Contemporary Clinical Trials Communications 8 (2017) 234–240

Contents lists available at ScienceDirect

Contemporary Clinical Trials Communications

journal homepage: www.elsevier.com/locate/conctc

Matão Controlling Hypertension (MatCH) project: Rationale and design

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ARTICLE INFO

Keywords:
Hypertension
Awareness
Blood-pressure control
Population community-based study

ABSTRACT

Background: Hypertension is the main risk factor for most cardiovascular diseases. A coordinated and organized system from the Brazilian Ministry of Healthy involving Family Health Strategy (FHS), a program for the prevention of chronic disease, and the Popular Pharmacy Program (PPP), which subsidizes medications for the population, could allow an earlier identification and better blood pressure (BP) control. Matão Controlling Hypertension (MatCH) is a community-based population project that aims to apply an organized, integrated and coordinated program in the city of Matão, Brazil, involving FHS and PPP in order to actively search, treat and follow-up hypertensive subjects.

Method: This is a population community-based, interventional, follow-up study where all subjects aged ≥ 40 years assisted by the FHS program in Matão will have BP assessed monthly by trained Community Health Agents (CHA) during a domiciliary visit. Identified hypertensive subjects will be referred to FHS physicians for non-pharmacological and pharmacological treatment. Most of the hypertensive drugs used will be available through the PPP. Prevalence of hypertension, awareness, demographics and risk factors will be correlated with BP control. The population study is expected to involve approximately 18.600 subjects. The study period will be four years.

Discussion: Considering that hypertension is asymptomatic in most cases, to reduce the population burden of BP-related deaths and diseases it is essential to detect and treat early all hypertensive patients. If we achieve our large-scale BP control, this program can be applied to other populations from developing countries.

1. Introduction

Hypertension is the main risk factor associated with the global burden of disease and mortality [1] due to its close association with cardiovascular diseases such as myocardial infarction and stroke, the two leading causes of mortality in the world.

Previous studies have demonstrated that low blood pressure (BP) levels were continuously associated with lower risks of fatal coronary heart disease and fatal stroke [2–4]. Also, the treatment of hypertension has been shown to reduce, on average, the incidence of stroke by 35–40%, the incidence of myocardial infarction by 20–25%, and the incidence of heart failure by more than 50% [5].

Despite clear evidence that hypertension is a major cardiovascular risk factor and that BP lowering is effective to reduce deaths and diseases, a large proportion of hypertensive subjects are not aware of their condition, or, if aware, do not undergo treatment, and target BP levels are seldom achieved regardless of whether treatment is prescribed or not [6].

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https://doi.org/10.1016/j.conctc.2017.10.007
Received 9 June 2017; Received in revised form 20 October 2017; Accepted 23 October 2017
Available online 28 October 2017

Abbreviations

BP	Blood Pressure
DBP	Diastolic blood pressure
SBP	Systolic blood pressure
FHS	Family Health Strategy
CHA	Community health agents
PPP	Popular Pharmacy Program

Although the prevalence of hypertension is falling in high-income settings due to better preventive and management programs, the opposite has been observed in low- and middle-income countries. While the expectation in higher income regions is a number of hypertensive individuals predicted to grow by 70 million people from 2000 to 2025, in lower-income regions, the number is predicted to grow by 500 million over the same period [7].

A decrease in cardiovascular disease mortality has been observed in the wealthiest regions of Brazil (South, South-East and Midwest), whereas an increase has been observed in the poorest Northeast and North regions [8]. This phenomenon could be attributed to some public healthy preventive programs such as the Family Healthy Strategy (FHS) [9] and the Popular Pharmacy Program (PPP) [10], both supported by the Brazilian Ministry of Healthy. FHS is focused on a community-based approach to providing primary health care. Physicians, nurses, and community health agents (CHA) visit residents in their homes to prevent complications and to take care of chronic diseases. CHA visit each household within their micro-area at least once a month and collect individual data. The PPP has been created by the government to improve the access of the Brazilian population to medications, including antihypertensive drugs.

