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ICCR Rotation – Research Project Proposal

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The effects of Home Blood Pressure monitoring devices on AIM Clinic patients with uncontrolled Hypertension.

1. Study Purpose and Rationale

Hypertension as defined by JNC 7 as SBP>140, DBP > 90[1] is very common in the US. According to the American Heart Association, as many as one in three adults age 20 and older, about 73 million people, have high blood pressure. Of all the people with high blood pressure, 61.4% are aware of their condition and undergoing treatment. Only 35.1% of these have their blood pressure under control[2]. Hypertension continues to be a leading risk factor for mortality. In 2004, hypertension was listed as the primary cause of death for 54,707 Americans. It was also listed as a primary or contributing cause of death in about 300,000 of the more than 2.4 million US deaths in 2004[2].

Hypertension is a major modifiable risk factor for stroke, and one of the major risks factors for coronary heart disease, congestive heart failure and renal disease. Despite advances in pharmacological therapy, and knowledge of the risks, a startling number of patients still do not have their blood pressure under control. Many studies have demonstrated that despite being prescribed seemingly appropriate doses of medications, a concerning number of patients are still not able to achieve BP goals [3-5]. In the Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial (ALLHAT), after approximately 5 years of follow-up, as many as 34% of their participants remained uncontrolled on an average of 2 medications[6]. Amongst other factors, poor adherence to antihypertensive therapy has been indentified as a major cause of lack of blood pressure control [7].

Poor adherence to antihypertensive medications is very common at the primary care level, and is especially common among inner city hypertensive patients [3-4]. Retrospective analyses indicate that approximately 40% of patients newly diagnosed hypertension will continue their prescribed antihypertensive regimen [8-9]. In a study to see determinants of persistence with antihypertensive drugs, during a period of 5-10 year follow up, less than 40% of patients persisted with their treatment [10]. Many clinicians have sought strategies to improve patients' adherence with antihypertensive medications. One promising strategy is to have hypertensive patients monitor their BPs at home using home BP measuring devices. Studies have demonstrated successes when adopting this strategy [11-13]. In Japan, home devices have been incorporated into hypertension treatment guidelines with success [14]. In the US in contrast, prescribing home BP device is not a common place practice. The purpose of this study is to see whether providing AIM clinic patients with uncontrolled HTN with home BP monitoring devices would improve adherence to medications and result in improved BP control.

2. Study Design and Statistical Analysis

Study setting: study will be set in AIM Medical Practice of the Dept of Medicine, Columbia Presbyterian

Study population: AIM Clinic patients (have Medical Residents as their PMDs) age 20 and above, who have been identified as having uncontrolled hypertension despite being on two medications. Uncontrolled hypertension is defined as blood pressures not at goal of <140/90mmHg in patients with essential hypertension or goal of <130/80 in patients with diabetes or chronic kidney disease as per JNC 7 recommendations. Patients would be included in the study if they are determined to have poor BP control on chart review over the preceding 6 months, they may have co-morbid conditions (such as diabetes, CHF , CRI)and should be on at least 2 anti-hypertensive medications. Patients to be included in the study would have to demonstrate they are able to use the home monitoring device and record their pressures in a log book. Patients would be excluded from the study if they have secondary causes of Hypertension (such as Renal artery stenosis or Pheochromocytoma) or if they have end stage renal disease and are on dialysis.

Study design: Randomized control trial, unblinded study

Randomization process: Patients who have consented to participate in the study will undergo a stratified randomization process. They would be stratified with respect to those who are active smokers and active heavy alcohol users. This would be done to prevent overrepresentation of this subpopulation within the test or control groups.

Study process: 200 patients would be recruited and randomized into either the intervention arm or the control arm of the study for a total of 100 subjects in each group. At the time of entry into the study, each patient would undergo a 30 minute education session on Hypertension. This piece would utilize the American Heart Association's website for graphics and patient centered information on hypertension. The education session would be available in both English and Spanish depending on the patient's language of preference. During the session, the need for each patient to "take control" of their blood pressure would be stressed. All patients would be asked to complete 4 questionnaires listed below.

Patients who have been selected by computer randomization to be in the intervention arm would receive an additional 15-30 minute session on how to use a home BP monitoring device. The patient would be asked to measure daily BPs, preferably first thing in the morning before taking their medications and record the values in a log book. The need to take their medications despite BP values would be stressed. Patients would also be educated to either call their physician or walk-into clinic if their blood pressure is >/= 200mmHg systolic or >/= 120mmHg diastolic.

Patients would be scheduled for their routine 3 months then 6 months follow-up appointments with their PMDs. At these visits, their blood pressures would then again be collected for the study.

Outcome measures: the primary outcome of the study will be reduction in systolic or diastolic blood pressure in the intervention group within a period of 3 months and checking if this is sustained at 6 months. Data would also be collected on patient demographics, patient's health beliefs with concern to hypertension and their ability (self efficacy) to impact their health condition.

Power analysis: Assuming 80% power, testing at P=0.05, in order to see a reduction of 20mmHg systolic pressure or 10mmHg in diastolic pressure in the intervention group, it has been determined using an unpaired t-test that there would need to be a minimum of 64 participants in each arm of the study.

Data and analysis: the mean systolic BP and diastolic BP of the intervention and control arms would be compared using simple T test. Multiple regression analysis would be used for modelling and hypothesis testing with respect to the secondary outcome variables.

3. **Study drugs**: there would be no new drugs introduced to the patients during this study. Patients would be however encouraged to take their current anti-hypertensive medications as prescribed by their PMD.

4. **Medical device**: Each participant in the intervention arm would receive a Microlife WatchBP Home device for self home blood pressure measurement. This tool has previously been validated as one that can accurately measure blood pressure in the home setting. [15]

5. **Study questionnaires**: patients in both arms would be asked to complete a SF 12 health survey, Moriasky scale: self reported adherence, self efficacy scale and also a questionnaire on knowledge/beliefs about hypertension.

6. **Recruitment of subjects**: Patients would be recruited by accessing a database of AIM clinic patients and identifying those with uncontrolled high blood pressure over the last six months. The PMD would be utilized to recruit their patients into the study, though these providers would be blinded as to what arm their patient is going into.

7. **Confidentiality of study data**: All patient information would be protected as per HIPAA regulations.

8. **Potential conflicts of interest**: There are no conflicts of interest

9. **Potential risks of study**: There are no particularly harmful risks of the study. The implied risk would include the risk of patients knowing their daily blood pressures.

10. **Potential benefits**: Mortality and morbidity benefits have been reported with better blood pressure control. Patients can feel a sense of ownership and be empowered with knowledge that they can be an active participant in their blood pressure control.

11. **Alternative therapies**: there are no alternative therapies being offered in this study.

12. **Compensation**: patients would not receive any compensation for their participation in the study.

13. **Cost to subject**: there will no costs to the participants in the study

References

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