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Effect of a combined intervention on the control of hypertension, in patients from primary care centers in Lisbon

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Efeito de uma intervenção combinada no controlo da Hipertensão Arterial, em doentes dos cuidados de saúde primários, em Lisboa

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Aos meus pais

À minha irmã

Ao Mica

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SUMMARY

Introduction: Although effective antihypertensive treatments have been developed in the last decades, 57.5% of the patients have uncontrolled blood pressure (BP), enforcing the need to develop better control strategies.

Study Objectives: The objective of the present study is to evaluate whether a combined intervention, which includes a tailored educational and behavioral component, improves BP control and medication adherence, compared to usual care.

Methods: This was a two-arm, randomized controlled trial, with three-month follow-up. Eligible patients had a diagnosis of hypertension, with a mean systolic blood pressure (SBP) ≥ 140 or diastolic blood pressure (DBP) ≥ 90 mmHg for the BP measurements from the previous 12-month period (SBP ≥ 130 or DBP ≥ 80 mmHg for patients with diabetes mellitus) and were taking no more than four antihypertensives. Eligible patients were randomly assigned to receive the education and behavioral intervention or usual care. The intervention was based on a tailored educational session and on a paper diary, developed to facilitate the registry of their BP levels and daily antihypertensive medication. Patients were advised to bring their diaries to each clinical visit, to be reviewed with the physician. The primary outcome was the change in the BP control from baseline to follow-up. We examined changes in SBP and DBP and in medication adherence as secondary outcomes.

Results: Of the 248 enrolled patients (Intervention=83; control=165), 198 patients completed the follow-up visit. At baseline, 33.7% of participants had controlled BP and 80.8% were adherent to antihypertensive medication. The control group contained more patients with diabetes (p=0.007) and a higher proportion of smokers (p=0.003). There were no differences in BP control after three months between the control and the intervention group (adjusted odds ratio (OR) 0.64; confidence interval (CI): 0.3-1.5; p=0.288). Mean BP decreased 6.45/4.73 and 5.47/2.7 mmHg in the control and intervention groups, respectively, with no differences between groups [p=0.679 (SBP) and p=0.166 (DBP)]. More intervention patients improved medication adherence, but

no group differences were observed at follow-up (adjusted OR 0.83; CI: 0.3-2.2; p=0.688). For patients with uncontrolled BP at baseline, the control group had a significantly greater reduction of SBP (-3.87mmHg, p=0.041) and DBP (-4.83mmHg, p=0.002) and a significantly higher improvement in BP control (adjusted OR 0.19; CI: 0.1-0.7; p=0.008) compared to the intervention group. In the sensitivity analysis, similar results to the primary analysis were observed.

Conclusions: This intervention did not lead to improvements in BP control or medication adherence. The high adherence and BP control rates at baseline, and the significantly higher proportion of patients with treatment changes in the control group, may explain why no intervention effect was observed.

Keywords: blood pressure; medication adherence; hypertension; intervention; primary care

RESUMO

Introdução: A hipertensão arterial é um dos mais importantes fatores de risco para as doenças cardiovasculares e apresenta uma elevada prevalência em Portugal. Apesar de, nas últimas décadas, terem sido desenvolvidas terapêuticas antihipertensoras eficazes, 57,5% dos hipertensos medicados não têm a sua hipertensão controlada, reforçando a necessidade de desenvolver estratégias para melhorar o controlo da pressão arterial em Portugal.

Diversas intervenções para melhorar a adesão em doentes hipertensos têm sido desenvolvidas e estudadas. O recurso a diários para preenchimento pelo doente hipertenso é uma ferramenta de autocontrolo utilizada para melhorar a adesão à terapêutica, promovendo um maior envolvimento e motivação do doente, além do facto de ser um meio de recordar a toma da medicação. A automonitorização da pressão arterial (em casa) pode ser efetiva na modificação da perceção do hipertenso face à sua pressão arterial, podendo, assim, incentivá-lo a cumprir melhor as modificações de estilo de vida e a toma da medicação. A combinação destas intervenções foi avaliada no projeto HyDia quanto à melhoria no controlo da pressão arterial, através da melhoria da adesão à terapêutica e conhecimento sobre a hipertensão e medicação antihipertensora e da facilitação da comunicação médico-doente quanto a esta patologia.

Objetivos: Inserido no projeto HyDia, o presente trabalho pretende analisar o efeito de uma intervenção combinada, que inclui uma componente educacional e comportamental, na melhoria do controlo da pressão arterial e da adesão à terapêutica, face aos cuidados de saúde habituais.

Métodos: O estudo HyDia é um ensaio clínico aleatorizado e controlado, sem ocultação e com três meses de seguimento dos participantes. Os participantes foram selecionados de centros de saúde/unidades de saúde familiar da região de Lisboa. Foram considerados como elegíveis, doentes hipertensos, com pressão arterial sistólica (PAS) ≥ 140 mmHg ou pressão arterial sistólica (PAD) ≥ 90 mmHg (PAS ≥ 130

mmHg ou PAD ≥ 80 mmHg para doentes com diabetes mellitus) nos 12 meses anteriores e a tomarem não mais do que quatro medicamentos antihipertensores. Foram excluídos do estudo indivíduos dependentes de terceiros para a toma da medicação, com problemas cognitivos, angina instável, doença renal ou hepática grave, insuficiência cardíaca grave, enfarte de miocárdio ou acidente vascular cerebral nos seis meses anteriores e grávidas. Os doentes elegíveis foram aleatoriamente designados para receber a intervenção educacional e comportamental ou cuidados habituais, na proporção de 1:2, respetivamente. A intervenção baseou-se numa sessão educacional adaptada ao perfil do doente e num diário em papel – Diário da Hipertensão – desenvolvido de forma a facilitar o registo das medições de pressão arterial e da medicação antihipertensora por parte dos doentes, de acordo com um protocolo predefinido. Os participantes do grupo intervenção receberam também um monitor Omrom® 6M e foi-lhes pedido que medissem a pressão arterial duas vezes por dia em dois dias da semana e que registassem os valores no diário. Os participantes foram aconselhados a levar os seus diários às consultas médicas, possibilitando a consulta e preenchimento pelo médico. Um mês e dois meses depois da sessão de intervenção, foram realizados telefonemas aos participantes com o objetivo de os encorajar a manter as alterações comportamentais e garantir que a intervenção estava a ser seguida de acordo com o protocolo. O outcome primário foi a alteração do controlo da pressão arterial. As alterações da PAS e PAD e da adesão à medicação foram analisadas como outcomes secundários.

Resultados: Entre janeiro de 2012 e março de 2013, foram selecionados um total de 554 indivíduos potencialmente elegíveis para o estudo dos seis centros de saúde/unidades de saúde familiar participantes. Destes, 86 (15,5%) estavam incontactáveis, 65 (11,7%) não preenchiam os critérios de inclusão e 148 (26,7%) recusaram participar. Dos 255 participantes incluídos no estudo, 85 foram colocados no grupo de intervenção e 170 no grupo controlo (cuidados habituais). Após a entrevista inicial, sete participantes foram excluídos (três não estavam a tomar medicação antihipertensora e quatro participantes estavam a tomar mais do que quatro medicamentos antihipertensores diferentes). Do total de 248 participantes com avaliação inicial, 198 participantes completaram a entrevista de seguimento. Na

entrevista inicial, não foram observadas diferenças significativas entre os grupos, exceto em relação à proporção de participantes com diabetes e à proporção de participantes fumadores, que foi significativamente superior no grupo controlo. Um total de 64 (33,7%) participantes tinham a sua pressão arterial controlada e 160 (80,8%) eram aderentes à terapêutica antihipertensora. Aos três meses verificou-se que a proporção de doentes com a pressão arterial controlada aumentou significativamente em ambos os grupos. Contudo, esse aumento não diferiu entre os grupos intervenção e controlo, mesmo após o ajuste para a covariáveis (OR 0.64; intervalo de confiança (IC): 0.3-1.5; p=0.288). Entre a entrevista inicial e a entrevista de seguimento, a PAS foi reduzida em 6,5 mmHg no grupo controlo (p <0,001), e 5,5 mmHg no grupo de intervenção (p = 0,004). As correspondentes reduções na PAD foram 4,7 mmHg (p <0,001), e 2,7 mmHg (p = 0,020), no grupo controlo e intervenção, respetivamente. Contudo, não se observaram diferenças significativas na redução da PAS e da PAD entre os grupos, mesmo após ajuste para as covariáveis [p=0.679 (PAS); p=0.166 (PAD)]. Verificou-se um maior aumento da proporção de aderentes no grupo de intervenção entre os momentos de avaliação, contudo não foram observadas diferenças significativas entre os grupos (OR ajustado 0.83; IC: 0.3-2.2; p=0.688). Porque o objetivo do estudo era aplicar a intervenção em doentes com hipertensão não controlada, as análises foram repetidas no subgrupo dos participantes com pressão arterial não controlada na avaliação inicial (66.3%). Para este subgrupo verificou-se que a pressão arterial passou a estar controlada num número significativamente superior de participantes do grupo controlo comparativamente ao grupo de intervenção, com um OR de 0.19 (IC 0,1-0,7) após ajuste para as covariáveis. Também para este subgrupo se verificaram reduções na PAS e PAD em ambos os grupos. Contudo, após ajuste para as covariáveis, a redução no grupo controlo foi significativamente superior ao do grupo intervenção tanto para a PAS (p=0.041) como para a PAD (p=0.002). À semelhança do que se observou para a amostra total, verificou-se uma tendência para o aumento da adesão à terapêutica antihipertensora no grupo intervenção. Contudo, a proporção de aderentes à terapêutica não foi significativamente superior no grupo de intervenção comparativamente ao grupo controlo aos três meses (OR ajustado 0.88; IC: 0.3-2.6; p=0.814). Para avaliar a robustez dos resultados, através de uma análise de sensibilidade, o efeito da

intervenção no outcome primário (controlo da pressão arterial) foi re-estimado de acordo com quatro cenários: (1) análise por "intenção de tratar"; (2) considerando todos os participantes perdidos para follow-up como não controlados na entrevista de seguimento; (3) excluindo os participantes com mais de 4,5 meses entre a entrevista inicial e a entrevista de seguimento; e (4) considerando as novas recomendações da Sociedade Europeia de Hipertensão e Sociedade Europeia de Cardiologia para o controlo da hipertensão nos hipertensos com diabetes mellitus (PAS <140 mmHg e PAD <85 mmHg). Na análise se sensibilidade foram observados resultados semelhantes à análise primária, confirmando assim a robustez dos resultados.

Conclusão: Esta intervenção educacional e comportamental não conseguiu aumentar o controlo da pressão arterial e da adesão à terapêutica no grupo de intervenção comparativamente ao grupo controlo. Apesar da pressão arterial ter sido significativamente reduzida entre os dois momentos, tanto aqueles que receberam a intervenção como os que não receberam, beneficiaram do estudo. A elevada proporção de aderentes e de controlados na avaliação inicial, bem como a proporção significativamente superior de participantes com alterações da medicação no grupo controlo, pode explicar porque é que não foram observados efeitos da intervenção.

Palavras-chave: pressão arterial; adesão à terapêutica; hipertensão; intervenção; cuidados de saúde primários

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ABBREVIATIONS

ACEI	Angiotensin-converting Enzyme Inhibitor
ACES	Health Centers Groups
AHT	Antihypertensive
ARB	Angiotensin Receptor Blocker
BMI	Body Mass Index
BP	Blood Pressure
CI	Confidence Interval
CV	Cardiovascular
CVD	Cardiovascular Diseases
DALY	Disability-adjusted Life Year
DBP	Diastolic Blood Pressure
DGS	Directorate-General of Health
ESC	European Society of Cardiology
ESH	European Society of Hypertension
GP	General Practitioner
HBM	Health Belief Model
HBPM	Home Blood Pressure Monitoring
HTN	Hypertension
IMB	Information-motivation-behavioral
IC	Intervalo de Confiança
ITT	Intention-to-treat
JNC	Joint National Committee
LDL	Low-density Lipoprotein
MPR	Medication Possession Ratio
NAMCS	National Ambulatory Medical Care Survey
NHANES	National Health and Nutrition Examination Survey
OR	Odds Ratio
PAS	Pressão Arterial Sistólica
PAD	Pressão Arterial Diastólica
PMT	Protection Motivation Theory
PYLL	Potential Years of Life Lost

RCT	Randomized Controlled Trial
SBP	Systolic Blood Pressure
SCT	Social-cognitive Theory
SD	Standard Deviation
TPB	Theories of Planned Behavior
TRA	Theory of Reasoned Action
UK	United Kingdom
US	United States
WHO	World Health Organization

Chapter 1

INTRODUCTION

Cardiovascular diseases (CVDs) remain the leading cause of deaths worldwide. According to the World Health Organization (WHO), more than 17.3 million people died from CVDs in 2008, nearly one third of the total deaths (1). In Portugal, despite significant declines in CVD death rates throughout the last two decades, CVDs continue to account for more deaths per year than any other cause of death (2). Furthermore, between 2002 and 2010, cerebrovascular diseases (24,109 - 13,960 years) and ischemic heart diseases (24,900 - 13,845 years) remained the most significant causes of Potential Years of Life Lost (PYLL) avoidable through healthcare in Portugal (3).

Hypertension (HTN) is the highest attributable risk factor for coronary heart disease and cerebrovascular disease (4). Blood pressure (BP) levels have been shown to be positively and progressively related to the risk of stroke and coronary heart disease (4). In some age groups, the risk of CVD doubles for each incremental increase of 20/10 mmHg of BP, starting as low as 115/75 mmHg (4). In addition to coronary heart disease and cerebrovascular disease, uncontrolled BP causes heart failure, renal impairment, peripheral vascular disease, damage to retinal blood vessels and visual impairment (4).

Approximately, 35% of strokes (5) and 18% of myocardial infarctions (6) are attributable to high BP. The negative impact of HTN on health status is clear, especially taking into account the morbidity, reduced quality of life, and mortality associated with stroke and CVD. HTN is estimated to cause 7.5 million deaths, about 12.8% of the total of all annual deaths, accounting for 57 million Disability-adjusted Life Years (DALYS) or 3.7% of total DALYS (1).

A. PREVALENCE OF HYPERTENSION

In 2008, worldwide, approximately 40% of adults aged 25 and above were diagnosed with HTN; the number of people with this condition rose from 600 million in 1980 to 1 billion in 2008 (1). In Europe, the prevalence of HTN appears to be approximately 30-40% of the general population (7).

In Portugal, the impact is no less impressive. According to a study from Espiga de Macedo et al. (2007) (8), 42.1% of the Portuguese adult population aged 18 to 90 years has HTN, representing 3,311,830 people (8). Similar results were found in a recent

study from Polonia et al. (2014) that reported an overall prevalence of HTN of 42.2% in the Portuguese adult population (9).

B. DEFINITION AND CLASSIFICATION OF HYPERTENSION

National and international guidelines define HTN as having SBP ≥ 140 mmHg and/or a DBP ≥ 90 mmHg (7, 10). The diagnosis of HTN in adults is made when the average of two or more DBP measurements on at least two subsequent visits is ≥90 mmHg, or when the average of multiple SBP readings on two or more subsequent visits is ≥140 mmHg (7, 10). Table 1 provides a classification of BP for adults 18 years and older.

