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Enhance Home Blood Pressure Monitoring Accuracy in uncontrolled Hypertension: a Randomized Controlled Trial

Background:

Being a highly prevalence global health problem, high blood pressure (BP) attributed to 13.5% of the global total premature death (1).Clinical findings in Hong Kong were shown to be comparable to the global situation. Locally, hypertension is the commonest chronic disease in Hong Kong with a prevalence of 27% among people aged 15 years or above.(2) It is the second commonest reason for consultation in Hong Kong primary care setting.(3) Control of BP to an optimal level is recommended to prevent irreversible cardiovascular event.

International guidelines including the European Society of Hypertension (EHS) (4), National Institute for Health and Clinical Excellence (NICE)(5) and the World Hypertension League(6) recommended appropriate use of home blood pressure monitoring (HBPM) in evaluate hypertension in certain clinical conditions. Systemic reviews have shown HBPM improve patients' BP control rate and compliance with treatment. (7,8) HBPM enables a more precise initial diagnosis of hypertension and more accurate titration of antihypertensive drug treatment (4), as shown by randomized control trials (9-12). Current Evidence suggested that blood pressure (BP) assessment are frequently inaccurate, with a high potential to misdiagnose a large segment of the population. (13). Therefore, the use of automated devices using oscillometry is recommended for HBPM (4).

As response to the recent promulgation by primary care clinicians (14), many patients with hypertension adopt HBPM (15). Local study also showed short term improvement of BP by one-off structured education program of home BP monitoring (16). However, sustainability of high quality HBPM technique remains unknown.

High quality HBPM depends on selection of validated device according to international recommendation; appropriate cuff size; conditions of measurement, correct procedure of measurement; and correct interpretation of HBPM readings.(4) Even with training, the use of standardized manual techniques(17) delcines rapidly without regular retraining and accuracy testing(6). The accuracy of monitors and operators was prone to error, mostly due to mistakes by operator.(18)

Therefore, we propose to provide structural group educations focus on accurate BP measurement, provided with validated home BP device, with regular reassessment of BP measurement technique. We are interested to find out whether the proposed intervention can lower BP and sustain high quality HBPM.

Study Aims and Objectives:

We aims at comparing providing validated home BP device, followed by group education of self-BP monitoring and regular assessment accuracy of BP monitoring, which may possibly improve BP control rate of patients with uncontrolled hypertensions in primary care setting. We would also like to evaluate whether the quality of BP measurement is sustainable, any change in biochemical markers, clinic BP readings in 6 months, 12 months and 18 months interval. We would also find out patients' view on home BP monitoring and the education program.

Research Questions

1. Do the people with uncontrolled BP have higher control rate after provision of validated BP device followed by education and assessment of BP measurement technique?
2. Are there improvements in the clinic BP body weight, BMI, biochemical markers followed by the HBPM education program?
3. Can quality of HBPM be sustainable by education followed by regular reassessment?
4. What is patients' view on HBPM?

Methods

We adopt prospective longitudinal randomized control trial. Subjects from four general outpatient clinics (GOPCs) located in urban residential area will be involved in the study.

Study Practices and randomization procedure

We aimed to determine the effectiveness of HBPM education and provision of validated home BP device. Since the intervention involve doctors, nurses and patient cooperation, cluster (using one clinic as one cluster) approach is utilized to minimize risk of treatment contamination. Three clinics are randomly assigned as intervention clinic and the other three will be assigned as usual care clinic. (Appendix 1) To avoid contamination, separate protocols will be sent to individual clinics assigned to intervention and control. The Research helper will assist subject recruitment and data collection. The measurements and lab test will be performed by local clinic nurses and doctors in control clinics.

Research Subjects Recruitment

The recruitment of subjects and study workflow is shown in **Figure 1**. We include adult subjects aged above 18 years old on hypertensive treatment more than 12 months with uncontrolled hypertension and no previous HBPM on the day of recruitment. Uncontrolled hypertension is defined as BP > 140/90mmHg(19,20) in subjects age < 80; and BP > 150/90mmHg(21) in subjects age$\geq$80. They will be invited to participate if they are willing and capable to perform home BP monitoring by themselves on daily basis. Appropriate subjects will be identified during doctor consultation and nurse consultations and subjects will be invited after normal consultation.

