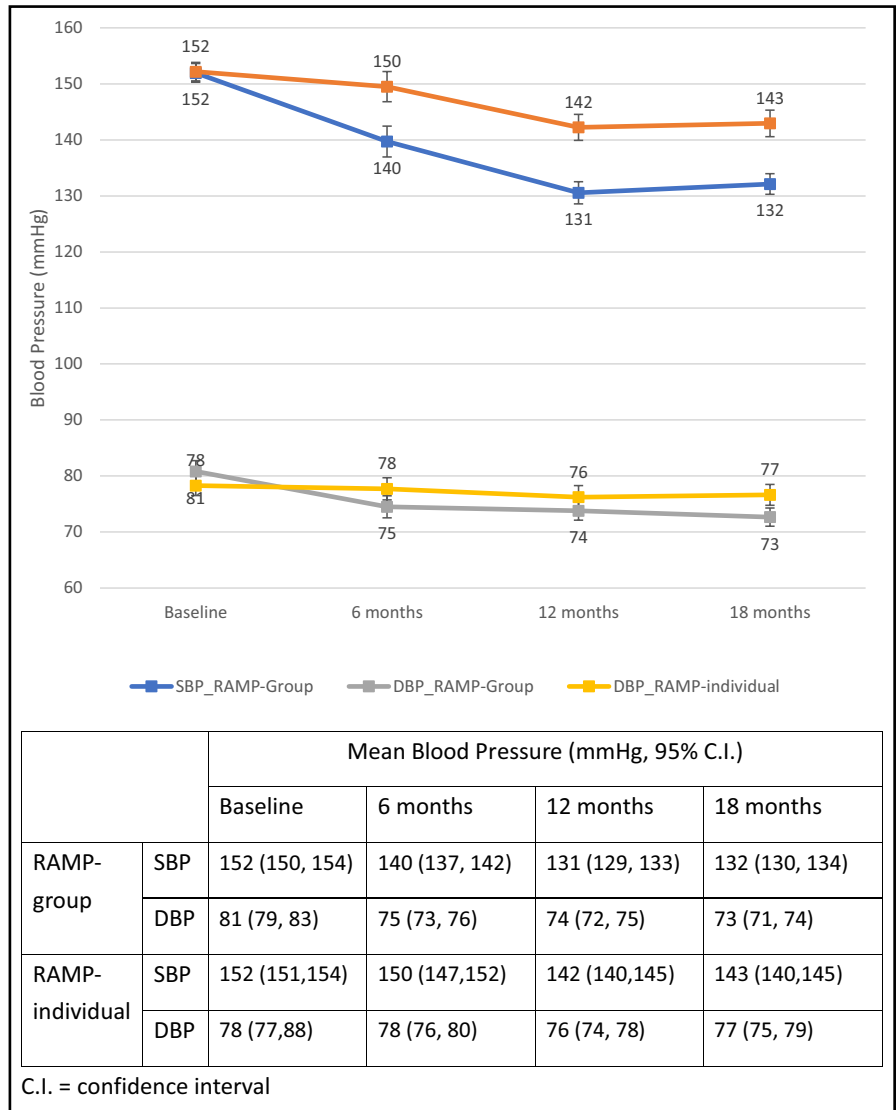
* The P -value for variable to enter and stay in the regression model is .05.

4 | DISCUSSION

The study result demonstrated a significant increase in BP control rate after participating in an intervention including a 2-hour education talk, demonstration of HBPM technique, borrowing of a validated HBPM device, and nurse follow-up. We compared the results from studies in the same clinical setting, with similar patient characteristics, such as mean age and sex ratio. Yu et al.¹⁸ found patients'

BP control rate at 12 months was 64% in the initial phase of RAMP individual. The BP control rate at 12 months was lower (39.1%) in our study. The different effect of RAMP could be because Yu et al. performed their study at the beginning of the RAMP in 2010. In this study, many of our patients have already attended RAMP services multiple times. The behavioral modification effect may be dampened with repeated RAMP every year. The intervention in this study tailored information for older patients with limited health literacy. The

FIGURE 4 Systolic blood pressure and diastolic blood pressure over time in RAMP individual (CC) and RAMP group (IC) [Color figure can be viewed at wileyonlinelibrary.com]



new elements, such as group education, new skills, knowledge, and hands-on experience like the use of HBPM, may refresh patients' treatment target, insight in keeping good adherence and engaging in self-care.