Our research group carried out a pilot study in Matão city, São Paulo state, Brazil, involving a population of 1434 subjects aged ≥40 years assisted by the FHS program [11]. The results revealed the presence of almost 70% hypertensive subjects, 80% of whom were aware of their hypertension. BP control were observed in 38,2% which is low when compared with ranges of 43,7% to 67,5%, according to a recent Brazilian meta-analysis of BP control [12]. Another important result was that a project involving CHA from FHS measuring BP in order to identify hypertensive subjects is feasible.

Therefore, the purpose of the Matão Controlling Hypertension (MatCH) project is to apply an organized, integrated and coordinated program of all health services in Matão, mainly involving FHS and PPP, for an earlier identification of hypertensive individuals, followed by treatment and follow-up in order to improve their BP control.

1.1. Objective

1 To identify hypertensive subjects aged ≥35 years in a defined population.
2 To control BP in this population by the optimization of the local public health system.

1.2. Hypothesis

A BP control in 60% of hypertensive subjects, can be obtained with an integrated and coordinated hypertension detection and control system involving the Family Healthy Strategy (FHS), Popular Pharmacy Program (PPP) and local public health services in a defined Brazilian population.

2. Methods

2.1. Study design

This will be a population-based, interventional, follow-up study.

2.2. Inclusion and exclusion criteria

All consented subjects aged ≥35 years, belonging to FHS and residing in Matão will be included. Subjects without these criteria will be excluded.

2.3. Study period

Four years.

2.4. Primary outcomes

Prevalence of hypertension at initial assessment, defined as number of subjects with the diagnosis of hypertension/number of subjects assessed.

Percentage of controlled BP at initial assessment and at the end of the study defined as number of subjects with SBP < 140 mmHg and DBP < 90 mmHg/number of subjects with diagnosis of hypertension.

2.5. Secondary outcomes

Correlation of demographics, risk factors and end organ diseases with hypertensive subjects, at initial assessment and with controlled BP subjects at the end of the study.

2.6. Study setting

The study will be conducted in Matão, Brazil, a city located in São Paulo state, in the Brazilian southwest, 300 km northwest to the state capital. According to the 2010 Brazilian census, the Matão population was 76,786 and the estimate for 2017 was 81,878 inhabitants, with no difference in sex distribution [13]. The economy is mainly based on industrial activities and on general services. Ethnicity is diverse, but most people are of Caucasian origin, descendants of European immigrants. The population is urban and stable, with a low rate of interurban migration. About 95% of all dwellings have piped water, a sewage network and electricity.

The public health system of Matão is well organized. As is the case for most Brazilian cities, Matão has FHS. There are 12 FHS in the city covering a population of 44.850 people, representing about 57% of the whole population [14]. The city also participates in the PPP.

There is only one hospital in the city, Carlos Fernando Malzoni Hospital, which serves the whole Matão population and two other small towns. The local health services count on 75 physicians who take care of public and private patients, six of them cardiologists and 32 general practitioners. Most of these physicians work at Hospital Carlos Fernando Malzoni and are responsible for primary care in public and private offices.

2.7. Study population

The 2010 Brazilian census indicated that 34.901 Matão inhabitants were ≥35 years old, representing 45% of the total population [13]. Considering a population of 41,400 covered by FHS, 45% of ≥35-year-old subjects represent a study population of about 18.600 subjects. The reason to include a population aged ≥35 years is justified by the fact that, according to Brazilian Ministry of Health, the prevalence of hypertension in Brazil is almost 20% among subjects aged ≥35 years [14].