We exclude subjects who are unable to perform the home monitoring either by themselves; or have arrhythmias, unstable angina, serum creatinine > 250 mmol/l, orthostatic hypotension, severe left ventricular impairment, severe aortic stenosis and pregnancy.

Data Collection

Subjects enrollment and baseline assessment take place before randomization. Follow up data collection will be conducted 6 months, 12 months and 18 months after intervention.

Baseline Assessment

At baseline, patient age, sex, smoking habits, body mass index, waist circumference, education level, occupation, payment method, household income and number of household family members, health literacy by Chinese Health Literacy Scale for Chronic Care (22)will be collected via questionnaires by clinic nurses and research helper. Medical history includes diabetes mellitus, nephropathy, manifest cardiovascular disease (namely ischaemic heart disease, cerebral vascular disease, and peripheral vascular disease), current medication including antihypertensives drugs, lipid lowering agents, and antiplatelet drugs, laboratory test results including fasting blood sugar, glycemic haemoglobin level, lipid profile, serum creatinine level, presence of significant proteinuria will be collected by investigators via computerized patient record.

Baseline blood pressure will be measured in clinic 3 times after taking at least 5 minutes rest in a sitting position by Ormon HEM-907 clinic use BP device (passed International Protocol of the European Society of Hypertension for elderly)(23); with an appropriately sized cuff in the right arm, which is accredited model by British Hypertension society. The BP will be taken at least one hour after the subject's last meal and at least 30 minutes after smoking or consumption of a caffeinated beverage. The systolic and diastolic blood pressure will be measured 3 times and we will take the mean of the second 2 out of 3 office reading each time).

For safety considerations, if any BP measurements were above 170 mmHg systolic or 105 mmHg diastolic, the BP were rechecked again 5 minutes later. If the BP remained above these levels, the result will alert attending physicians for further management.

Usual Care (Control Group)

All subjects see their physicians and / or nurse for routine BP measurement and /or adjust medication at the discretion of the health professional. They received nurse individual counselling explained management of uncontrolled hypertension in patients' understandable language will be arranged as routine practice.

Intervention Group

1. Two 2 hours Training sessions (by nurses/ doctors)

All subjects will attend a 2 hours training in the education room of study clinics. There will be 15 to 30 subjects in each education group, depends on size of venue.

Nurses or doctors will brief subjects about basic hypertension medical knowledge, lifestyle modifications and hypertensive complications for 30 minutes. Automated Brachial type home BP device AND UA651 (Appendix 5) will be loaned to subjects up to 3 months.

It follows by 1 hour interactive seminar

1. Select appropriate cuff size by nurses
2. Stepwise education on home BP monitoring procedure
3. Standard Home BP Record Hand Book (Appendix 6).
4. Method of recording

Finally, it will be demonstration of assessment of the HBPM procedure. (Appendix 7) All subjects will undergo the same assessment when they return the BP device.

2. Next scheduled clinic visit (1-3 months after Training Session

- In the next doctor consultation (within 12 weeks of education talk), BP device will be returned
- Clinic nurses will assess the self-monitoring technique, home BP records , body weight and BMI and the clinic BP levels

3. 6 months, 12 months and 18 months post intervention

Clinic nurses will assess the self-monitoring technique, home BP records, body weight and BMI and the clinic BP levels

4. 18 months post intervention

The above measurement will be collected via questionnaires by clinic nurses and research helper. Medical history includes diabetes mellitus, manifest cardiovascular disease (namely ischaemic heart disease, cerebral vascular disease, and peripheral vascular disease), current medication including antihypertensives drugs, lipid lowering agents, and antiplatelet drugs, laboratory test (6 to 18 months post intervention) results including fasting blood sugar, glycemic haemoglobin level, lipid profile will be collected by investigators via computerized patient record.

Data analysis

The Outcome Measurement includes

1. Blood pressure control rate (Primary outcome)
2. Change in clinic mean systolic and diastolic BP between baseline and each of the follow up point
3. Accuracy of HBPM by standard checklist in 1-3 months and 9-12 months post-intervention
4. Practice of HBPM 6-months post-intervention
5. Change in biochemical markers

6. Change in Body Weight and BMI
7. Adverse effect (reported by research subjects)

Sample size calculation will be based on the mean difference in blood pressure between intervention and controls at 9-12 months after baseline. Accounting for the clustering effect by practice, the intraclass correlation (ICC) for the intra-cluster correlation in primary care setting was taken as 0.01 which was a median estimate reported in previous study (24). In order to have 80% power and 5% false positive error to detect a difference in blood pressure of 3mmHg with assumed standard deviation of 5mmHg, there will be 216 subjects (25) which will be obtained by sampling 6 general outpatient clinics randomly, with 36 subjects each clinic in intervention group and 36 subjects each clinic in control group. Assuming 20% of attrition rate for 6-12 months follow-up, we need to recruit 45 subjects in each group per clinic at baseline, in total of 270 subjects.