In comparison with systemic meta-analysis results of interventions using HBPM, which showed an overall reduction of SBP -3.2 mm Hg, this study also had a positive effect on BP control.^{9,11} The reduction in mean difference of SBP in this study was -19.7 mm Hg (95% CI -22.0, -17.4) and DBP was -8.1 mm Hg (95% CI -9.7, -6.6). The RAMP group consisted of HBPM with counseling and face-to-face follow-up; it was one of the most intensive interventions, which resulted in a higher degree of BP reduction. Given the positive outcomes of this study, subsequent RAMP-HT program may consider introducing group education with HBPM and provision of HBPM devices to patients in need.

This study demonstrated patients attended RAMP group had a more significant reduction of office BP than those who attended RAMP individual. The advantages of group education may be that all groups were performed by the first five authors, who were selected

doctors and nurses with strong interpersonal and communication skills. The RAMP-group speakers offered patient-centered advice in patients' lifestyle medication. Patients were allowed for group discussion. A similar study comparing the group to individual education for patients with diabetes also demonstrated a favorable result in group education.³⁶ The reasons could be the longer duration of patient-professional interaction in a group (90 minutes vs 20 minutes). The group interaction and dynamic could enable patients with the same disease to bring up their problems and share for discussion and advice. Another observed benefit in this study was the facilitators' and speakers' advance familiarity with the discussion topics. With the practice of answering similar questions from the group, they became more familiar with the common mistakes made by the patients during HBPM. As a result, patients gave positive feedback to us during the subsequent individual counseling follow-up. In short, the model of group education performed by a group of primary care professionals should perhaps be considered as a practical approach for the high prevalence of uncontrolled hypertension in the primary care setting.

TABLE 3 Paired *t* test for changes in patient outcomes after 18 mo

	RAMP group (intervention cluster) N = 152				RAMP individual (control cluster) N = 137			
	Baseline (Mean, SD)	18 mo Mean, SD	Mean difference (95% CI)	<i>P</i> -value	Baseline (Mean, SD)	18 mo Mean, SD	Mean difference (95% CI)	<i>P</i> -value*
Systolic BP (mm Hg)	152.0, 10.4	132.2, 11.5	-19.7 (-22.0, -17.4)	<.001	152.2, 9.8	142.9, 14.1	-9.3 (-12.1, -6.4)	<.001
Diastolic BP (mm Hg)	80.8, 12.2	72.6, 10.1	-8.1 (-9.7, -6.6)	<.001	78.3, 10.6	76.6, 11.1	-1.7 (-3.6, 0.2)	.078
BW (kg)	63.23, 11.85	62.89, 11.87	-0.34 (-0.71, 0.037)	.077	64.91, 13.10	65.58, 13.37	0.67 (0.27, 1.08)	.001
BMI (kg/m ²)	26.31, 4.27	26.30, 4.37	-0.013 (-0.21, 0.18)	.896	26.46, 4.33	26.73, 4.33	0.27 (0.067, 0.47)	.010
FBS (mmol/L)	6.28, 1.40	6.26, 1.49	-0.018 (-0.21, 0.17)	.849	6.17, 1.56	6.45, 2.11	0.28 (-0.016, 0.57)	.064
LDL (mmol/L)	3.33, 0.95	3.08, 1.45	-0.25 (-0.50, -0.005)	.046	3.07, 1.00	2.85, 0.96	-0.23 (-0.36, .092)	.001

Abbreviations: BMI, body mass index; BP, blood pressure; BW, body weight; CI, confidence interval; FBS, fasting blood sugar; LDL, low-density lipoprotein; SD, standard deviation.