Table 1: Definitions and classification of office BP levels

Category	**Systolic** (mmHg)		**Diastolic** (mmHg)
Optimal	<120	and	<80
Normal	120-129	and/or	80-84
High normal	130-139	and/or	85-89
Grade 1 HTN	140-159	and/or	90-99
Grade 2 HTN	160-179	and/or	100-109
Grade 3 HTN	≥180	and/or	≥110
Isolated systolic HTN	≥140	and	<90

C. BLOOD PRESSURE GOALS IN HYPERTENSIVE PATIENTS

The 2007 European Society of Hypertension (ESH)/European Society of Cardiology (ESC) Guidelines (11), recommended two distinct BP targets, namely, below 140/90 in low, moderate risk hypertensives and, below 130/80 mmHg in high-risk hypertensives (with diabetes, cerebrovascular, cardiovascular (CV), or renal disease). The 2013 ESH/ESC Guidelines (7) follow the same recommendation for the low, moderate risk hypertensives. However, a careful review of the available evidence, led to the re-appraisal of the recommendations in some high-risk groups.

Hypertension in the elderly

Evidence from several randomized controlled trials (RCT) of antihypertensive (AHT) treatment in the elderly, show that, it may be difficult to achieve SBP values of <140 mmHg (7). Moreover, different studies have found contradictory evidence around the benefits of lowering the SBP below 140 mmHg in these patients (7). Therefore, the 2013 ESH/ESC Guidelines recommend reducing SBP to between 150 and 140 mmHg in elderly hypertensives less than 80 years old with a SPB ≥ 160 mmHg (7). In individuals older than 80 years and with an initial SBP of ≥160 mmHg, it is recommended reducing SBP to between 150 and 140 mmHg provided they are in good physical and mental condition (7).

Patients with diabetes mellitus

Evidence reviewed in the 2013 ESH/ESC Guidelines (7) supports that lowering BP is associated with important reductions in CV events in patients with diabetes mellitus. The beneficial effect is seen from DBP reductions to between 80–85 mmHg, whereas SBP was ever reduced below 130 mmHg in any trial (7). Therefore, the guidelines recommend a SBP goal of <140 mmHg and a DBP target of <85 mmHg in patients with diabetes. It should nevertheless be considered that DBP values between 80 and 85 mmHg are safe and well tolerated.

D. HYPERTENSION CONTROL

In the last years, several RCTs have demonstrated the benefits of lowering BP to target levels in the reduction of CV morbidity and mortality (12-15).

A recent meta-analysis estimated that a reduction in BP is associated with a reduction in the risk of stroke of about 36%, 43% for the risk of heart failure and a reduction in all-cause mortality of about 11% (15). Despite the benefits of BP control, only a small proportion of hypertensive patients achieve the target BP of less than 140/90mmHg.

In Polonia et al. study (9), 76.6% of the hypertensive subjects were aware of their HTN condition and 74.9% were receiving pharmacologic treatment. In the overall hypertensive population, 42.5% of hypertensive subjects had their BP controlled

(<140/90 mmHg) and, among the patients treated with AHT medication, 55.7% had their HTN controlled (9).

These results underscore the urgent need to develop national strategies to improve prevention, detection, and treatment of HTN in Portugal (8).

In response to this recognized problem, the Portuguese Directorate-General of Health (DGS) defined the National Program for Cerebro- cardiovascular Diseases as one of the National Priority Programs (16).

E. PUBLIC HEALTH IMPLICATIONS OF UNCONTROLLED HYPERTENSION

The high prevalence of uncontrolled HTN suggests that a substantial number of CV events could be prevented by improved BP control (17). Several studies have attempted to quantify the societal cost of uncontrolled HTN in clinical and financial terms. He et al. (18) estimated that in the United Kingdom (UK) approximately a third of stroke and a third of ischemic heart disease could be prevented if all hypertensive individuals had their BP controlled. Moreover, controlling all hypertensive individuals to a SBP of 140 mmHg would prevent approximately 21,400 stroke deaths and 41,400 ischemic heart disease deaths each year in the UK (18). Using the National Health and Nutrition Examination Survey (NHANES) 2001-2002 data, Lopez and colleagues (19) estimated that control of BP to normal levels (<140/90 mmHg) would prevent 19% and 20% of coronary heart disease events in men and women, respectively. If BP was controlled to optimal levels (<120/80 mmHg), 33.6% of coronary heart disease events in men and 47.9% of coronary heart disease events in women could be prevented (19).

F. FACTORS ASSOCIATED WITH INADEQUATE HYPERTENSION CONTROL

Poor control is determined by both the patient's characteristics and physician's related factors (17, 20-25). Provider's practice habits, particularly the reluctance to intensify treatment, have been implicated in the failure to meet BP goals in a higher percentage of the general population (23). Patient's adherence with treatment is also a major

contributor to the short- and long-term outcomes of treatment (23). Other patient's characteristics such as age, sex, race, access to healthcare, socioeconomic status and comorbidities seem to contribute to the burden of uncontrolled HTN in the community (17).

The role of the healthcare provider

- **Clinical inertia**

Clinical inertia has been described as a physician's attitude of not intensifying medication regimens at encounters with patients who have uncontrolled risk factors (26).

The 2013 Task Force guidelines for the management of arterial hypertension of the ESH/ESC (7), recommend the use of AHT drugs in patients whose BP is ≥140/90 mmHg (if grade 2 or 3 HTN or grade 1 when total CV risk is high) and in elderly when SBP is ≥160 mmHg. Further, the guidelines state that no matter which drug is employed, monotherapy can effectively reduce BP in only a limited number of hypertensive patients and that most patients require the combination of at least two drugs to achieve BP control (7). The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood Pressure (JNC7) also emphasizes the need for treatment with at least two AHT drugs to attain BP control (27).

Despite these recommendations, physicians are often conservative in their approach, not making alterations to therapy even if BP remains elevated (20).

In a Wang and colleagues study (28), of 11,969 patients with inadequately controlled HTN, only 38% in the United States (US) and 15%-28% across European countries received any medication increase during the physicians visit. A study analyzing medical visits using the National Ambulatory Medical Care Survey (NAMCS) data from 2005 through 2009, showed that among 7,153 observations (representing 261 million visits) of patients with elevated BP and currently seeing physicians who usually manage BP, only in 19.5% of the visits was a new BP medication prescribed (29).

Okonofua and colleagues (30), showed that a 50% decrease in therapeutic inertia would increase BP control, from 45.1% to a projected 65.9% in one year.

Several factors are proposed to justify clinical inertia, including lack of confidence in the BP measurements (25, 31), disagreement with guidelines (17, 25), satisfaction with existing BP values (32), patient's overall health status (25), poor compliance (25, 31), and fear of adverse events (25, 31).

In a study by Ferrari and colleagues (31), in 16 countries in Latin America, Eastern Europe, Africa and Asia, the leading cause for unchanged treatment was the physician's perception that the time after starting the new drug was too short to assess its full effect.

In a study with Portuguese General Practitioners (GPs), the physicians declared that the BP measured at time of consultation was not representative of the usual BP if the self-measured values of BP were normal and that they were less likely to change the treatment of those patients who were non-adherent to the AHT treatment (33).

Reluctance of some physicians to adopt the SBP threshold recommended by the guidelines may contribute to reduced adherence to guidelines (17, 25). Some physicians may have a more permissive approach toward elderly patients with isolated systolic HTN (17). In the Nicodème and colleagues study (25), in about one third of the cases, physicians considered that the BP was satisfactory in the context of their patients' lives based on DBP alone.

Patient-related factors

Several patient characteristics have been associated with uncontrolled HTN. Some are risk factors for HTN itself and contribute directly to difficult BP control (17).

Non-modifiable risk factors

- **Age**

Age is a non-modifiable risk factor for HTN and is associated with the lack of BP control (34, 35). Hyman et al. (34) reported that an age of at least 65 years accounted for the greatest proportion of the attributable risk of uncontrolled HTN among patients

who were aware of their condition. Evidence indicates that age is more strongly associated with the increase in SBP than DBP (35).

- **Gender**

There have been conflicting data on the association of gender with hypertension control. In the study of Polonia and colleagues (9), higher percentages of awareness, treatment and control were observed in women more often than in men. However, in a study of Ong and colleagues (36), BP control in women was not significantly inferior compared with men. Several studies have found the male gender to be a significant predictor of poor BP control (34, 37, 38) but other studies reported a better control in men (39, 40).

- **Race/Ethnicity**

Race is related in a complex manner to HTN control because it might interact with a multiple of other factors, including access to care, susceptibility to HTN, response to AHT drug therapy and comorbid conditions such as obesity (17, 41). Ethnic disparities in HTN control are well documented in the US (42, 43). A cross-sectional analysis among 21,489 US adults participating in the NHANES survey (2001-2006) showed that, among hypertensive patients, African and Mexican Americans had 40% higher odds of uncontrolled BP compared to Caucasians after adjustment for socio-demographic and clinical characteristics (43). The racial-ethnic differences persisted even after further adjustment for modifiable health behaviors which included medication adherence. In Europe, racial/ethnic differences in BP control have also been described (44, 45). In a study of ethnic differences in BP control in London, marked ethnic differences were found with black patients significantly less likely to achieve BP targets than their Caucasian counterparts (45).

Modifiable risk factors

- **Obesity**

Obesity is highly prevalent in hypertensive patients and it is associated with poor BP control (35, 46-48). For every 10% increase in body weight, it has been estimated that

SBP increases by 6.5 mmHg (49). The increasing prevalence of obesity poses a great concern for the burden of HTN and HTN-related CVD (50). Patients with obesity-related HTN often have other co-morbidities that require lower BP goals and multidrug therapy is often necessary to achieve BP goals (50). BP responds to weight loss. In a meta-analysis of RCTs, an average net weight reduction of 5.1Kg was associated with a significant reduction in SBP of 4.44 mmHg and a significant reduction in DBP of 3.57mmHg (51). Unfortunately, despite multidrug regimens, BP remains uncontrolled in a high proportion of obese hypertensive patients (50).

- **Lack of exercise**

Lack of physical exercise is significantly associated with the persistence of elevated BP (18). Several studies demonstrated that higher levels of physical activity are associated with a decrease in SBP and DBP in hypertensive patients (52, 53). A recent meta-analysis showed that dynamic endurance training resulted in a mean BP decrease of 7.11 mmHg /5.15mmHg (54). Physical exercise also favorably affects other important CV risk factors including low-density lipoprotein (LDL) and total cholesterol, plasma triglycerides, peak oxygen uptake and body mass index (BMI) (52-54).

- **Dietary salt intake**

The evidence regarding the risks of excess salt consumption has been compelling. The causal relation between dietary salt intake and BP has been established through experimental and epidemiological studies (55). The evidence suggests that, for most individuals, the higher their sodium consumption, the higher their BP (56). On the basis of the results of a meta-analysis of RCTs that evaluated the effect of sodium intake on BP, it was estimated that a reduction of sodium intake of 40 mmol/day (≈2.3g salt/day) or more would be associated with reductions of 3.39 mmHg in SBP and 1.54 mmHg in DBP (57).

- **Alcohol**

The positive relationship between the amount of alcohol consumed and BP is one of the strongest associations of potentially modifiable risk factors for HTN (58, 59). The higher the alcohol intake, the higher the BP; more than an average intake of two drinks

per day (59, 60). This positive association usually persists after adjustment for important confounders such as age, BMI, smoking, exercise, and sodium and potassium intake (58, 59). Some studies demonstrated a "U" or "J"-shape relationship between alcohol consumption and BP, with light and moderate drinkers having lower BP levels that either nondrinkers or heavy drinkers (61-63).

A meta-analysis of RCTs conducted to examine the effects of alcohol reduction on BP showed that overall, alcohol reduction was associated with a significant reduction in mean [95% confidence interval (CI)] SBP and DBP of -3.31 mmHg (-2.52 to -4.10 mmHg) and -2.04 mmHg (-1.49 to -2.58 mmHg), respectively (59). A dose-response relationship was observed between mean percentage of alcohol reduction and mean BP reduction (59).

- **Smoking**

Smoking is one of the major independent risk factors for CVD and stroke, particularly in terms of its involvement in the initiation, and acceleration of the atherothrombotic process (64-68).

Cigarette smoking exerts an acutely hypertensive effect, mainly through the stimulation of the sympathetic nervous system (68). However, evidence on the impact of chronic smoking on BP is not consistent. In some studies, smoking was associated with a persistent increase in BP and was a risk factor for poor BP control (69-73). In other studies, a reduction/cessation of a smoking habit did not result in any significant change or produced a very small effect (74, 75).

- **Medication Non-adherence**

In patients with HTN, lack of medication adherence is a significant, often unrecognized risk factor that contributes to poor BP control (76). The WHO defined adherence as "the extent to which a person´s behavior – taking medication, following a diet, and/or executing lifestyle changes- corresponds with agreed recommendations from a health provider" (77).

Generally, it is estimated that adherence to long-term therapies averages only 50% (77). Patient's adherence with AHT drug therapy was reported to vary from 34% to 78% (78). In one US study, Hyre and colleagues (79), found that only 35.6% of the patients had good adherence defined as having a score of 8 in the 8-item Morisky Medication Adherence Scale. A cross-sectional survey conducted in the Eastern Central Region of Portugal reported that only 48.2% of patients were considered to be highly adherent to AHT medication (80). Most patients were long-term hypertensives, with 74.1% of patients taking AHT medications for at least 5 years (80). An Italian study found that newly diagnosed hypertensive patients are less likely to adhere to AHT medication, with only 8.1% of patients having an adherence level ≥ 80% (81).

Factors related to medication adherence

Medication adherence is a multidimensional behavior determined by the interplay of five dimensions: social and economic factors, healthcare team and system-related factors, condition-related factors, therapy-related factors and patient-related factors (77). Factors affecting adherence to the AHT drug treatment are listed in Table 2.

Table 2: Factors contributing to lack of AHT medication adherence

Category	Factors affecting medication adherence
Social and economic	Poor socioeconomic status; illiteracy; unemployment; limited drug supply; high cost of medication
Health care team and system-related	Lack of knowledge and training for healthcare providers on managing chronic diseases; inadequate relationship between the healthcare provider and the patient; lack of knowledge, inadequate time for consultations; lack of incentives and feedback on performance
Hypertension-related	Lack of symptoms; wrong perceptions about HTN; chronicity of the disease
Therapy-related	Complex treatment regimens; duration of treatment; low drug tolerability; adverse effects of treatment
Patient-related	Inadequate knowledge and skill in managing the disease symptoms and treatment; no awareness of the costs and benefits of treatment; non-acceptance of monitoring

The impact of non-adherence on outcomes

Inadequate adherence to AHT medication is associated with reduced treatment benefits. Data from a retrospective review of medical and pharmacy claims over a four-year period from 13 US health plans, showed that non-adherent patients are less likely to have their BP controlled (82). In this review, medication possession ratio (MPR) was used to classify patient adherence into high adherence (MPR=80-100%), medium adherence (MPR=50-79%) and low adherence (MPR<50%), and the results showed that high-adherence patients were 45% more likely to achieve BP control than those with medium or low adherence after controlling for age, gender, and comorbidities (odds ratio (OR) = 1.45; P = 0.026) (82).

Furthermore, non-adherence to AHT therapy has been associated with increased risk of mortality and morbidity. A study that evaluated the effect of AHT medication adherence on health outcomes found that non-adherence increased the risk of all adverse health outcomes, including all-cause mortality and hospitalization for CVD (83). Another study from Mazzaglia et al. (81) with 18,806 newly diagnosed hypertensive patients followed up in primary care, showed that high adherence to AHT treatment is associated with a 38% decreased risk of CV events compared with lower adherence.

Medication non-adherence increases health care service utilization and overall health care costs, leading to poor outcomes (84). A retrospective claims database analysis of patients discharged from the hospital with a primary diagnosis of heart failure or myocardial infarction revealed that adherence and persistence with angiotensin-converting enzyme inhibitors (ACEIs) or angiotensin receptor blockers (ARBs) were associated with lower healthcare costs and lower risk of re-hospitalization (85).