Descriptive statistics including mean, standard deviation of continuous outcomes and proportion of dichotomous outcomes will be calculated. Primary analysis will be an intention-to-treat analysis of the difference in outcomes between groups at 6-18 months after baseline. As with repeated measurement for patients, generalized estimating equation models using identify link will be conducted to assess differences in continuous outcomes within-group and between groups, adjusting for baseline patients' characteristics and clustering of patients per practice. Generalized estimating equation models using logistic link will be conducted to analyze differences within-group and between groups for dichotomous outcomes, adjusting for same sets of patients' characteristics. Missing values will be imputed using last value carrying forward method. Repeated analysis will be done for per-protocol analysis.

All statistical analyses will be performed using SPSS Windows 21.0 program. P-value less than 0.05 will be considered statistically significant.

Data collection throughout the trial

Demographic Questions	Measurements
Duration of HT	BMI (BH/ BW)
Past Medical history	Waist circumference
Contra-indications to antihypertensive drugs	Clinic BP (sitting position/ standing position)
Current HT medication	Lab Test: FBS, Lipid profile, eGFR, Urine PCR
	HBPM Technique

Qualitative Study on Evaluation of the Programme

Individual interviews (30-45 minutes) to 30 subjects from intervention group will be performed 2-4 months after education seminar and 1st doctor consultation (whenever later). Views on the self-monitoring, home BP reading interpretation blood pressure treatment targets, will be collected.

Sampling Method: 30 subjects with uncontrolled hypertension, some have attended intervention group, with different sex, age group, health literacy and occupations will be interviewed.

Semi-structured interview guide for patients and their family caregivers using social cognitive theory(26) as framework

Framework	Interview questions
Overall experience & attitude	Does high blood pressure (BP) border you? Why? Tell us about your general impression on Self-blood pressure monitoring (SBPM)
Self-monitoring mechanism - Value of Behaviour - Motivation	Why do think it is important / not important for SBPM? Probing 1: (if important) What do you expect from SBPM? How and Why? Probing 2: (if not important) What are more important than SBPM in your disease management? Is there any particular person, or reason, asked you to perform SBPM regularly?
- consistency	Do you get your BP checked regularly? How to do it? Probing: Where? Who? What is / are the machine(s)?
- temporal proximity - self-diagnosis	Do you notice anything will affect the SBPM readings? What was your observation? What do you think was the relationship? Do you think the BP readings means anything? probing 1: such as have, or have no health problem probing 2: where did you learn that BP reading means problem/ no problem? Tell me more about that
Self-judgment mechanism - Self-comparison	You have measured many BP readings at home. How's the BP reading change in different time of the day/ over a period time? What do you think was the reasons of your BP variation?
- Social comparison	How were your BP readings when compare with your friends or family, or other patients? How do you feel about that? Why do you have that feeling?
- Statistical comparison	Do you know what is the standard BP target readings? How did you acquire the BP level? Do you think your BP is up to standard? Why?
- Education - Modelling	How did you learn SBPM? Tell me about your experience

	Do think your SBPM technique is correct? How did you do it at home? Probing: (if not correct) Did anyone comment on your SBPM technique, can you share the comment with me? Did you observe anyone else how to measure BP? Probing: How did you feel about learning SBPM?
Self-evaluation mechanism - Self-satisfaction	Are you happy with/ worry about your SBPM readings so far? What are you goal? (aim or target from SBPM)
- Self-incentives	If any, what are the benefit of SBPM? (Negatively, what are the unwanted or negative effects of SBPM?) Why?
- External Reward	Any tangible benefits of SBPM regularly? Can you describe?
Overall Comment on Education program	(If attended before) What is your comment on the RAMP education program? Have you learnt anything new? Do you change (your behaviour) after attending the program?