2.8. BP assessment

BP will be measured by the CHA using automated devices validated by the European Society of Hypertension (ESH) international protocol [15]. The CHA will be trained to measure BP properly according to the following protocol: BP will be measured in both arms; if the readings are different, the arm with the higher reading will be used for subsequent measurements made 1–2 min apart and the average of these measurements will be considered. A wider cuff will be used for patients with an arm circumference of more than 32 cm. The patient's arm being used for the measurement will be at the same level as the heart. BP will be measured after the patients empty their bladders, with no smoking during the last 30 min. The patients will sit with their backs supported and with their legs resting on the floor in the uncrossed position for 5 min [16].

2.9. Hypertension diagnosis, classifications and definitions

The diagnosis of hypertension will be confirmed if systolic blood pressure is ≥ 140 mmHg or diastolic pressure is ≥ 90 mmHg, or both, in two different measurements separated by about 30 days or if subject is taking anti-hypertensive medication [16].

Hypertension will be classified as stage 1, 2 a 3 according the table below:

Controlled BP will be defined as systolic blood pressure < 140 mmHg and diastolic blood pressure < 90 mmHg among hypertensive subjects.

2.10. Follow-up

The BP of the study population will be measured monthly by CHA. If BP is above normal ranges and continues to be elevated at the second monthly measurement, the subject will be followed up by the FHS physician, through weekly appointments. If BP continues to be elevated, even with optimized treatment, the subject will be referred to and followed up by the cardiologist from the public health service connected to FHS. The monthly BP values obtained will be inserted in a data base and software developed by our research team. This software will identify subjects with BP values above the targets and a message will be sent to the FHS nurse coordinator who will refer the patient to appropriate management. Fig. 1 describes the selection and follow-up process.

2.11. Subject evaluation

Subject data will be collected with a structured questionnaire about age, gender, years of education, previous history of hypertension, stroke, coronary artery disease, chronic kidney disease, diabetes mellitus, peripheral artery disease, dyslipidemia, alcohol abuse, smoking, and physical activity.