G. INTERVENTIONS TO IMPROVE ADHERENCE TO BLOOD PRESSURE LOWERING MEDICATION

Health behavior models

The most successful public health programs and initiatives to help people maintain and improve health, reduce disease risks, and manage illness, are usually based on an understanding of health behaviors and the contexts in which they occur (86). Understanding how illness representations affect health behaviors is particularly important when designing interventions to improve BP control and adherence to AHT medication (87). Firstly, since high BP is considered a silent or asymptomatic condition, how people come to identify it in themselves, is of special interest. Secondly, HTN requires the long-term adoption of a variety of prescribed behaviors, such as medication taking, and lifestyle changes. The perception and representation of HTN affects the adoption of lifestyle modifications and the way in which patients make decisions about their treatment (87). Both the asymptomatic quality and the long duration of HTN suggest that understanding the disease may be important in achieving long-term adherence to AHT and consequently BP control (87).

Leventhal and Cameron (88) outlined five general theoretical perspectives on adherence: 1) biomedical, 2) behavioral, 3) communication, 4) cognitive, and 5) self-regulatory. Each perspective encompasses several theories. More recently, the stage perspective has emerged, which includes the transtheoretical model. The most commonly used theories are those within the cognitive perspective and the transtheoretical model (89).

- **The biomedical perspective**

The biomedical approach to adherence assumes that patients are passive recipients of physicians' instructions (89). Non-adherence is understood in terms of characteristics of the patient (personality traits, sociodemographic background), and patient factors are seen as the target of efforts to improve adherence (77). This approach has helped to elucidate the relationships between disease and treatment characteristics on the

one hand, and adherence on the other (77). Technological innovations (e.g. assessing levels of adherence using biochemical measures, developing new devices to administer medications) are sometimes rooted in this perspective (77, 89). However, despite its implicit use by many health professionals, this perspective is not frequently used explicitly in interventions. A fundamental limitation of this theory is that it ignores other important factors, for example, patients' perspectives of their own illness; psycho-social influences; and the impacts of the socio-economic environment (89).

- **Behavioral (learning) perspective**

Behavioral (learning) theory emphasizes the importance of positive and negative reinforcement as a mechanism for influencing behavior, and this has immediate relevance for adherence (77).

The likelihood of a patient following a specific behavior will partially depend on internal (thoughts) and external factors (environmental cues), while consequences in the form of punishments or rewards will discourage or encourage such behavior (90). From a theoretical standpoint, it would be possible to “control” the behavior of patients, if one could control the events preceding and following a specific behavior. From a practical standpoint, behavioral principles can be used to design interventions that have the potential to incrementally shape behavior at each level of influence (i.e. patient, provider and system) to address adherence problems (77).

- **Communication perspective**

This perspective suggests that improved provider-patient communication will enhance adherence and implies that this can be achieved through patient education and good health communication skills (89). This led to an emphasis being placed on the importance of developing rapport, educating patients, employing good communication skills and stressing the desirability of a more equal relationship between patient and health professional (77). Critiques of this perspective argue that it ignores attitudinal, motivational and interpersonal factors that may interfere with the reception of the message and the translation of knowledge into behavior change (89). Reviews that

examined the effects of interventions, including communication elements, have shown limited and mixed evidence on the effect of these interventions on patients' adherence (89). Adopting a warm and kind style of interaction with a patient is necessary, but is insufficient in itself to effect changes in the adherence behaviors of patients (77).

- **Cognitive perspective**

The cognitive perspective includes theories such as the health belief model (HBM), social-cognitive theory (SCT), the theories of planned behavior (TPB) (and its precursor, the theory of reasoned action (TRA)) and the protection motivation theory (PMT) (77). These theories focus on cognitive variables as part of behavioral change, and assume that health-related behavior is best understood by examining patients' attitudes and beliefs, as well as expectations based on intentions patients may have formed earlier (91). Although these approaches have directed attention to the ways in which patients conceptualize health threats and appraise factors that may be barriers to, or facilitate adherence, they do not always address behavioral coping skills well (77).

- **Self-regulation perspective**

This model explains medication adherence from the patient's perspective and personal experiences. Self-regulation models hypothesizes that adherence is directly influenced by illness experiences (e.g., symptoms, medication side effects), social interactions, sources of information, and cognitive/affective processes (92). People observe and interpret health-related situations, forming an appraisal of the situation (93). They select and implement actions to manage the situations and evaluate their initial perceptions and the response to their actions based on the feedback they receive (93). Adherence or non-adherence to health-related behaviors is based on a person's appraisal of the condition, the availability and relevance of particular actions for management of the health threat, and an evaluation of the outcomes (both costs and benefits) of those actions (93). These models suggest the content of adherence interventions should directly address adherence factors by providing accurate information, building behavioral skills, and providing affective support (92). The self-regulation theory offers little guidance related to the design of interventions, and no

meta-analyses examining evidence for the effectiveness of this theory, were identified. While the theory seems intuitively appropriate, specific suggestions are needed as to how these processes could promote adherence (89).

Although these theories and models provide a conceptual framework for organizing thoughts about adherence and other health behaviors, no single approach may be readily translated into a comprehensive understanding of, and intervention for, adherence (77).

Meichenbaum and Turk (94) suggested that adherence behavior is explained by four independent factors – knowledge and skills, beliefs, motivation and action. The deficit is that any one of them contributes to the risk of non-adherence (94).

- **Information-motivation-behavioral skills theory**

The information-motivation-behavioral (IMB) skills model was developed to be conceptually based, generalizable and simple (95, 96). It presents the additional assumption that information, motivation and behavior exert potentiating effects on each other and are fundamental determinants of performance of health behaviors (97).

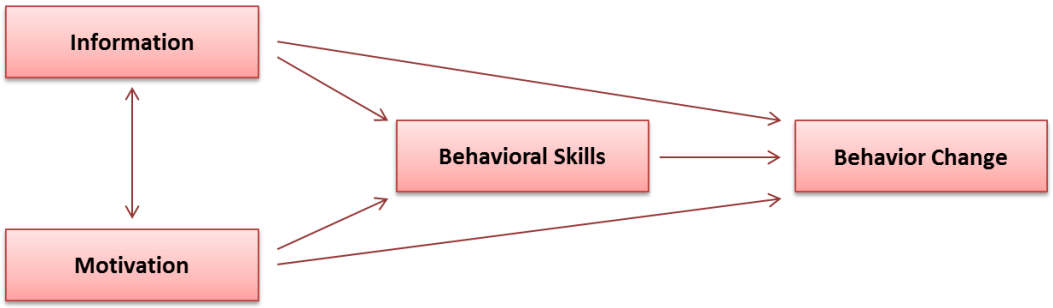
- Information relates to the basic knowledge about a medical condition, and is an essential prerequisite for behavior change, but not necessarily sufficient in isolation (89).
- Motivation includes both personal (attitudes toward personal performance of health promotion behavior) and social motivations (social support for enactment of health promotion behaviors) (97).
- The behavioral skills component of the IMB focuses on an individual's objective abilities and his or her sense of self-efficacy concerning performance of a given health-related behavior (97).

To the extent that individuals are well informed, motivated to act and possess the requisite behavioral skills for effective action, they will be likely to initiate and maintain health-promoting behaviors and to experience positive health outcomes (97). In

contrast, to the extent that individuals are poorly informed, unmotivated to act, and lack behavioral skills required for effective action, they will tend to engage in health risk behaviors and to experience negative health outcomes (97).

The IMB model specified that health promotion information and motivation work, primarily through health promotion behavioral skills, influences health promotion behavior (97). However, when the behavioral skills are not novel or are uncomplicated, information and motivation may have a direct effect on health behavior (Figure 1).

Figure 1: Information-motivation-behavioral skills model



The relationship between the information and motivation constructs is weak (77). In practical terms, a highly motivated person may have little information, or a highly informed person may have low motivation (77). However, in the IMB model, the presence of both information and motivation increase the likelihood of adherence (77).

Interventions

Many interventions have been performed in order to improve patients' adherence to therapy and BP control:

- **Technical interventions** - are usually directed at simplifying the medication regimen. Most adherence interventions in this domain are aimed either at reducing the number of doses per day, for example, through extended release

formulations, or at reducing the number of different drugs in the regimen, for example, by using fixed-dose combination pills (98).

- **Behavioral interventions** - the most common behavioral interventions provide patients with memory aids and reminders, whether by mail, telephone, computer, or by home visits. Other classes of interventions consist of monitoring, by means of calendars or diaries, and providing feedback, support or rewards (98, 99).

- **Educational interventions** - includes teaching and providing knowledge to the patients. There are different ways to educate patients: individual versus group education, face to face contact, audio-visuals, in writing, by telephone, by e-mail or via home visits (98).

- **Simplification of the medication regimen**

The 2007 ESH/ESC Guidelines underlined that, no matter which drug is employed, monotherapy can effectively reduce BP in only a limited number of hypertensive patients and that most patients require the combination of at least two drugs to achieve BP control (11). However, these multidrug regimens are associated with lower adherence (100-104). Drug regimen complexity, i.e., taking multiple daily doses of an intervention, is a critical factor affecting medication-taking behavior (100). Several studies including meta-analysis, have showed that medication adherence is inversely proportional to the complexity of the regimen (number of doses per day) (100-104).

In the ambulatory setting, simplifying dosing regimens has proven to increase adherence to BP medication in hypertensive patients. A cluster RCT, to determine the effectiveness of a simplified treatment algorithm, found that a simplified dosing regimen is implementable, changes physician-prescription patterns, and results in better BP control than conventional guideline-based care (105). Similarly, a retrospective cohort database analysis that compared two different dosing regimens of chronic-use medications used by patients with CV disease showed that a once-daily dosing regimen was related to greater adherence versus a twice-daily regimen (103).

Fixed-dose combinations are designed to simplify the medication regimen and potentially improve adherence. Studies show that fixed-dose combination pills provide improved BP lowering, often with a lower frequency and/or severity of side effects, compared to higher doses of the individual agents, which might improve tolerability (106). The additive effect of combination therapy with respect to efficacy means that lower doses of the individual components can be used, which translates into a reduced likelihood of adverse events (24). Single-pill combination therapy is likely to increase adherence and persistence compared with free combination therapy, because it simplifies the treatment regimen to a single once-daily pill. An open label RCT by Selak et al. (107) found that among a treated primary care population, fixed-dose combination treatment improved adherence to the combination of all recommended drugs. The European guidelines also favor the use of combinations of two AHT drugs at fixed doses in a single tablet (7).

While most studies confirm the benefit of the medication regimen simplification on medication adherence, the impact on BP control remains uncertain. The Cochrane review of interventions, for improving adherence to treatment in patients with high BP, concluded that reducing the number of daily doses appears to be effective in increasing adherence to BP lowering medication, and should be tried as a first line strategy, although there is less evidence of an effect on BP reduction (108). In the study from Selak et al. (107) the fixed dose combination improved adherence but improvements in risk factors were small and did not reach statistical significance.

- **Home blood pressure monitoring**

Use of new technologies, through which the efficacy of therapy can be monitored, could help patients to get more involved in the daily care of their treatment, and to cooperate better with the physician (109). One of the methods used to obtain a better therapy adherence and therefore a more effective BP control, is self-measurement of BP at home by automatic electronic devices. Home blood pressure monitoring (HBPM), the BP measurement method that requires particular cooperation by the patient, may be particularly effective in favorably affecting patients' perceptions of their HTN and may encourage them to be compliant with lifestyle modifications and AHT therapy

(110). HBPM is recommended in the 2013 Guidelines for the Management of Arterial Hypertension of the ESH/ESC (7), as it provides a large number of BP measurements away from the medical environment, which provides a better a more reliable assessment of actual BP than office BP (7).

Several studies have shown that HBPM results in better BP control and greater achievement of BP target compared to usual primary care (111-114). A systematic review and meta-analysis of RCTs that evaluated the effect of HBPM showed that, among patients with HTN, compared with clinic BP monitoring alone, HPBM plays a small but significant role in improving systolic, diastolic, and mean BP (115). In the HBPM allocation groups from 22 studies, the mean change in SBP was -2.63 mmHg and in DBP averaged -1.68 mmHg. Compared with clinic BP monitoring, HBPM led to a greater reduction in medication (relative risk= 2.02 [95%CI, 1.32 to 3.11]) (115). Furthermore, the assessment of BP at home has a superior prognostic value (116-119). A study carried out in Finland showed that despite home and office BP are both predictive of overall CV events, home BP values provide prognostic information about CV risk and total mortality above and beyond that of office BP, even with a low number of measurements (116).

HBPM may also have some positive effect on patients' adherence with AHT medication (120), which makes this approach a particularly valuable adjunct in patients with treatment-resistant HTN due to poor adherence (110).

In Portugal, the first results of the "Auto-Medição da Pressão Arterial na Hipertensão Arterial" (AMPA) study, that was designed to increase knowledge and raise awareness of HBPM, have demonstrated that HBPM provides a better characterization of each patient's BP profile, enabling improved therapeutic and clinical decisions (121).

Notwithstanding the advantages of HBPM, this method has some limitations to its more widespread use, particularly the need for patient training, possible use of inaccurate devices, measurement errors and limited reliability of BP values reported by patients (110). HBPM may not be feasible because of cognitive impairment or physical limitations, or may be contra-indicated because of anxiety of obsessive patient behavior (7).

A systematic review of the trial evidence on the comparative effectiveness of HTN management with HMBP monitoring, concluded that HBPM, with or without additional support, may confer a small benefit in BP control compared with usual care (122). Furthermore, the effect of HBPM in medication adherence and BP control is greater if combined with other strategies and additional support (122, 123). Nevertheless, additional research is needed to clarify the effectiveness of HBPM in a primary care setting and to determine its long-term consequences (122, 123).

- **Patient diaries**

The use of a patient diary is a self-monitoring tool used to improve patient adherence (124, 125). A clinical trial that evaluated the compliance of completing medication diaries suggested that a completion of a daily diary is positively associated with patient adherence in medication intake (125). The patient diary seems to be associated with more patient involvement and motivation, given that it can be reviewed and discussed during clinic visits, which can result in an adjusted treatment and a better comprehension of the disease by the patients themselves (125, 126). Moreover, the diary is a visible reminder for completion and subsequent medication intake (125, 126). Additional evidence supports these findings, indicating that involving patients in the self-monitoring of their medicines adherence through recording medication intake in diaries appears to increase medication adherence (125, 127).

Patient diaries are also accessible, inexpensive, and easy to use tools associated with patient satisfaction (127, 128). A study found that 70% of patients used the medication diaries, with the majority (61%) being satisfied (127, 128).

- **Patient education**

A key component of any adherence-improving plan is patient education (129). Patients who understand their condition and its treatment will be more informed, are more likely to comply, and have more control (130). A study that evaluated the influence of hypertensive patients' education in adherence with their medication, showed that hypertensive individuals who are educated about the importance of their medication and about the consequences of not taking the prescribed dosage, will show better

adherence with their prescribed drug regimen (131). An educational intervention is used best when a patient is willing to take the medication but needs information on how to do so (132). Education may also be useful when a patient is intentionally non-adherent because of a misunderstanding over the use of the medication (132). For patients who are intentionally non-adherent, education about the appropriate use of a medication may allow them to change their minds (132). However, if such counseling is provided only once, or briefly, deeply ingrained values and beliefs may remain unmoved (132). The complexity of medication taking often impedes the benefits of education when it is given as the sole intervention.

Evidence of the effect of patient education on BP control is also controversial. A systematic review of the literature showed that education alone, directed either to patients or health professionals, is unlikely to influence control of BP as a single intervention, as results were highly heterogeneous or of marginal clinical importance (133).