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PATIENT INFORMATION

Enhance Antihypertensive Compliance in Response to Home Blood Pressure Monitoring in Older People with Uncontrolled Hypertension

Conducted by:
Department of Family Medicine & Primary Health Care, Kowloon West Cluster, Hospital Authority

Background

Hypertension is common and it is well known that appropriate treatment can help to prevent or delay disease complication. We notice that many older people concern about their blood pressure control and therefore performing home blood pressure (blood pressure) monitoring. They want to participant in the discussion of their hypertension drug treatment. We are interested to find out whether older people can have better blood pressure control by involving patients in the decision of hypertension treatment as well as nurse education and follow up. By doing so, we hope to make a strategy for improvement hypertension patient health status

Study procedure

This is a questionnaire, measurement, doctor consultation, followed by nurse group education and individual follow up study last for 6 to 9 months.

1. The questionnaire will be conducted today by face to face or self-administered with the help from our research helper. You will be asked a set of questions about your symptoms and performing measurement on your body weight and waist circumference. The questionnaires and measurement will be repeated 6 months later
2. Doctors will review all of your health status and prescribe most appropriate treatment as usual.
3. You may or may not be invited to attend 2 group education seminars lead by clinic nurse and doctors each will last for 2 hours, a Blood Pressure Device will be loaned to you, followed by nurse individual follow up
4. 2 Laboratory blood and urine test will be performed within 4 weeks and 6 months later. We will check your blood sugar, cholesterol level, urate level, kidney functions as well as urine protein concentration. The test results will be explained to you during nurse individual follow up.
5. You are expected attend as scheduled. All of your home record should be shown to your doctors and nurses every time you come back to clinic

We will retrieve your data including sex, age, educational level, disease information and recent investigation results from the hospital computer system for data analysis. There will be no sensitive date (neither your name nor ID number) appear in the research record.

Risk

There may be mild discomfort during blood taking.

Benefits

You will not have any direct benefit by participating in this study. However, we will gain an understanding condition of hypertension because of the data obtained by your involvement in the study. This information may help further strategic planning of health services thereby helping future patients.

Upon completion of the study, a supermarket coupon valued of fifty Hong Kong dollars as a token of appreciation for your time and contribution
If any extra visit (e.g. education talk, nurse follow up) is required, a supermarket coupon of fifty dollars Hong Kong dollars will be reimbursed.

Confidentiality

Your participation in the study will be treated as confidential and any records or results relating to the study will not be disclosed to any third party other than investigators. Research ethics committee or regulatory authority(ies) will be granted direct access to the subject's original medical records for verification of clinical trial procedures and/or data, without violating the confidentiality of the subject, to the extent permitted by the applicable law and regulations.

Only your unique patient number will appear in the study document. Information obtained in the study may be used in publications or reports but you will not be identified or referred to by name.

Consent

The decision to join this study is entirely voluntary. You can refuse to participate or withdraw from the study at any time without providing reasons and your standard of care will not be affected. You will be timely updated of new information that may be relevant to your willingness to continue participation in study. If you withdraw from the study, your information will be destroyed and the data will not be used in the study.

Questions

If you have any questions related to this study at any time please contact Ms Margaret Lam in Ha Kwai Chung GOPC, Tel: 7321 7578.

PATIENT INFORMED CONSENT

Protocol Number:

Enhance Antihypertensive Compliance in Response to Home Blood Pressure Monitoring in Older People with uncontrolled Hypertension

Conducted by:

Department of Family Medicine & Primary Health Care, Kowloon West Cluster, Hospital Authority

Subject Number

I_____(Name of patient) _____ (HKID number) have obtained adequate information of the above study and understand its nature, purpose, possible benefits and potential risks. I understand I will receive a copy of my signed consent form. I also understand that my doctor and the sponsor organization can stop my participation in this study without my consent. I have no obligation to participate and can withdraw at any time without any reason and my medical care will not be affected in future. I have also been given enough time to decide whether to participate or not.

As a participant in the study, I understand that my record will be accessible to authorized persons but the records will be kept confidential.

I hereby confirm my agreement to the above and to participate voluntarily in this study.

Signature of Participant Date

Name and Signature of Witness Date

Physician/Investigator Statement: I have carefully explained to the participant the nature of the study. I hereby certify that to the best of my knowledge the participant signing this consent form understands clearly the nature, demands, risks and benefits involved in participating in this study. A medical problem or language or educational barrier has not prevented a clear understanding of the participant's involvement in this study.

Name and Signature of Research staff Date