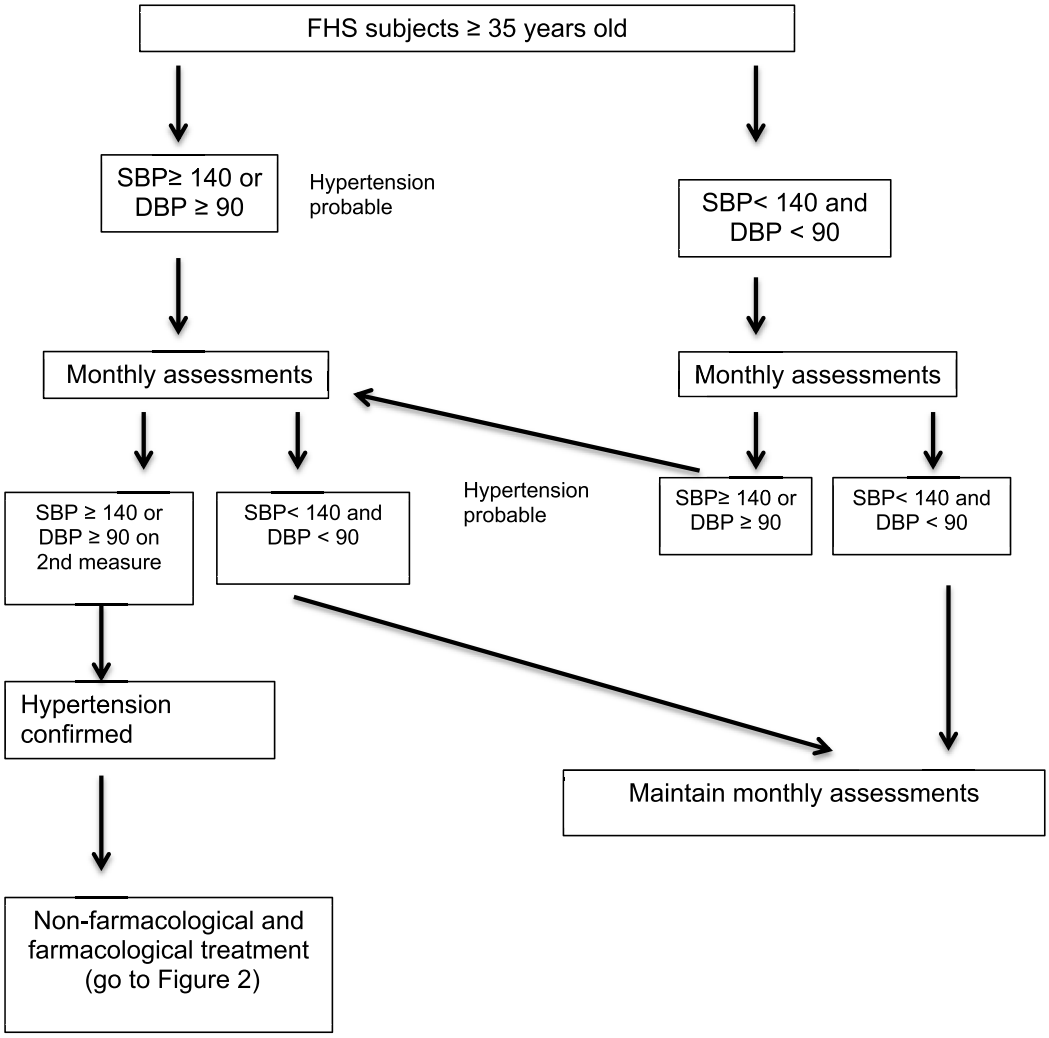

Fig. 1. Flow chart of the MatCH project describing selection and follow-up process. FHS: family healthy strategy; SBP: systolic blood pressure; DBP: diastolic blood pressure; BP: blood pressure.

2.12. Risk factor definition

Hypertension awareness will be defined if the subject had previous knowledge of a diagnosis of hypertension. A self-reported history of diabetes mellitus and chronic kidney disease will be used to define diabetes mellitus and chronic kidney disease. A previous history of stroke will be used to define ischemic or hemorrhagic stroke. Coronary disease will be defined as a history of angina or myocardial infarction. Peripheral artery disease will be defined as a history of intermittent claudication and peripheral disease. Smoking status will be defined as never or current smoker, i.e., individuals who smoked any tobacco in the previous 12 months. Alcohol use will be defined as current alcoholism with the consumption of at least 30 g of ethanol for men (equal to approximately two 365 mL cans of beer, two 150 mL glasses of wine, or two 50 mL doses of whiskey) and 15 g of ethanol for women (the equivalent of half the doses described for men) at least three times a week. Dyslipidemia will be considered if a subject is using any hypolipidemic drug or had a previous diagnosis of dyslipidemia. Physically active individuals will be defined as being regularly involved in walking, ciclying, running, swimming or other activities 4 h or more per week.

2.13. Treatment of hypertension

The treatment of hypertension will be based on the recent VII Brazilian Guidelines of Arterial Hypertension [17,18].

2.13.1. Nonpharmacological treatment

All hypertensive patients will be counseled to initiate life style changes. They will receive verbal and written orientations regarding weight loss, salt reduction, exercise, reduced alcohol consumption, smoking cessation, and the introduction of more fresh fruits and