H. OPTIMISING MEDICATION ADHERENCE STRATEGIES

IMPORTANCE OF COMBINED AND TAILORED INTERVENTIONS

The ability of patients to follow treatments in an optimal manner is frequently compromised by more than one barrier. Interventions to promote adherence require several components to target these barriers (77).

Many interventions intended to improve medication adherence tended to be used alone (77). However, a single factor approach is expected to have limited effectiveness, given that the factors determining adherence, interact and potentiate each other's influence (77). The most effective interventions are complex, multi-faceted, combined interventions which are more likely to address the multiple barriers of non-adherence and result in a difference in adherence rates (134).

A study by Bosworth et al. (135), that examined the effects of HBPM, patient behavioral intervention, and a combination of these interventions, showed that the combined intervention had the greatest increase in BP control. These finding were

supported by a systematic review that showed that the interventions most effective in improving long-term medication adherence were complex, including the combination of several interacting components (136).

No interventional strategy has been shown to be effective across all patients, conditions and settings. Consequently, interventions that target adherence must be tailored to the type and cause of non-adherence and the specific needs of the patient in order to achieve maximum impact (77, 137).

Tailored interventions provide individualized information based upon a specific theoretical framework, demographic characteristics or a combination of variables (77). "Tailoring" was defined by Rimer and Kreuter as the process for creating individualized communication by gathering and assessing personal data related to a given outcome, in order to determine the most appropriate information or strategies to meet a patient's unique needs (138).

Tailored communications and tailored interventions appear to be more effective in influencing health behaviors than non-tailored strategies (139, 140). A tailored message appears to stimulate greater cognitive activity than do messages that are not tailored, and health communication programs and materials that succeed in making information relevant to their intended audience, are more effective than those that do not (141).

I. CONTEXT OF THE DISSERTATION: THE HYDIA STUDY

This dissertation is part of the HyDia study – a randomized controlled open-label trial designed to assess the effectiveness of a combined intervention with a tailored educational and behavioral component, compared to usual care.

The HyDia study proposed the improvement of BP control through an improvement of patients' adherence, knowledge of the medication and disease mechanism and by facilitating communication between patient and provider.

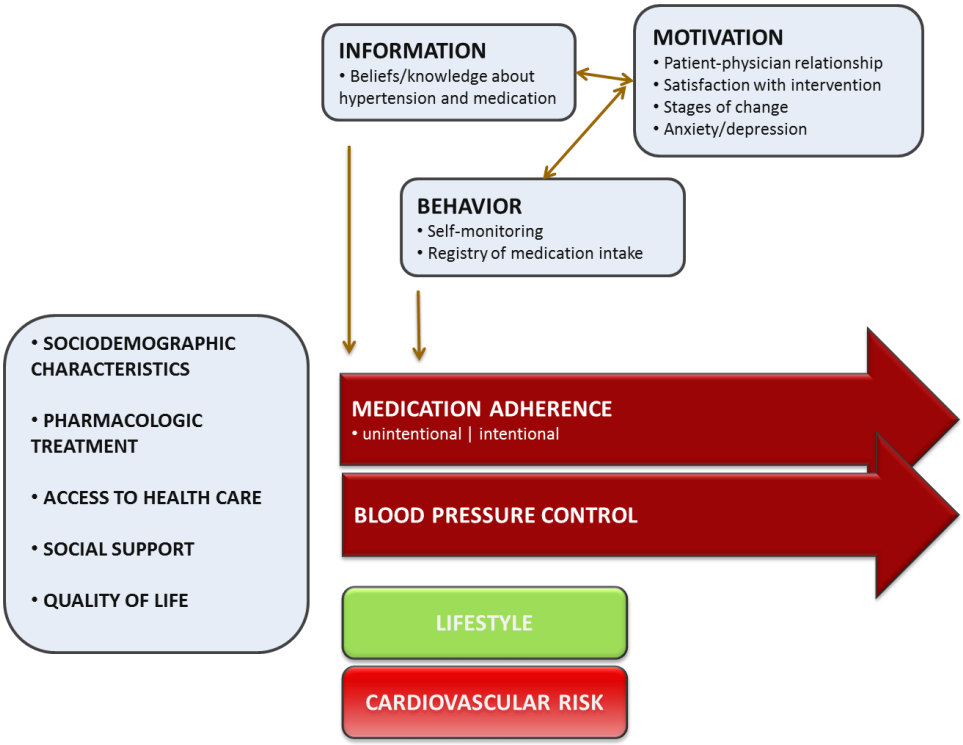
The primary outcome of the study was the improvement on HTN control, measured as the proportion of participants with BP < 140 / 90 mmHg or < 130 / 80 mmHg (in

patients with diabetes mellitus). The secondary outcomes were the SBP reduction in the interventional group, and the improvement in patient adherence to AHT medication. Other outcomes were related to the intervention's applicability in daily practice, measuring physician and patient satisfaction concerning the diary, and the impact in therapeutic change.

J. CONCEPTUAL MODEL

The conceptual model that supports this intervention is illustrated below.

Figure 2: Conceptual model



Chapter 2

OBJECTIVES

The study aims to evaluate the effect of an educational and behavioral intervention on BP control and medication adherence compared to usual care.

- The primary outcome is the improvement on HTN control, measured as the proportion of participants with BP < 140 / 90 mmHg or < 130 / 80 mmHg (in patients with diabetes mellitus).
- Secondary outcomes are:
    - SBP and DBP reduction, and
    - Improvement in patient adherence to AHT medication

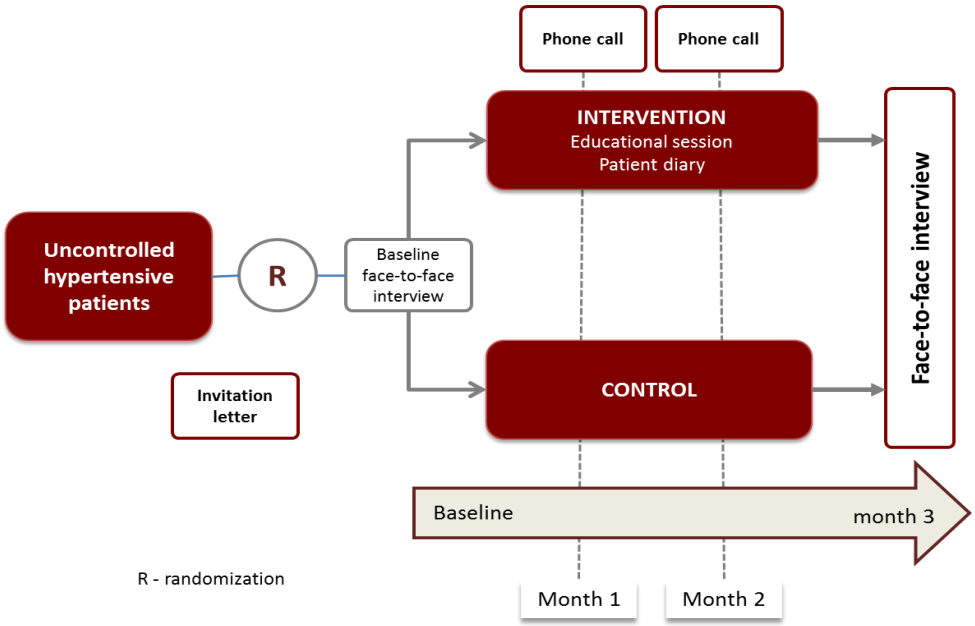
Chapter 3

METHODS

A. STUDY DESIGN

This is a two-arm, randomized controlled open-label trial, with three-month follow-up (Figure 3). Uncontrolled hypertensive patients were randomly assigned to the intervention or control group.

Figure 3: HyDia study design



B. STUDY POPULATION, RECRUITMENT AND ENROLLMENT

The trial occurred in primary care health centers in the Lisbon Region. Potentially eligible individuals were identified from clinical records as having a diagnosis of HTN, uncontrolled BP levels, a clinical visit in the previous 12 months, aged between 40 and 85 years old and taking AHT medication at the time of the baseline visit. Once the patients were identified, the research team mailed invitation letters explaining the study and requesting participation in the trial. The potential participants were then contacted by phone to further explain the study and to confirm their eligibility (Table 3) and their willingness to take part in the study. Consenting patients were randomized to a control or interventional group. The refusals were replaced with other eligible participants randomly selected.

Table 3: HyDia eligibility criteria

Inclusion criteria	• Diagnosis of HTN • Aged between 40 and 85 years • Currently taking AHT medication (≤4 different medicines) • Uncontrolled BP, defined as SBP ≥ 140 mmHg or DBP ≥ 90 mmHg for non-diabetic patients and SBP ≥ 130 mmHg or DBP ≥ 80 mmHg for patients with diabetes mellitus, according to the medical records of the previous 12 months • Last clinical visit in the previous 12 months • Responsible for taking their own AHT medication • Willing and able to participate fully in all aspects of the intervention
Exclusion criteria	• Dementia diagnosis • Pregnancy • Unstable angina • Severe renal and hepatic disease • Severe heart failure • Previous myocardial infarction or stroke in the past 6 months

C. RANDOMIZATION

Eligible and willing participants were identified by a unique ID number and were randomly assigned to either the control or the intervention group. Randomization was performed using a stratified (according to age and number of AHT drugs) block randomization procedure within each center. Patients were randomized to an intervention group or control group in a ratio of 1:2. Four strata were defined and randomization was performed within each stratum using different blocking patterns as illustrated in Table 4.

Table 4: Randomization

	1 or 2 AHT	3 or 4 AHT
Age ≥ 65	ICC, CIC, CCI	ICC, CIC, CCI
Age < 65	ICC, CIC, CCI	ICC, CIC, CCI

I – Intervention; C – Control

D. STUDY MEASURES

All study measurements obtained from the participants were collected during face-to-face and phone interviews. The patients' baseline questionnaire collected information on demographics, including socioeconomic status and family environment. Smoking habits, alcohol use, diet, and amount of exercise were assessed. Patients were asked to bring all their current medication, which was registered and further information was collected regarding the perceived efficacy of the drugs, side effects associated with the AHT medication, use of over-the-counter medicines and non-pharmacological treatments. Detailed information about the clinical aspects of HTN, comorbidities and disease awareness, were also obtained. The amount of social support patients received and the satisfaction with the primary care physician was assessed. Other measurements included the weight, height and waist circumference. Table 5 shows the measurements taken at each assessment visit in the study.

Table 5: Measures obtained in the study

Variable	Baseline	3 month
Demographics (age, sex, ethnicity, etc.)	x	
Quality of Life (EuroQoL)	x	
Anxiety and depression	x	
Knowledge/Beliefs about HTN and AHT medication	x	x
Lifestyle health behaviors	x	x
Health services utilization	x	x
Medication	x	x
Medication adherence (Morisky Scale)	x	x
BP	x	x
Anthropometric measurements	x	x
Social support	x	x
Opinion about the intervention protocol		x

Primary outcome

The primary outcome of the study is the difference in the proportion of hypertensive patients achieving BP control, between the control and the intervention groups, at the three month face-to-face interview.

At each face-to-face interview, three BP measurements were performed at regular intervals using a digital automatic BP monitor (Omrom® M6 confort). BP was measured as a continuous variable. Inadequate BP control was defined as SBP ≥ 140 mmHg or DBP ≥ 90 mmHg or SBP ≥ 130 mmHg or DBP ≥ 80 mmHg for patients with diabetes mellitus according to the 2007 ESH/ESC Guidelines for the Management of Hypertension (11).

Secondary outcomes

Secondary outcomes included reduction in SPB and DBP and impact on medication adherence.

Reduction in SBP and DBP

BP reduction was evaluated by comparing the changes in SBP and DBP from baseline to follow-up between the control and intervention groups.

Impact on medication adherence

Impact on medication adherence was assessed through a comparison in the proportion of non-adherent patients achieving medication adherence, between the control and the intervention groups, at the three month face-to-face interview.

Self-reported adherence was measured using the Portuguese version of the 7-item Morisky Medication Adherence Scale (142). This scale includes the following seven items with yes/no response options:

In the last two weeks…

1. Did you ever forget to take your BP medication?
2. Are you careless at times about taking your medications?

3. Have you ever stopped taking your high BP medication by your initiative because you felt better?
4. Have you ever stopped taking your high BP by your initiative because you felt worse?
5. Have you increased the dose of your high BP medication by your initiative because you felt worse?
6. Have you ever stopped taking your high BP medication because you run out of BP medication?
7. Did you ever stop taking your high BP medication for any other reason besides doctor's indication?

Patients were classified as *non-adherent* if they answered yes to at least one of the seven questions, and further classified as *non-intentional non-adherents* if they answered yes to question 1 or 2 or as *intentional non-adherents* otherwise.

Other measures

BMI was calculated applying the formula: weight (kg) / [height (m)] ^{2} and the participants were subsequently divided in the categories recommended by the WHO for adults (143).

High waist circumference was considered for men and women who had waist circumference over 102 cm and 88 cm, respectively (144).

Excessive daily alcohol consumption was defined as above two drinks in men and one in women (> 30 g and > 15 g of ethanol, respectively) (145).

The participants were defined according to physical activity recommendation when they practiced 150 minutes of moderate to intense physical activity and/or 75 minutes of vigorous physical activity per week (146). Walking was not considered as a moderate activity due to the fact that participants described a level-walk of low intensity.

Mean arterial pressure was calculated according to the following formula: SBP + (DBP)/3

E. INTERVENTION

This is a combined patient-centered intervention with an education component aiming to improve patients' knowledge on HTN, and a behavioral approach – patient diary and self-measurement of BP – intended to enhance patients' HTN management. The framework of this intervention was derived from the IMB Skills Model.

Educational intervention

A major emphasis of the educational intervention was to improve patients' knowledge on HTN and on AHT medication and to initiate and maintain health behaviors related to HTN.

Participants randomized to the intervention group attended an individual intervention session approximately one week after the baseline interview. At the session, a trained pharmacist delivered information related to HTN knowledge, AHT medication, medication adherence, medication beliefs and lifestyle health behaviors. The information was both standardized and tailored to patients' needs. To ensure that the information was standardized, the pharmacists used a flowchart which contained predetermined scripts and tailored algorithms (ANNEX I). The counselling was tailored individually according to the answers provided in the baseline questionnaire.

Education modules

- Hypertension knowledge

All patients received information about what is HTN, what are the causes and risks associated with high BP, what do BP numbers measure and how should high BP be controlled and treated.

According to the responses to the baseline questionnaire, patients who did not know what HTN was and who did not understand the risks associated with high BP, received more detailed information and counselling on the importance of maintaining BP control by underscoring the benefits of maintaining adequate BP.

- Antihypertensive medication

Each participant's medication was reviewed and it was ascertained if they were aware of their treatment plan, if the medication was taken as prescribed and if there was any specific side-effect related to AHT medication use. The purpose of the AHT medication was described and the patients were taught how to manage their medication properly. The recommendations were emphasized in those patients that were not familiar with their medication and dosing schedule.

The patients were encouraged to contact their family physician if drug interactions, unnecessary therapeutic duplication, or side-effects were identified.

- Medication adherence

Patients received information on the importance of taking the AHT medication correctly and the risks and consequences of non-adherence.

Patients who reported having difficulties remembering to take their medication or having skipped a dose of medication because they had forgotten – unintentional non-adherents – were provided with several mnemonic strategies such as setting an alarm, creating a routine, using of pillbox, keeping the medicines visible, etc.

Among the patients identified as intentional non-adherents, the pharmacist addressed the misperceptions that lead to non-adherence and emphasized the pros of adherence to the regimen. The misperceptions may include the perception that the medication could be stopped when the condition improved or worsened.