* Bold values denote statistical significance at the *P* < .05 level.

The logistic regression results aligned with the previous literature in the following ways. First, we demonstrated that female patients had better BP control than male patients. The effect was the same as a systematic review.¹¹ Secondly, health literacy level played a vital role in effective BP control in previous literature. Rajah et al.³⁷ revealed a significant effect on better BP control in patients with better health literacy. However, no significant difference in BP control rate was observed between the adequate and inadequate health literacy groups in this study. The result echoed to a similar positive effect of BP control after interventions tailored to patients' understanding level in both adequate and inadequate health literacy groups.

There were several strengths of this study. Firstly, it was a pragmatic multi-disciplinary group education interventional study targeting primary care patients from the lower socioeconomic classes. The model of care could potentially apply to primary care patients with limited health literacy. Secondly, the response rate in participant recruitment was high (86.4%), demonstrating patient acceptance to the program. Thirdly, the attrition rate was lower than expected. The attendance rate of the RAMP group was 100% due to the arrangement of flexible after-hour appointment and telephone reminder. Less than 5% of participants refused to participate in a subsequent face-to-face follow-up or never attended again within 18 months. The lost to follow-up rate in this study was also low. The findings could suggest an excellent continuity of care to those particular community clinics for the populations regularly followed up in Hong Kong public primary care clinics.

Nevertheless, there are some potential limitations to our study. Firstly, only office BP was recorded in all outcome measures. To assess a more comprehensive BP reading, the study outcomes may include ambulatory BP readings or home BP readings by HBPM device with digital memory or wireless transmission functions.³⁸ Secondly, since we had a limited number of HBPM devices, participants have to take turns to use the HBPM devices over the study period. Patients may discontinue HBPM because they had limited access to HBPM device. Thirdly, although we have tried to minimize the contamination by cRCT, the potential contamination may still

be existed because of staff rotation from intervention clusters to control clusters.

5 | CONCLUSIONS

Interactive group education targeting at high-quality home BP monitoring and subsequent individual counseling could reduce the proportion of patients with uncontrolled hypertension in comparison with the conventional individual counseling RAMP. The positive effects were seen in both patients with adequate and inadequate health literacy. Male patients, those with low drug compliance and those who have not attended group intervention, were less likely to have controlled BP 18 months after the RAMP group. The new element proposed in this study should be implemented into the primary care for patients characterized by lower educational level and older age-group.

CONFLICT OF INTEREST

The authors declare that they have no competing interests.

AUTHOR CONTRIBUTIONS

SNF, MCD, WL, MCHL, ISFH, SKC, CKHW, and BMYC participated in the study design and analyses. SNF, MCD, MCHL, and ISFH conducted the study; SNF, MCD, and CKHW performed the statistical analysis. SNF wrote the first draft of the manuscript. MCD, CKHW, WL, MCHL, ISFH, SKC, and BMYC commented on this draft and performed critical revisions. All authors have read and approved the manuscript.

ETHICAL APPROVAL

The study was approved by the Research Ethics Committee, Kowloon West Cluster, Hospital Authority of Hong Kong S.A.R. approval number: KW/EX-15-115(88-14).

CONSENT TO PARTICIPATE

Written informed consents were sought before study participation.

DATA AVAILABILITY STATEMENT

All data generated or analyzed during this study are included in this published article.

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APPENDIX

Number of missing values imputed by mean values

	Baseline		6 mo		12 mo		18 mo	
	R-I	R-G	R-I	R-G	R-I	R-G	R-I	R-G
N	139	152	139	152	137	152	137	152
Systolic BP	0	0	1	2	4	9	6	10
Diastolic BP	0	0	1	2	4	9	6	10
Body weight	0	0	1	2	4	9	6	10
Fasting blood sugar	0	0	4	5	4	9	6	10
Low-density lipoprotein	0	0	3	5	4	9	6	10

Abbreviations: BP, blood pressure; R-G, RAMP group; R-I, RAMP individual.