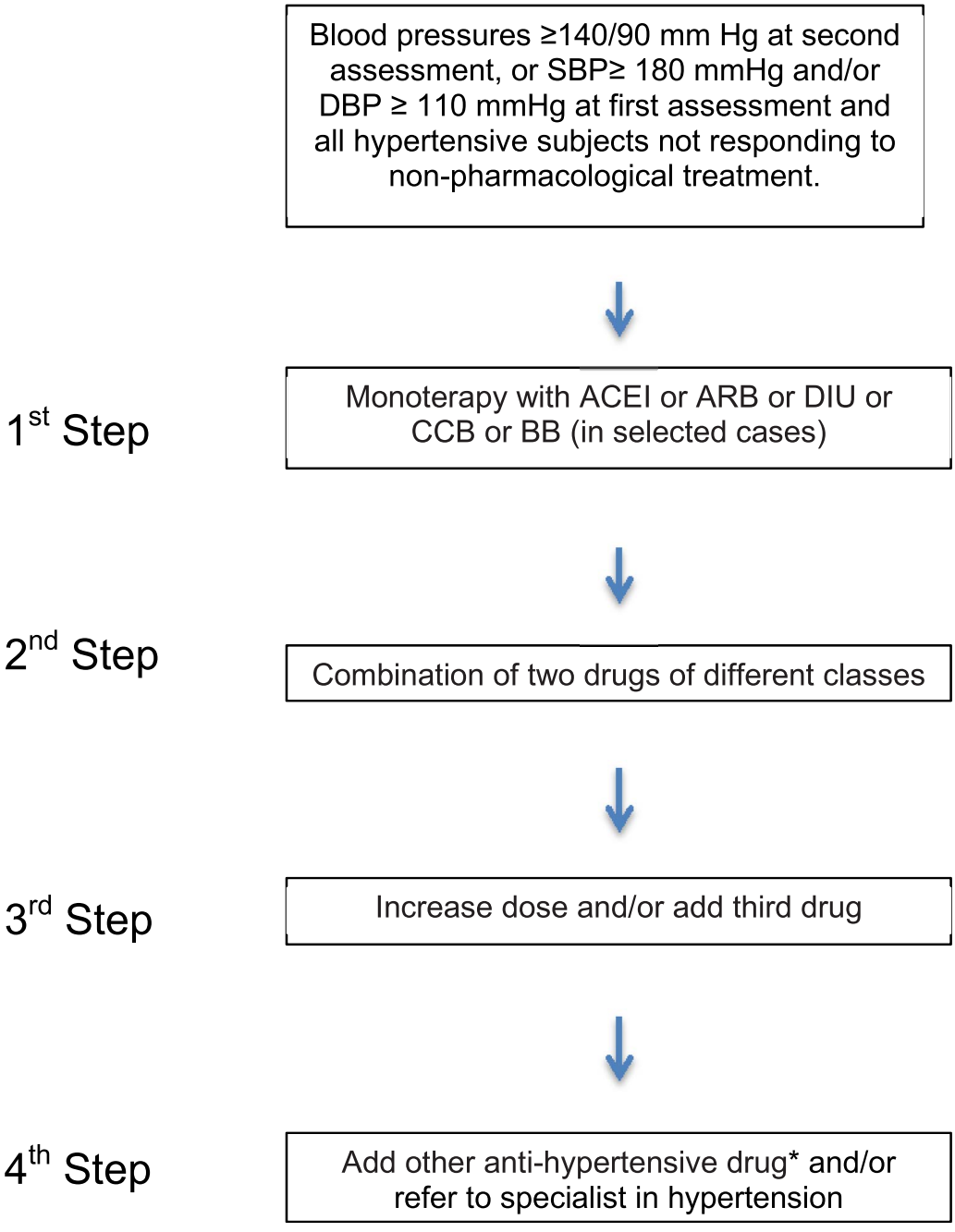

Fig. 2. Summary of pharmacological treatment. ACEI = angiotensin-converting enzyme inhibitors. ARB = angiotensin receptor blocker. CCB = calcium channel blockers. DIU = diuretics (hidroclortiazide and chlortalidone) BB = Beta-blockers. * Other anti-hypertensive drug = central a-agonists, loop diuretic, clonidine, spironolactone, hydralazine.

vegetables in their diets.

2.13.2. Pharmacological treatment

Drug treatment will be started for subjects with BP ≥ 140/90 mm Hg at second assessment, those with SBP≥ 180 mmHg and/or DBP ≥110 mmHg at first assessment and all hypertensive subjects that are not responding to nonpharmacological treatment.