The patients were encouraged to contact their family physician to ask questions and share information related to their medication-taking behavior.

- Medication beliefs

Patients might have lay knowledge and beliefs on medication that can, consequently, reduce adherence (147). Fear might be expressed about the long-term use of AHT medication, possibility of becoming addicted to the medication, concern about the adverse events, perception that AHTs are damaging to the body, etc. (147).

Patients that expressed the wrong beliefs towards AHT drugs received adequate information to reduce the fear and anxiety related to the use of medicines, and the purpose of therapy and consequences of non-adherence were emphasized.

- Lifestyle health behaviors

All patients received recommendations on appropriate lifestyle changes that can help control BP and other CV risk factors and clinical conditions. Individuals identified as being obese or overweight (BMI>25 for men and BMI>24 for women), with a high sodium intake, currently smoking, men drinking more than two alcoholic drinks per day and women drinking more than one alcoholic drink per day, and participants not doing regular physical activity, received intensified counselling regarding weight reduction, salt restriction, smoking cessation, moderation of alcohol consumption and regular physical activity, respectively.

Patient Diary

The paper diary - ***Hypertension Diary*** – was developed to facilitate patients on the registry of their BP levels and AHT medication, according to a predefined measuring protocol. Patients were advised to bring their diaries to each clinical visit so they could be reviewed by the physician. The Hypertension Diary consisted of a booklet with the following elements:

1. Personal patient information, doctor and health-care center contacts, research team contacts;
2. Educational introduction about HTN and its risks, AHT medication and the importance of medication adherence, that was used by the interviewer for the educational component of the intervention;
3. Protocol for the medication registry, with specific instructions and examples;
4. Protocol for HBPM , with instructions regarding how to measure BP;
5. Medication registry, to be filled in daily, at the time the medication was taken, with the number of pills taken for each drug. The AHTs' names were previously introduced during the baseline interview, with the supervision of the interviewer.

During the study follow-up, and for each newly prescribed AHT, the patient inserted the name and filled in the medication intake registry;

6. BP values registry;
7. Patient could write his annotations / comments regarding medication and BP measurement, in specific fields;
8. A physician's area, where the following could be included:
    a. The visit schedule
    b. Therapeutic changes and in-office BP values
    c. Comments and other information that the physician would find relevant
9. An area for the patient's general notes and comments.

Self-measurement of BP

Patients randomized to the intervention group received an Omron M6C arm monitor. In the intervention session, the interviewers trained the participants to take their own BP and subsequently confirmed if the participants were able to correctly use the monitor. At each telephone interview, the participants were asked if the monitor was working properly and if they had any questions or problems related to the use of the monitor. If necessary, a brief visit could be scheduled to clarify any problems.

The participants were asked to measure their BP at home according to the following instructions:

a. Twice a day (morning and evening, approximately at the same time of the day), two times weekly on two separate days (one weekday and once during the weekend) (135);
b. Using the automated and validated BP device given by the research team;
c. Always on the same arm that presented a higher BP during the measurement performed by the interviewer at baseline (110).

Condition of measurements was the one's defined in ESH/ESC guidelines for blood pressure monitoring at home (110):

a. Five minutes rest, 30 minutes without smoking or caffeine;

b. Seated, back supported, arm resting on the table;
c. Correct cuff bladder placement;
d. Immobile, legs uncrossed, not talking, relaxing.

F. DATA COLLECTION

Data was collected throughout a three-month follow-up period, (table 6) according to the following steps:

1. Three trained pharmacists conducted face-to-face interviews at baseline, including:
    a. Explanation of the study objectives and collection of the informed consent;
    b. Administration of the baseline questionnaire;
    c. BP measurement according to the 2013 ESH/ESC Practice Guidelines for the Management of Arterial Hypertension (7);
    d. Anthropometric data collection.
2. Educational intervention of the patients, with a brief explanation regarding HTN and AHT therapy, according to the pre-defined protocol;
3. Patients' registry of medication intake and BP values from HBPM according to a behavioral protocol;
4. Monthly phone calls (months one and two) while the intervention was delivered, to encourage patients to maintain behavioral changes and to ensure the intervention was proceeding according to the protocol;
5. Face-to-face interview at month three where a final BP measurement was taken, review of patient's diary, and application of a questionnaire regarding their opinion about the protocol.

Specific questionnaires were used to collect the information (Annex II and III).

The physicians were informed about the intervention protocol and that the patients included in the study were advised to bring their diaries to the appointments. The physicians were asked to act according to their regular practice.

The study instruments were previously assessed by a panel of three physicians – two cardiologists and one GP – with experience in HTN management, and were pre-tested by application to five hypertensive patients. A manual of procedures was developed, including, data collection procedures, interventional protocol and data entry protocol.

Table 6: Data collection procedures

Data Collection		Baseline	Follow-up		
			1M	2M	3M
Patients	Face-to-face interview to identify participants' initial profiles	**X**			
	Tailored educational intervention and patient training on the specified protocol, applied only to the interventional group		**X**		
	Follow-up with phone interview, applied only to the interventional group		**X**	**X**	
	Final face-to-face interview, applied to both groups and a satisfaction questionnaire applied only to the interventional group				**X**
Physicians	Follow-up with brief formulary	At each appointment			

- Control Group

Patients assigned to the control group did not receive any change in care. However, they had a baseline interview and a three-month face-to-face interview in order to collect the same measures as the intervention group. Patients in the control group were excluded from the one-month and two-month telephone interviews.

G. SAMPLE SIZE CALCULATION

To be able to detect a difference of at least 11.5% in the proportion of patients achieving BP control by month three, considering two controls per case, at a two-tailed significance level of 0.05, and a power of 80%, 80 patients in the intervention group

and 160 patients in the control group were needed, considering a lost to follow-up of 10%.

H. DATA VALIDATION AND STATISTICAL ANALYSIS

The data was collected in paper form and was subsequently entered in an electronic database. To confirm the accuracy of the data entered, the information registered in the database was verified in a randomly selected sample of 10% of the questionnaires.

Descriptive statistics of patient demographics and health-related variables were used for the sample characterization and to assess for any differences between the intervention and control groups at baseline. Student t-test or Wilcoxon rank sum test was performed for continuous variables and Pearson's chi-square test or Fisher's Exact test was performed for categorical variables.

The Pearson's chi-square test was used to compare the proportion of adherent patients and BP controlled patients at follow-up between the two groups. Within-group changes from baseline to follow-up were examined using the two sample generalization of the McNemar´s test.

To compare the changes in DBP and SBP in the intervention group to the changes in the control group between baseline and the follow-up, an unpaired t-test was used. Paired t-tests were calculated to test for within-group changes.

Multivariate analysis was used to evaluate the effect of the intervention in the outcomes of interest, adjusting for age, sex, health-care center, baseline outcome measures and baseline characteristics that were significantly related, at the α=0.10 level, to either the outcome of interest or intervention group. For the dichotomous outcomes (proportion of patients with BP controlled and proportion of patients adherent to AHT medication at the end of the study), multiple logistic regression models were used. For the outcomes that were continuous (changes in SBP and in DBP from baseline to the end of the study) multiple linear regression models were performed. Patient´s assignment group (control/intervention) was the main independent variable in the models.

Subgroup analysis

For the primary outcome (BP control), we repeated the analyses on the subgroup of patients:

- With baseline SBP≥150 mmHg – to assess the intervention's effect for more extreme HTN
- Participants 65 years or older – given that the problem of uncontrolled HTN and medication non-adherence is compounded in the elderly (148) (due to the complexity of drug regimens, memory loss, inadequate patients education, etc.), these patients could potentially benefit more from the intervention

Sensitivity analysis

To assess the robustness of our results, using a sensitivity analysis, we re-estimated the intervention effect in the primary outcome using different scenarios:

- Intention-to-treat principle (ITT): the missing values for the outcome variable (BP control) were imputed based on the "last observation carried forward" approach. Given that the last obtained value for the patients that were lost to follow-up was the baseline interview, the same BP values were assumed for baseline and follow-up.
- Considering that all the patients that were lost to follow-up had uncontrolled BP at the end of the study
- Excluding patients with more than 4.5 months between baseline and the follow-up interview
- Considering the new ESC/ESH recommendations of BP target levels for diabetic patients: SBP <140 mmHg and DBP <85 mmHg

We estimated 95% confidence intervals for parameters of interest and adopted a 5% significance level for all statistical hypotheses tests.

Data analysis was carried out using SPSS software, version 21.

I. ETHICAL AND LEGAL ASPECTS

The HyDia project was authorized by the Faculty of Medicine of Lisbon Ethics Committee, the National Data Protection Authority and the Health Regional Administration of Lisbon and Tagus Valley (see Annex IV, V and VI). The Health Centers Groups (ACES) approved the collaboration of the Health Units in the study.

All participants provided the written informed consent, and received a copy of the signed informed consent. Participants were free to withdraw from the study at any time and to refuse to answer any question. Confidentiality was maintained as none of the patient information was provided to their physicians, primary care center, or others without the patient's permission. Health-care data contain sensitive personal information therefore, data such as name, birthday, address and telephone contact were de-identified for data analysis purposes. Patients and health care providers were coded with a unique non-identifying number. Only grouped data will be presented and published. Access to the database was protected with restricted access, password protection, and servers were protected with firewalls and anti-virus software.

The intervention was non-invasive and harmless. Compensation was not given to the study participants and the study did not have any commercial objectives.

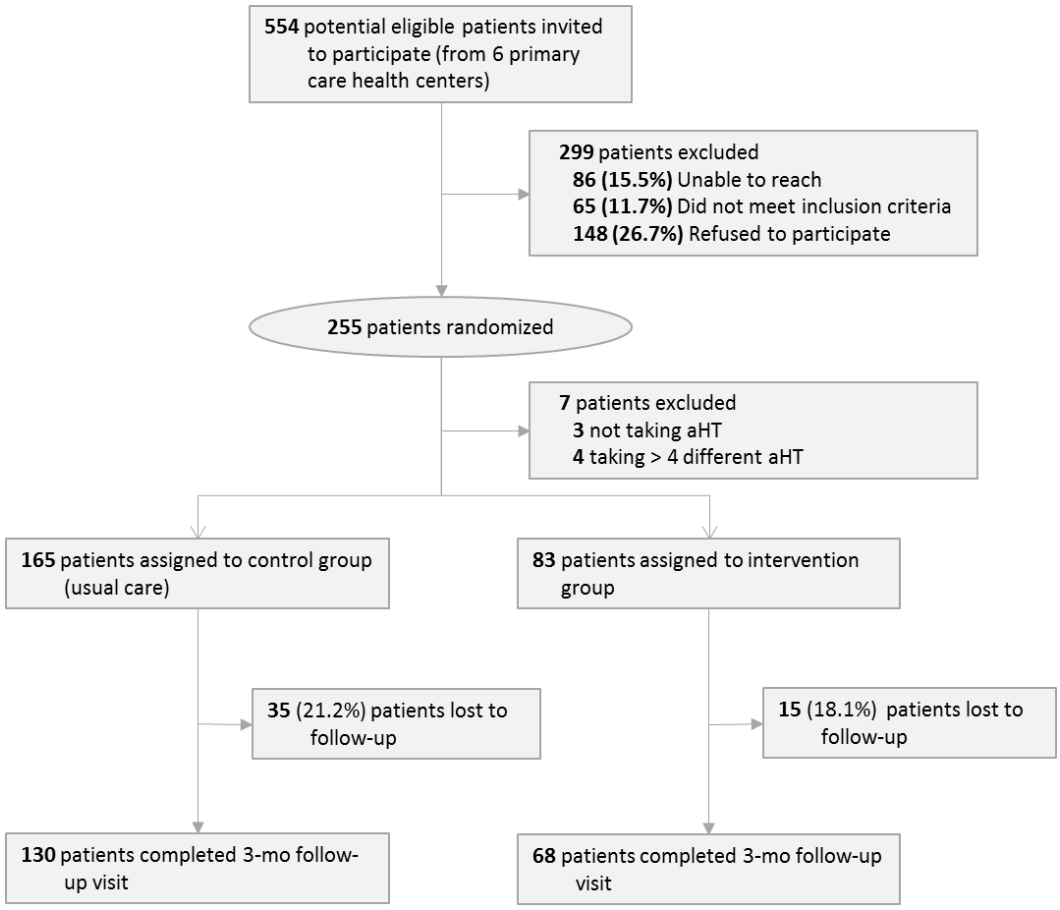
Chapter 4

RESULTS

A. STUDY FLOW

Between January 2012 and March 2013, 554 potentially eligible patients from six primary care health centers were identified based on data from electronic clinical records. Of those, 86 (15.5%) were unreachable by phone, 65 (11.7%) did not meet the inclusion criteria and 148 (26.7%) refused to participate (Figure 4). The high rate of refusals and unreachable patients significantly delayed recruitment. Of the 255 patients enrolled in the study, 85 were assigned to the intervention group and 170 were assigned to the control group (usual care). After the baseline assessment, seven participants were excluded: three patients were not taking AHT medication and four patients were taking more than four different medicines. The proportions of patients attending the follow-up visit at three months were 81.9% for the intervention group and 78.8% for the control group. Completion rates did not differ significantly by study group (p=0.561).

Figure 4: Study flow diagram



Only the 198 patients (68 in the intervention group and 130 in the control group) who completed the baseline interview and the three month follow-up visit, were included in the analysis. The baseline characteristics of the 248 patients with baseline assessment are described in Annex VII.

Descriptive statistics were used to compare the baseline characteristics of the lost to follow-up and non-lost to follow-up patients. Compared to the lost to follow-up patients, the group of patients that completed the study was more educated, and had a proportion of dyslipidemia and of high waist circumference 19.3% and 16.2% lower, respectively. The lost to follow-up group had a proportion of smoking patients 4.5% lower, had more 10.9% of intentional non-adherents and a lower proportion of patients with a health subsystem than the non-lost to follow-up group. There were no statistically significant differences regarding the other baseline characteristics.

B. PATIENT CHARACTERISTICS

Patient characteristics are detailed by study group in Table 7. Baseline characteristics of both groups were comparable at baseline ($P > 0.05$), except for the proportion of patients with diabetes and currently smoking. To account for these differences, these variables were adjusted for in the multivariate analyses.

At baseline, the 198 patients had a mean age of 68.9 years, 53.0% were men and 97.0% were Caucasian. Most patients were married or were in a common-law marriage and nearly one quarter had earned a college degree (23.9%). Many patients had comorbid conditions, including obesity (36.3%), diabetes (33.0%) or dyslipidemia (56.6%) and more than half had a high waist circumference (60.3%). Forty percent of participants had measured their own BP at least once a week over the last 12 months.

The majority of patients followed a healthy diet (76.6%), and reported moderate alcohol consumption (87.9%). The smoking rate was 10.1% and 27.3% of patients performed regular physical activity.

Patients had been on AHT medication for approximately 15 years and half of the patients (51.5%) reported taking one AHT.

Table 7: Baseline characteristics by randomized group

Variable	Total (n=198)	Control Group (n=130)	Intervention Group (n=68)	*p-value*
Sociodemographic variables				
Male sex, n (%)	105 (53.0)	70 (53.8)	35 (51.5)	0.750
Age (years), mean±sd	68.92±9.55	68.64±9.12	69.46±10.36	0.317
Main occupation, n (%)				0.460
Have a job/student/ Housekeeping	50 (25.3)	31 (23.8)	19 (27.9)	
Unemployed	7 (3.5)	6 (4.6)	1 (1.5)	
Retired/ with illness/ permanently Incapacitated	141 (71.2)	93 (71.5)	49 (70.6)	
Marital status, n (%)				0.710
Married/common-law marriage	143 (72.2)	95 (73.1)	48 (70.6)	
Unmarried	55 (27.8)	35 (26.9)	20 (29.4)	
Education, n (%)				0.756
Primary education not completed	11 (5.9)	7 (5.6)	4 (6.3)	
Basic education – 1st cycle	74 (39.4)	45 (36.3)	29 (45.3)	
Basic education – 2nd and 3rd cycles	21 (11.2)	14 (11.3)	7 (10.9)	
Secondary/post-secondary education	37 (19.7)	27 (21.8)	10 (15.6)	
Higher education	45 (23.9)	31 (25.0)	14 (21.9)	
missing, n (%)	*10 (5.1)*	*6 (4.6)*	*4 (5.9)*	
Ethnicity, n (%)				0.412
Caucasian	192 (97.0)	127 (97.7)	65 (95.6)	
Other	6 (3.0)	3 (2.3)	3 (4.4)	
No. people in the household, median (IQR)	1.0 (1.0-2.0)	1.0 (1.0-2.0)	1.0 (1.0-1.0)	0.998
Clinical variables				
Time since diagnosis, mean±sd (years)	16.68±12.41	16.64±11.81	16.75±13.53	0.760
missing, n (%)	*28 (14.1)*	*20 (15.4)*	*8 (11.7)*	
Time since AHT drugs, mean±sd (years)	14.85±11.12	14.97±10.66	14.62±12.03	0.485
missing, n (%)	*25 (12.6)*	*17 (13.1)*	*8 (11.7)*	
Number of AHT drugs, n (%)				0.861
1	102 (51.5)	68 (52.3)	34 (50.0)	
2	63 (31.8)	40 (30.8)	23 (33.8)	
3	29 (14.6)	20 (15.4)	9 (13.2)	
4	4 (2.0)	2 (1.5)	2 (2.9)	
Number of total drugs, median (IQR)	5.0 (3.0-7.0)	5.0 (4.0-7.0)	5.0 (3.0-7.0)	0.335
BMI (Kg/m^2), n (%)				0. 469
Non-Obese (<30)	123 (63.7)	78 (61.9)	45 (67.2)	
Obese (≥30)	70 (36.3)	48 (38.1)	22 (32.8)	
missing, n (%)	*5 (2.5)*	*4 (3.1)*	*1 (1.5)*	
Diabetes, n (%)	65 (33.0)	51 (39.5)	14 (20.6)	**0.007**
missing, n (%)	*1 (0.5)*	*1 (0.8)*	*0 (0.0)*	
Dyslipidemia, n (%)	112 (56.6)	78 (60.0)	34 (50.0)	0.178
High waist circumference, n (%)	111 (60.3)	74 (61.7)	37 (57.8)	0.611
missing, n (%)	*14 (7.1)*	*10 (7.7)*	*4 (5.9)*	
BP measurement routine, n (%)				0.788
At least once a week	81 (40.9)	51 (39.2)	30 (44.1)	
At least once a month	60 (30.3)	41 (31.5)	19 (27.9)	
Every three months or less	57 (28.8)	38 (29.2)	19 (27.9)	
Have a BP monitor	146 (73.3)	94 (72.3)	52 (76.5)	0.527
Mean arterial pressure*, mean±sd	102.56±11.26	101.92±11.63	103.72±10.54	0.295

Variable	Total (n=198)	Control Group (n=130)	Intervention Group (n=68)	*p-value*
Lifestyle and knowledge about HTN				
Regular physical exercise, n (%)	54 (27.3)	35 (26.9)	19 (27.9)	0.879
Excessive alcohol use, n (%)	24 (12.1)	16 (12.3)	8 (11.8)	0.911
Follow healthy diet, n (%)	151 (76.6)	96 (73.8)	55 (82.1)	0.195
missing, n (%)	*1 (0.5)*	*0 (0.0)*	*1 (1.5)*	
Smoking habits, n (%)				**0.003**
Smoker	20 (10.1)	19 (14.6)	1 (1.5)	
Ex-smoker	68 (34.3)	37 (28.5)	31 (45.6)	
Never smoked	110 (55.6)	74 (56.9)	36 (52.9)	
knowledge about meaning of HTN	129 (65.2)	86 (68.5)	40 (58.8)	0.177
Health services variables				
To treat HTN, during last year, has resorted to, n (%)				
Physician	80 (40.4)	53 (40.8)	27 (39.7)	0.885
Health care professional other than physician	11 (5.6)	9 (6.9)	2 (2.9)	0.245
Satisfaction with primary care physician, n (%)				
Very satisfied, satisfied	182 (94.9)	120 (95.2)	62 (94.0)	0.739
Neither satisfied or dissatisfied, dissatisfied and very dissatisfied	10 (5.1)	6 (4.8)	4 (6.0)	
missing, n (%)	*6 (3.0)*	*4 (3.1)*	*2 (2.9)*	
Satisfaction with primary care health center, n (%)				-
Very satisfied, satisfied	189 (97.5)	122 (96.0)	67 (100.0)	
Neither satisfied or dissatisfied, dissatisfied and very dissatisfied	5 (2.5)	5 (4.0)	0 (0.0)	
missing, n (%)	*4 (2.0)*	*3 (2.3)*	*1 (1.5)*	

sd – standard deviation
IQR – interquartile range

C. CLINICAL MEASURES

Blood pressure

At baseline, BP measurements were performed on 190 patients. Table 8 shows the mean values for SBP and DBP and the proportion of controlled patients at baseline by study group. Patients in the intervention and control groups had similar BP control rates. A total of 35.8% and 29.9% of patients in the control and intervention groups, respectively, had their BP controlled, as defined by the ESH/ESC guidelines (11) (SBP<140 mmHg or DBP<90 mmHg or <130/80 mmHg in patients with diabetes mellitus). A large proportion of patients had Grade I HTN at baseline (43.1% in the control group and 40.3% in the intervention group). No statistical significant differences between groups were found in the classification of BP levels at baseline (p=0.397) (Figure 5).

Both SBP and DBP follow a normal distribution in the total study sample (Figure 6). No statistical significant differences were found in the baseline SBP and DBP values between the study groups.

Table 8: Baseline BP measurements by randomized group

	TOTAL (n=190)	CONTROL (n=123)	INTERVENTION (n=67)	
Controlled BP				**p-value**
n (%)	64 (33.7)	44 (35.8)	20 (29.9)	0.409[a]
SBP				
Mean±sd	142.70±17.07	141.62±17.05	144.68±17.05	0.238[b]
Median (iiq)	142.7 (132.3-154.7)	141.3 (129.7-150.7)	147.0 (133.3-155.7)	0.206[c]
Min-max	94.7-187.7	94.7-187.7	107.0-182.3	
DBP				
Mean	82.49±10.79	82.08±10.82	83.24±10.77	0.479[b]
Median	82.2 (74.7-89.3)	82.0 (73.3-89.7)	82.3 (77.7-89.3)	0.459[c]
Min-max	51.0-115.0	55.0-114.7	51.0-115.0	

[a] Chi-square test
[b] Unpaired t-test
[c] Wilcoxon rank sum test

Figure 5: Blood pressure levels at baseline by randomized group

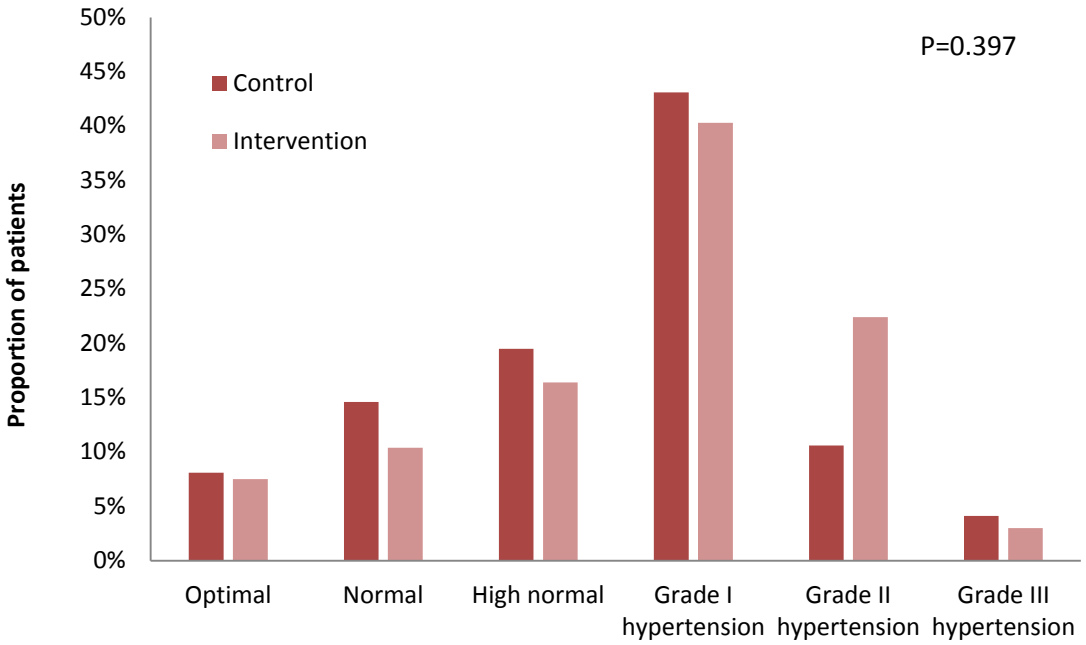
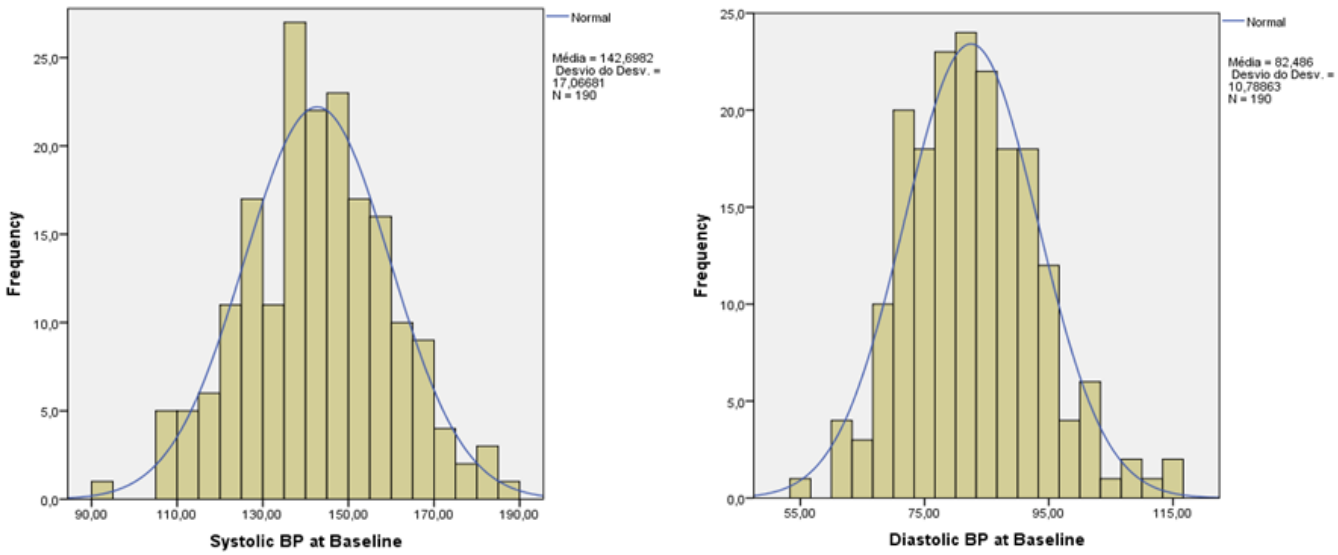


Figure 6: Histograms of distribution of blood pressure at baseline



Systolic and Diastolic Blood Pressure

There was a significant reduction in SBP and DBP in both the control and intervention groups from baseline to follow-up (Figure 7, Figure 8, Table 9).

Figure 7: Changes in SBP from baseline to follow-up by randomized group

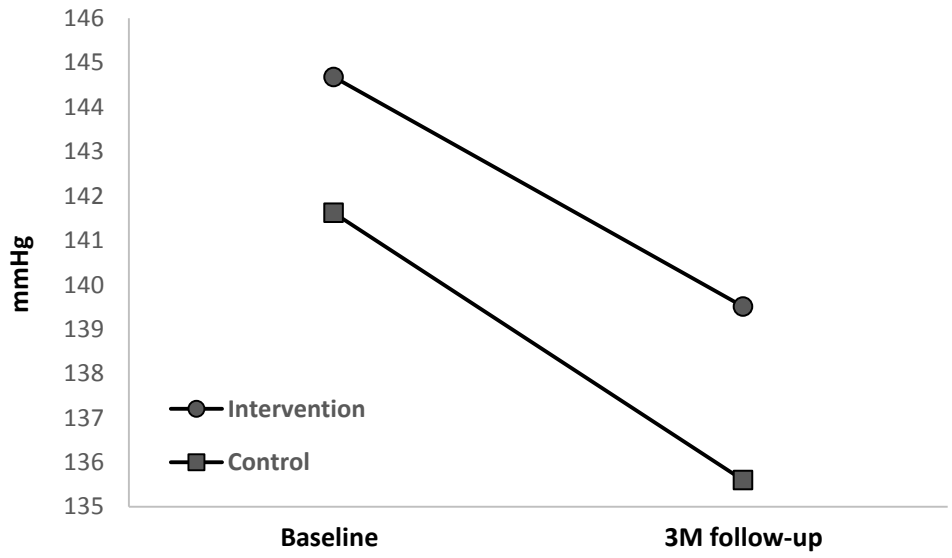
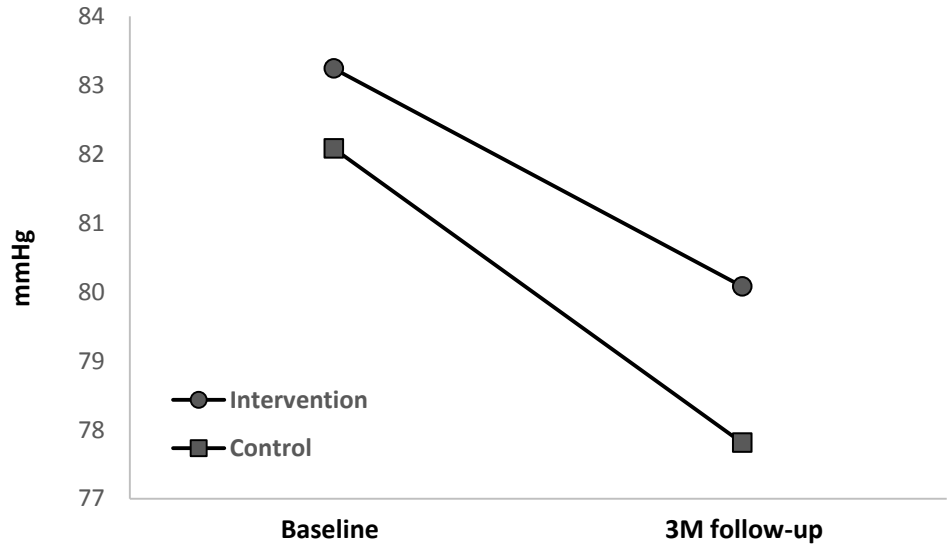


Figure 8: Changes in DBP from baseline to follow-up by randomized group



From baseline to follow-up, mean reduction in SBP was 6.5±15.6 mmHg in the control group (p<0.001), and 5.5±14.7 mmHg in the intervention group (p=0.004). Corresponding DBP reductions were 4.7±9.4 mmHg (p<0.001), and 2.7±9.0 mmHg (p=0.020), respectively (Table 9). There was no statistically significant difference in the SBP or the DBP reduction in the intervention group compared to the control group at follow-up.