In a first step, the first lines of anti-hypertensive medication will be the angiotensin-converting enzyme inhibitors (ACEI) captopril and enalapril, or the angiotensin receptor blocker (ARB) losartan, or calcium channel blockers (CCB), nifedipine, diltiazem and verapamil, or diuretics, the thiazide-type diuretic hydrochlorthiazide or chlortalidone, or beta-blockers, atenolol, in selected cases. In a second step, if BP is not controlled, a combination of two drug classes will be tried. If BP is not achieved, in a third step, a third drug class will be added. All of these anti-hypertensive drugs are available in the PPP (36). In a fourth step, when BP control is not yet obtained, other antihypertensive drugs will be requested from the city public health department, preferably low costs drugs such as clonidine, spironolactone, hydralazine and amlodipine. During this phase, a consultation with a hypertension specialist physician will be provided. The combined use of ACEI and ARB will be avoided. For individuals with chronic kidney disease, initial antihypertensive treatment will include an ACEI or ARB. This includes all chronic kidney disease patients with hypertension independent of diabetes and race. Fig. 2 shows the steps of pharmacological treatment.

2.14. Ethical approval

The project was approved by the Ethics Committee of Universidade de Araraquara, which is accredited by the Office of Human Research Protections as an Institutional Review Board, process nº 1.985.885. All participants will give written informed consent to participate.

This project is registered with ClinicalTrials.gov number NCT03147092.

2.15. Statistical analysis

The sample size of 18.630 subjects is justified by the objective of this study which is to analyze the impact of a BP control program, on a whole population aged ≥35 years old, covered by FHS.

At first assessment, a binary variable answer (dependent variable) will be obtained, i.e., if subject is hypertensive or not. Demographics, risk factors and presence of end organs diseases will be the independent variables. Binary logistic regression will be used to verify the simultaneous influence of each independent variable. According to the first analysis, a multinomial logistic regression will be used to verify the effect of the independent variable when compared with each stage of hypertension (Table 1). The option for logistic regression is because it can measure the effect size. To compare all BP measures during the follow-up will be used the mixed-model repeated measures analysis of variance. In specific situations where the univariate test will be applied, the level of significance of 5% will be considered after Bonferroni adjustment (0,05/number of tests performed).

3. Discussion

The World Health Organization and the World Bank have recognized the importance of BP–related diseases not only as a cause of premature death and disability but also as a threat to social and economic development [19,20]. This issue is relevant mainly for low- and middle-income countries.

Large-scale epidemiological studies have clearly demonstrated the enormous impact of nonoptimal BP levels on the risks of major cardiovascular events in both higher- and lower-income regions [21,22]. Those analyses have shown that approximately two thirds of all strokes and half of all coronary diseases can be attributed to nonoptimal BP [23].

In order to reduce the enormous burden of BP-related deaths and diseases, it is essential to detect and treat early all hypertensive patients. Furthermore, target BP levels recommended by current guidelines for the treatment of hypertension should be achieved.

Hypertension awareness in Brazil ranges from half to more than two thirds of the population. Although in some Brazilian regions BP control was reported in 67,5% [13], in most part of the country, BP control is reached in less than 40% of the hypertensive population [24–26]. A better BP control would be expected in Brazil as the Brazilian FHS covers most of the country. In the United States, awareness is 60.6% but only 46.5% of the population has BP control [27]. Again, a better BP control would be expected in the United States population, where almost 90% of adults with uncontrolled hypertension usually have a source of health care and medical insurance [27].

Just considering BP control, the Brazilian and US health services are examples that the simple availability of health care assistance is not sufficient to reach a better BP control rate in the whole population.

Although in Brazil CHA have the obligation to assess, record, and follow up BP in a coordinated and organized system [28], this is not done routinely in practice. A coordinated and organized system could allow a better identification and BP control of hypertensive subjects. Therefore, we assume that a program directed at BP control involving FHS, PPP and other integrated local public health services could be more successful for BP control.