Table 9: Differences in BP change from baseline to follow-up for all patients completing follow-up

	CONTROL N=115	INTERVENTION N=63	
Mean SBP			**p-value****
Baseline	141.62±17.05	144.68±17.05	
Follow-up	135.60±16.27	139.51±16.02	
Difference	-6.45±15.63	-5.47±14.71	0.683
p-value*	<0.001	0.004	
Mean DBP			
Baseline	82.08±10.82	83.24±10.77	
Follow-up	77.81±9.88	80.08±9.01	
Difference	-4.73±9.36	-2.70±8.98	0.161
p-value*	<0.001	0.020	

* Within-group comparison (paired t-test)
** Between-group comparison (unpaired t-test)

Table 10: Effect of the intervention on BP change from baseline to follow-up for all patients completing follow-up

	Standardized coefficients	p-value
SBP		
Intervention group	-0.027 [a]	0.679
DBP		
Intervention group	-0.093 [b]	0.166

[a] Coefficients from a multiple linear regression model adjusted for baseline SBP, baseline DBP, age, sex, health care center, diabetes, smoking status, waist circumference, no. AHT and have resorted to the doctor the previous year to control HTN. $R^2 = 0.442$

[b] Coefficients from a multiple linear regression model adjusted for baseline DBP, baseline SBP, age, sex, health care center, diabetes, smoking status, no. AHT, BP measurement routine. $R^2 = 0.379$

After adjustment for baseline covariates, differences between groups regarding changes in SBP and DBP remained non-significant (Table 10).

BP control

Table 11 shows the proportion of patients in each group with BP controlled at baseline and at follow-up. At three months, the proportion of patients with controlled BP significantly increased in both the intervention and the control group compared to baseline (29.9% to 43.8% and 35.8% to 50.8%, respectively). No differences were observed in the proportion of controlled patients at the end of the study between the two groups (P=0.359).

Table 11: Differences in the proportion of BP controlled patients from baseline to follow-up for all patients completing follow-up

	CONTROL N=115	INTERVENTION N=63	
Controlled patients			**p-value***
Baseline, %	35.8	29.9	
Follow-up, %	50.8	43.8	0.359
Difference, %	15.0	13.9	
p-value*	0.003	0.022	

* Within-group comparison (McNemar test)
** Between-group comparison (Chi-square)

Table 12: Effect of the intervention on BP control at follow-up for all patients completing follow-up

	Adjusted OR[a]	95% CI	p-value
Group assignment			
Control	Reference		
Intervention	0.64	0.28-1.47	0.288

[a] OR from a multiple logistic regression model adjusted for baseline BP control, age, sex, health care center, diabetes, smoking status, no. AHT, main occupation and knowledge about meaning of HTN
R^2 = 0.406
Hosmer-Lemeshow = 0.973

After adjusting for baseline covariates, BP control in the intervention group was still no significantly greater than in the control group, at follow-up (Table 12).

Medication adherence

Medication adherence rates at baseline are summarized in Figure 9. The evaluation of adherence based on the 7-item Morisky Medication Adherence Scale showed that 83.1% of the patients in the control group and 76.5% of patients in the intervention group were adherent to the AHT medication at baseline. No statistical significant differences were found in the medication adherence rates between the study groups (p=0.476).

Figure 9: Medication adherence rates at baseline by randomized group

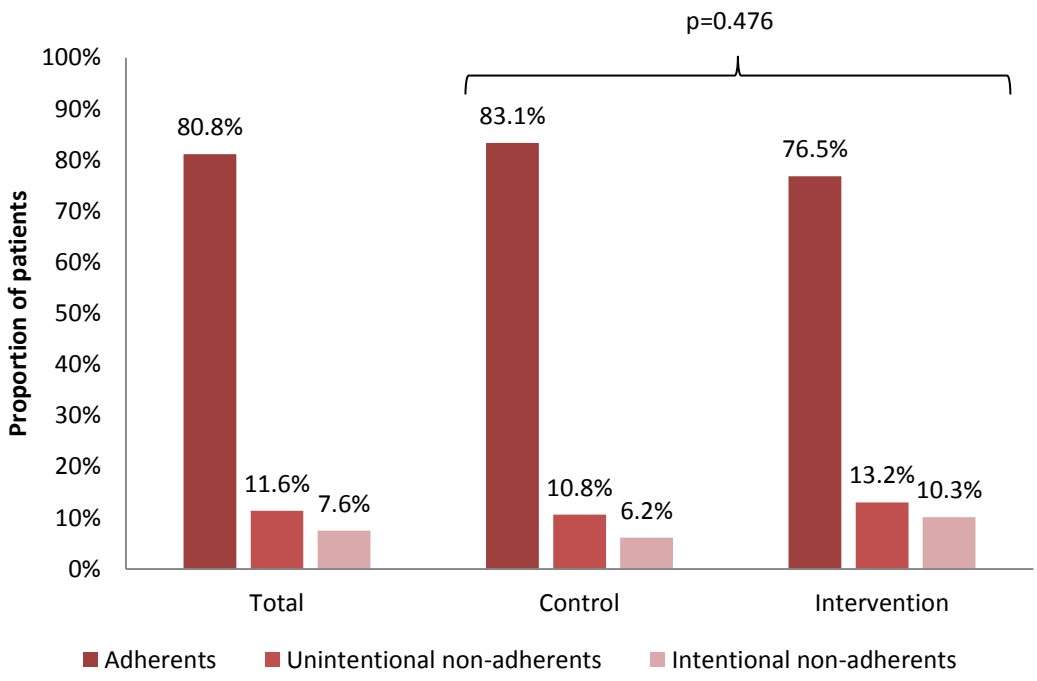


Table 13: Differences in the proportion of adherents to medication from baseline to follow-up for all patients completing follow-up

	CONTROL (n=130)	INTERVENTION (n=68)	
Adherents			**p-value****
Baseline, %	83.1	76.5	
Follow-up, %	79.2	79.4	0.721
Difference, %	-3.9	2.9	
Intentional non-adherents			
Baseline, %	6.2	10.3	
Follow-up, %	7.7	13.2	0.967
Difference, %	1.5	2.9	
Unintentional non-adherents			
Baseline, %	10.8	13.2	
Follow-up, %	13.1	7.4	0.235
Difference, %	2.3	-5.8	
p-value*	0.392	0.774	

* Within-group comparison (McNemar test)
** Between-group comparison (Chi-square)

Medication adherence rates over the study period are summarized in Table 13. In the intervention group, the proportion of adherent patients increased from baseline to the three-month follow-up (76.5% vs. 79.4%), whereas, in the control group, the proportion of adherent patients decreased between the two time points (83.1% vs. 79.2%). Although an improvement in medication adherence was only observed in the intervention group, no statistical significant differences were found between the two groups in the adherence levels at the end of the intervention (p=0.721). The intervention group saw a reduction in the proportion of unintentional non-adherents of 5.8%, whereas in the control group an increase of 2.3% was observed, however this difference did not reach statistical significance (Table 13). In both groups, a similar increase in the proportion of intentional non-adherents was found (1.5% in the control

group and 2.9% in the intervention group). No significant within-group differences were found in the change of the proportion of adherent patients from baseline to follow-up in the control group (p=0.392) or intervention group (p=0.774).

Table 14: Effect of the intervention on medication adherence at follow-up for all patients completing follow-up

	Adjusted OR[a]	95% CI	p-value
Group assignment			
Control	Reference		
Intervention	0.83	0.33-2.18	0.688

[a] OR from a multiple logistic regression model adjusted for baseline medication adherence, age, sex, health care center, diabetes, smoking status, baseline SBP and waist circumference
R^2 =0.243
Hosmer-Lemeshow = 0.484

Even after adjusting for baseline covariates, medication adherence in the intervention group was no greater than in the control group, after three months (Table 14).

D. SUBGROUP ANALYSIS

Patients uncontrolled at baseline

Since the initial goal of the intervention was to intervene on patients with uncontrolled HTN, a subgroup analysis was performed that was limited to those participants with uncontrolled BP at baseline. A total of 126 participants (66.3%) had uncontrolled HTN at baseline.

Blood pressure

As seen for the total sample, subjects from both groups had similar baseline SBP and DBP (Table 15).

Table 15: Baseline BP measurements by randomized group for patients uncontrolled at baseline

	TOTAL (n=126)	CONTROL (n=79)	INTERVENTION (n=47)	p-value
SBP				
Mean±sd	151.6±12.4	150.9±12.2	152.6±12.7	0.454[a]
Median (iiq)	149.7 (142.7-158.3)	148.0 (142.3-158.3)	153.7 (144.3-161.3)	0.227[b]
Min-max	121.0-187.7	129.3-187.7	121.0-182.3	
DBP				
Mean	86.0±10.3	86.1±10.3	85.8±10.5	0.875[a]
Median (iiq)	86.0 (78.3-91.7)	87.3 (77.3-92.0)	82.6 (78.3-87.3)	0.672[b]
Min-max	63.3-115.0	63.3-114.7	66.7-115.0	

[a] Unpaired t-test
[b] Wilcoxon rank sum test

As seen for the total sample, in this subgroup, pairwise analysis showed that SBP significantly decreased during the study period in both the control and intervention groups (Table 16). However, no difference was found between the two groups in the SBP decline from baseline to follow-up (P=0.155). Similarly, DBP declined over time in both arms, however, in this subgroup, the differences in the intervention group were no longer significant and statistically significant differences in the DBP reduction between the two groups were observed, in favor of the control group (p=0.005).

Table 16: Differences in BP change from baseline to follow-up for all patients uncontrolled at baseline

	CONTROL N=75	INTERVENTION N=45	
Mean SBP			**p-value****
Baseline	150.9±12.2	152.6±12.7	
Follow-up	139.4±14.6	145.5±13.9	
Difference	-11.58±13.70	-7.71±15.29	0.155
p-value*	<0.001	0.002	
Mean DBP			
Baseline	86.0±10.3	85.8±10.5	
Follow-up	78.9±10.1	83.1±7.6	
Difference	-6.92±8.99	-2.09±8.69	0.005
p-value*	<0.001	0.114	

* Within-group comparison (paired t-test)
** Between-group comparison (unpaired t-test)

Table 17: Effect of the intervention on BP changes from baseline to follow-up for all patients uncontrolled at baseline

	Standardized coefficients	p-value
SBP		
Intervention group	-0.19 [a]	0.041
DBP		
Intervention group	-0.26 [b]	0.002

[a] Coefficients from a multiple linear regression model adjusted for baseline SBP, baseline DBP, age, sex, health care center, diabetes, smoking status, time since HTN diagnosis, no. AHT and have resorted to the doctor the previous year to control HTN. $R^2 = 0.433$

[b] Coefficients from a multiple linear regression model adjusted for baseline DBP, baseline SBP, age, sex, health care center, diabetes, smoking status, no. AHT, main occupation and have resorted to the doctor the previous year to control HTN. $R^2 = 0.434$

When changes in SBP and DBP were adjusted for baseline covariates, the allocation group remained statistically significant, with control patients having a greater reduction in both SBP and DBP, than patients in the intervention group (Table 17).

Table 18: Effect of the intervention on BP control at follow-up for all patients uncontrolled at baseline

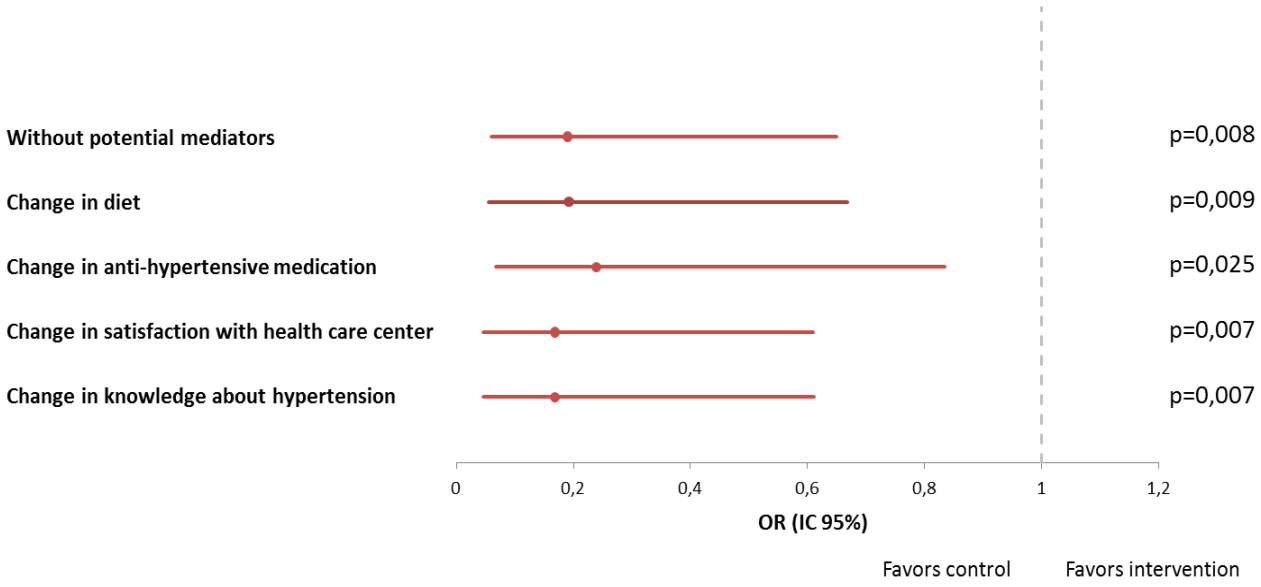
	Adjusted OR[a]	95% CI	p-value
Group assignment			
Control	Reference		
Intervention	0.19	0.06-0.65	0.008

[a] OR from a multiple logistic regression model adjusted for baseline BP control, age, sex, health care center, diabetes, smoking status, marital status, no. AHT, have resorted to the doctor the previous year to control HTN and have BP monitor
R^2 = 0.446
Hosmer-Lemeshow = 0.337

For the subgroup of patients uncontrolled at baseline, BP was controlled in significantly less patients in the intervention group than the control group at follow-up, with an OR of 0.19 (95%CI 0.06-0.65) after adjustment for covariates (Table 18).

To explore potential mediators of the effect of the allocation group on BP control, a series of multiple logistic regression models were conducted. These potential mediators were hypothesized to serve as mechanisms through which the effect of the allocation group on BP control was achieved. The analyses were conducted by entering the potentially mediating variables into the multiple logistic regression model that assessed the effect of the allocation group on BP control and observing the patterns of attenuation in the group effect. The potential mediators explored were variables whose change from baseline differed between groups, and therefore, could potentially explain why the improvements in BP control in the control group were significantly higher. Figure 10 presents the allocation group effect adjusted for the potential mediators.