We believe that, only population campaigns about hypertension and, spontaneous demand based on the desire of hypertensive subjects themselves to take care of a disease that does not cause suffering or short-term harm, will not be sufficient to produce better results regarding BP control. For a better population BP control we need to concentrate efforts on an active search of hypertensive individuals and on their treatment with a permanent vigilance system and follow-up.

Previous studies have suggested that community interventions that have included BP monitoring in a non-clinical setting and utilized community resources show promising results regarding the reduction and control of BP among hypertensive patients [29–32]. Community resources such as volunteers, health nurses, and local organizations are underutilized to support disease prevention and primary health care. Synergy created by connecting family physicians, patients, peer volunteers and local resources can lead to better health outcomes for community residents [33].

Our proposal is in accordance with these studies, as it will be applied through local health services with the efforts involving the CHA, physicians and nurses from the FHS program. The method for BP assessment by CHA with an electronic device will prevent errors in BP values, since these devices provide more reproducible results than the auscultatory method and are not influenced by variations in technique or by observer bias [34].

Our project has many positive aspects. The local health care system has already been structured. No additional cost will be necessary regarding human resources or new buildings and most of the antihypertensive drugs are available at PPP [10,18]. Individuals aged ≥ 35 years will be included, so that it will be possible to identify and reduce earlier the risk of cardiovascular disease in hypertensive patients.

The possible disadvantage would be the high cost to reach a large population. However, the financial resources of FHS are the same as

Table 1
Hypertension classification.

Stage	SBP, mmHg	DBP, mmHg
1	140 to 159	90 to 99
2	160 to 179	100 to 109
3	≥180	≥110

those already implemented for five years. Also, considering that this study will be conducted on the wealthiest state in Brazil, the conclusions can not be extended to the other parts of the country. Not all recommended anti-hypertensive drugs will be immediately available for pharmacological treatment. However, evidence has been obtained showing that the magnitude of BP reduction achieved is a more important predictor of the cardiovascular benefits obtained than the drug choice [35].

Hypertension control on a large scale can be a challenge, with barriers attributed to patients, healthcare providers, health-care systems, and the silent nature of the disease [36], therefore some challenges are expected. Our pilot study [11], showed that in almost 50% of cases it was not possible to assess BP during CHA visits. Most of the subjects were out working and a minority refused to take BP assessment. An alternative to this problem is to make an appointment with these missing subjects at weekend. As provided on a legal work contract between municipality and FHS program, the CHA has a flexible time job and it is possible to change the hours of weekdays to weekend, without additional costs. Another challenge is to convince the target population to take their medications even if there are no hypertension-related symptoms. To achieve this goal, population strategies supported by communication media will be implemented, with concerned actions of local authorities in order to induce cultural changes, better treatment adherence and the adoption of a healthy lifestyle.

This present study proposal is a proof of concept. If we have success to show that it is feasible to control BP in 60% among hypertensive subjects in Matão, instead of actual almost 40%, using a system that already exists, with a coordinated, centralized and organized program directed at BP control, our model can be applied not only in other regions in Brazil, but also in other countries which has health programs similar with Brazilian FHS.

4. Conclusions

Matão Controlling Hypertension (MatCH) is a community-based population project that aims to apply an organized, integrated and coordinated program in the city of Matão, Brazil, involving Brazilian Ministry of Healthy programs in order to actively search, treat and follow-up hypertensive subjects in a large scale population. This project can identify hypertensive asymptomatic subjects and initiate an early treatment when indicated.

Funding

Neurologic Center of Research and Reabilitation (Centro Neurológico de Pesquisa e Reabilitação – Cenp Reab) and Hospital Carlos Fernando Malzoni.

Conflicts of interest

All authors have no conflicts of interest to report.

Authors' contributions

CM wrote the paper and designed the study.
All co-authors read and approved the final manuscript.

Acknowledgements

The authors would like to thank directory executive and administrative of Hospital Carlos Fernando Malzoni and Municipal Health Division of Matão.

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