Figure 10: Assignment group effect adjusted for potential mediators

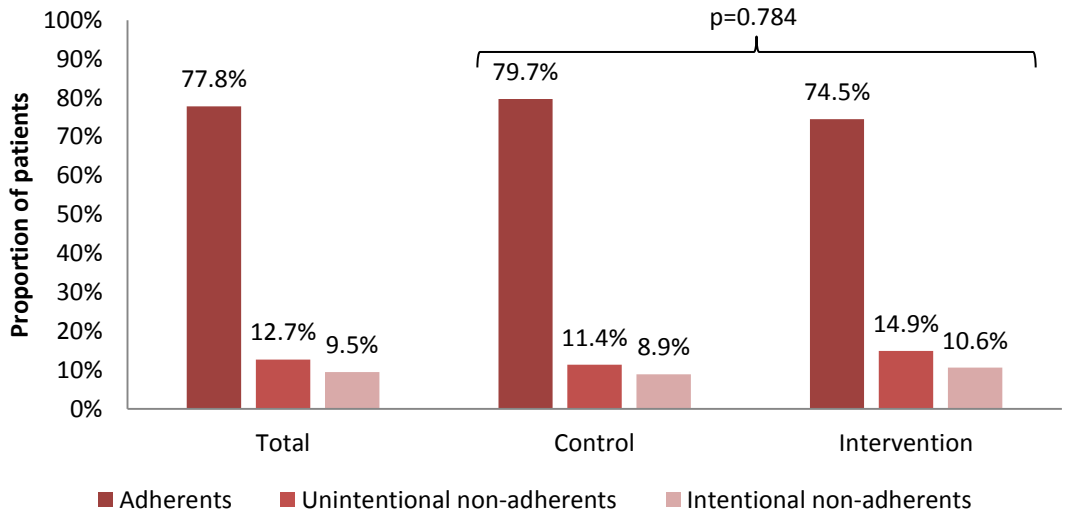


Adding the potential mediators to the multiple logistic regression model did not change the allocation group effect. The change in AHT medication from baseline was significantly superior in the control group and seems to be the only variable that attenuated the effect of the allocation group. However, because the effect is still statistically significant, we cannot conclude that this variable is a potential mediator of the improvements on BP control in the control group.

Medication adherence

Medication adherence rates at baseline for the patients with uncontrolled BP at baseline, are summarized in Figure 11. The rates of medication adherence did not differ between patients in the intervention and control groups (p=0.784).

Figure 11: Medication adherence rates at baseline for patients uncontrolled at baseline



The subgroup analysis of patients uncontrolled at baseline showed similar results as for the total sample in terms of medication adherence and unintentional non-adherence rates. At the end of the trial, there was a trend towards a small increase in the proportion of adherents in the intervention group (74.5% vs. 78.7%) (Table 19). In the control group, the percentage of adherence was similar between baseline and the endpoint (79.7% vs. 78.5%). There was no statistically significant difference between the intervention and control groups with regards to the change of adherence levels from baseline to follow-up. A reduction of the proportion of unintentional non-adherents of 6.4% was observed in the intervention group, whereas the control group experienced an increase of 3.8%. However, this difference was not statistical significant. As opposed to what was observed for the total sample, the proportion of intentional non-adherents in the control group decreased in this subgroup. However, the increase in the proportion of intentional non-adherents in the intervention group was maintained. No significant within-group differences were found in the change of

the proportion of adherent patients from baseline to follow-up in the control group (p=0.852) or intervention group (p=0.517).

Table 19: Differences in the proportion of adherents to medication from baseline to follow-up for all patients uncontrolled at baseline

	CONTROL (n=79)	INTERVENTION (n=47)	
Adherents			**p-value****
Baseline, %	79.7	74.5	
Follow-up, %	78.5	78.7	0.809
Difference, %	-1.2	4.2	
Intentional non-adherents			
Baseline, %	8.9	10.6	
Follow-up, %	6.3	12.8	0.537
Difference, %	-2.6	2.2	
Unintentional non-adherents			
Baseline, %	11.4	14.9	
Follow-up, %	15.2	8.5	0.264
Difference, %	3.8	-6.4	
p-value*	0.852	0.517	

* Within-group comparison (McNemar test)
** Between-group comparison (Chi-square)

Table 20: Effect of the intervention on medication adherence at follow-up for all patients uncontrolled at baseline

	Adjusted OR[a]	95% CI	p-value
Group assignment			
Control	Reference		
Intervention	0.88	0.30-2.63	0.814

[a] OR from a multiple logistic regression model adjusted for baseline adherence, age, sex, health care center, diabetes, smoking status, baseline DBP and knowledge about meaning of HTN
$R^2 = 0.282$
Hosmer-Lemeshow = 0.346

After adjusting for baseline covariates, medication adherence in the intervention group was no greater than in the control group at follow-up for patients uncontrolled at baseline (Table 20).

Other subgroups

For the primary outcome (BP control at follow-up), the planned analysis was repeated to assess the intervention effect in the subgroup of patients 65 years of age or older and in the subgroup of patients with a baseline of SBP≥150 mmHg.

- **Patients 65 years of age or older**

In the subgroup of patients 65 years of age or older (n=136), no significant difference was observed in BP control rates at follow-up between the study groups (OR 0.56; 95% CI= 0.18-1.75).

- **Patients with a baseline of SBP≥150 mmHg**

In the subgroup of patients a with baseline of SBP≥150 mmHg (n=62), no significant difference was observed in BP control rates at follow-up between the study groups (OR 0.23; 95% CI= 0.02-2.46).

E. SENSITIVITY ANALYSIS

To assess the robustness of our results, using a sensitivity analysis, we re-estimated the intervention effect in the primary outcome (BP control) under different scenarios (Table 21). First, we repeated our analysis considering a scenario where all patients lost to follow-up had the same BP values at baseline and follow-up, and found that this ITT analysis confirmed the results of the primary analysis. A second scenario considered that all subjects lost to follow-up had uncontrolled BP at the end of the study. This scenario also provided similar results to the primary analysis. When patients with more than 4.5 months between baseline and the follow-up interview were excluded, the results remained non-statistically significant but favored the intervention group. However, due to the large width of the confidence interval, this

estimate might not be very precise. In the scenario where the new ESH/ESC recommendations of BP target levels for diabetic patients were considered (140/85 mmHg), similar results to the primary analysis were also observed.

Table 21: Sensitivity analysis: effect of the intervention on BP control at follow-up under different scenarios

Scenario	Adjusted OR[a]	95% CI	p-value
ITT	0.63	0.30-1.31	0.214
Lost to follow-up uncontrolled at follow-up	0.76	0.38-1.53	0.442
<4.5 months from baseline and follow-up	1.60	0.37-6.93	0.533
Diabetics controlled at 140/85 mmHg	0.67	0.29-1.54	0.152

[a] OR from a multiple logistic regression model adjusted for baseline BP control, age, sex, health care center, diabetes, smoking status, no. AHT, main occupation and knowledge about meaning of HTN

Chapter 5

DISCUSSION

The purpose of this study was to test whether a combined educational and behavioral intervention improves HTN control and patient adherence to AHT medication in uncontrolled hypertensive patients versus usual care controls. We examined changes on BP, and medication adherence over three months in patients randomized to intervention and control groups and compared between-group findings. A general overview and discussion of the findings of the current study will be presented, followed by a review of the limitations, and concluding remarks and recommendations for future research.

A. BLOOD PRESSURE

The primary goal of this study was to determine whether an educational and behavioral intervention improves BP control in hypertensive patients.

As the differences between groups in terms of reduction of BP levels and improvement of BP control were not significant, we are unable to conclude that this particular intervention had a positive effect on BP in hypertensive patients. In addition, sensitivity analysis showed similar and consistent results, thus indicating the robustness of our findings.

Other studies have suggested that there is a potential for combined interventions to yield significant improvements in SBP and DBP, and BP control levels (135, 149-152). A study by Logan et al. (2012) (149) showed that HPBM, combined with self-care support, reduced the BP of diabetic patients with uncontrolled systolic HTN and improved HTN control. Similarly, in a RCT with a two year follow-up, a combined HBPM and tailored behavioral telephone intervention improved BP control, SBP, and DBP at 24 months relative to usual care (135).

Previous studies, reported no differences between intervention and control groups with respect to BP control, however they were mostly single-component interventions, addressing only one factor in isolation (133, 153, 154).

Some hypotheses can explain why no differences between groups were observed. First, the level of HTN control observed at baseline was higher than anticipated. The study was powered to detect a difference of at least 11.5% in the proportion of

patients achieving BP control, assuming that 100% of patients were uncontrolled at baseline. However, 34% of patients had their HTN controlled. This might have limited the ability of the study to demonstrate differences in terms of BP control between the two groups because more patients were controlled than anticipated in the power calculations. Despite uncontrolled BP was an inclusion criterion, the classification to enter the study was based on the last three readings registered in the clinical record, whereas the BP control rates reported above refer to the baseline interview measurements. The difference in the proportion of controlled patients might be explained by a potential improvement in BP control between the last GP visit and the baseline interview and/or the reduction of the white coat effect given that in the baseline interview the BP was assessed without a physician or nurse being present. Recent studies have also highlighted the risk of misclassification based on clinic or home BPs alone (155, 156). Since using an average of recent routine clinical BP measurements to identify eligible patients seems to include many patients who have, in fact, normal BP, it is not surprising to fail to find an improvement in BP over and above usual care (155).

A second possibility for the lack of differences between the intervention and control groups, could be related to medication adherence. In fact, this intervention intended to improve BP control by means of improving medication adherence. However, as we failed to improve adherence in these patients, this may have limited the potential effect of the intervention on BP control.

Another aspect is that patients in the control group did not receive a genuine usual care. Instead, patients were informed about the study, were asked to give informed consent, asked to respond to questions about their health and underwent examinations, drawing their attention to their HTN and possible intervention (157). Moreover, the patients in the control group were informed of their BP values, measured during the interview, and some of them asked the interviewer about their BP target goals at the beginning of the study. These actions may have raised patients' consciousness about their disease and may have induced a help-seeking behavior or influenced their complaints. The number of medical appointments did not differ between the two groups, however, this assessment was limited to the month

preceding the follow-up interview. In fact, treatment intensification was significantly higher among the control group.

Furthermore, the fact that the BP control improved in both groups in the present study could suggest a Hawthorne effect, whereby patients' knowledge that their BP was being monitored caused them to change their behavior accordingly (158).

Although the difference between groups was not statistically significant, both the control and intervention groups showed a significant decrease in SBP and DBP and a significant increase in BP control levels. Given that medication adherence rates did not significantly change from baseline, drug therapy adjustments may have contributed to improvements in BP control in both groups (151). The magnitude of SBP reduction was greater than the magnitude of DBP reduction in both groups. This might be explained by the controlled DBP values observed at baseline (mean 82.5 mmHg), which is expected in a population with a mean age of 68.9 years old, given the increased arterial stiffness observed in older adults (159).

In a subgroup analysis we examined the effect of the intervention in older adults. Despite evidence suggests that older patients can benefit from interventions to improve BP control (160-162) no significant difference was observed in BP control rates at follow-up between the study groups in the subgroup of patients 65 years of age or older. Besides the hypotheses previously discussed, one possible explanation for these results is that physicians may adopt a less aggressive therapeutic attitude when they face a BP increase in the elderly (because of lack of full perception of its risks and/or fear of a "J" curve phenomenon) (159). Moreover, it is particularly difficult to lower SBP to less than 140 mmHg in older adults, possibly because of the limited reversibility of an increase in arterial stiffness (7, 159). In a large number of clinical trials of AHT treatment in the elderly, the average achieved SBP never attained values < 140 mmHg (7).

When the analysis was limited to patients with SBP≥150 mmHg, no significant difference was observed in BP control rates at follow-up between the study groups.

Although a study by Green et al. (159) has achieved a greater net reduction in SBP in patients with baseline SBP ≥ 160 mmHg, high BP values are usually more difficult to treat. As previously mentioned, normalization of SBP may be intrinsically more difficult than normalization of DBP, possibility because of the difficulty of reversing the pathophysiological abnormalities responsible for the elevation of SBP (163). Moreover, given the small number of patients with baseline SBP≥150, this subgroup analysis is likely to have had low statistical power to detect an intervention effect.

When the analysis was limited to the subgroup of individuals whose BP was uncontrolled at baseline, unexpectedly, the control group showed significantly greater improvements in BP levels and BP control compared to the intervention group. We were unable to find any published trial that reported similar findings.

A potential explanation for our results is that treatment intensification - the most effective way of improving BP control (7) - was significantly higher among the control group, which is more marked in patients with uncontrolled HTN. When the group effect was adjusted for the treatment intensification, the effect was slightly attenuated, indicating that treatment intensification partially mediated the effects of the allocation group on BP control. However, as the effect remained statistically significant, we were not able to conclude that treatment intensification accounted for the relationship between the allocation group and the BP control.

Because patients in the intervention group knew they were being closely monitored by the research team, this may have prevented them from seeking provider care even when they were aware of their uncontrolled BP values.

B. MEDICATION ADHERENCE

In general, this population was highly adherent at baseline. According to a 2003 WHO report, 50% to 80% of patients treated for HTN were non-adherent to their treatment regimen (77). More recent RCTs of interventions to improve BP control, or medication adherence in hypertensive patients, reported baseline non-adherence rates of 39% to 50% (164-166). In this study, less than 20% of patients reported being non-adherent to AHT medication at baseline. The reason for the differences between the non-

adherence rates reported in the literature, and the rates observed in this study, is difficult to ascertain. However, some hypotheses may be suggested.

Adherence may have been overestimated, because it was assessed by patient self-report. Despite being commonly used in clinical practice, self-report measures tend to overestimate adherence, due to recall bias and social-desirability effects (167). Furthermore, the questionnaire was administered in a face-to-face interview which might have encouraged a socially desirable behavior (168). The inclusion of patients with a clinical visit in the previous 12 months might have biased the selection of patients, given that non-adherent patients are more likely not to seek care or to drop out of care, and therefore to be missing from the sample (169). Moreover, those agreeing to participate may be more adherent to medication than those who decline (169, 170).

One of the objectives of this study was to induce an improvement in medication adherence through an education intervention aimed to change patient knowledge, and the use of a patient diary, intended to encourage a behavioral change regarding medication intake.

The results of this study suggest that this intervention did not improve medication adherence when compared to standard of care. Interestingly, there was a trend toward a small improvement in medication adherence in the intervention group, whereas a small reduction was observed in the control group. Similarly, an intervention effect on medication adherence was not observed when the analysis was limited to the subgroup of individuals whose BP was uncontrolled at baseline.

Previous studies have reported significant increases in adherence to AHT therapy owing to combined educational and behavioral interventions. A literature review and meta-analysis by Morgado et al. (151) showed that pharmacist interventions can significantly improve medication adherence in patients with essential HTN. In this review, almost all the interventions that were effective for medication adherence or BP control improvements were complex and included combinations of medication management, educational programs directed at the patient, scheduling of more frequent follow-up appointments, medication reminders, counseling, self-monitoring

of BP, and other forms of additional supervision or attention (151). Despite including a combined intervention, our study did not significantly improved medication adherence.

There are several hypotheses that can explain why no effect was observed. First, the level of adherence in both groups was high, which may have exerted a ceiling effect on potential improvements in medication adherence. When baseline adherence is high, the interventions are unlikely to show a statistically significant improvement in this outcome (171, 172). A second possibility for the lack of differences between the intervention and control groups could be that for most people, behavioral changes occur gradually over time (173, 174). This was a three-month intervention with only one intervention session of 45 minutes, which might not have been sufficient to promote behavioral changes. In the Cochrane review of interventions for improving adherence to treatment in patients with high BP, Schroeder et al. (108) suggested that interventions should be tested over a period of at least six months. Another aspect is that patients in the intervention group were encouraged to embed their medication-taking habits in their individual daily routines to promote medication adherence. However, the routine reinforcement was likely helpful in a few cases only given that a high proportion of the participants (62%) reported at baseline that their medication-taking behavior was already integrated into their daily habits. Finally, this intervention did not comprise changes in the medication regimen. However, reduction of patient barriers such as complexity of drug regimens through reduction of number of daily doses, appears to be one of the most effective means of increasing adherence to medication (108, 134).

Fikri-Benbrahim et al. (175), performed a similar intervention study in patients with high baseline adherence rates. The intervention consisted of a written and oral education session on medication adherence and HTN, adapted to each patient based on their responses to an ad hoc questionnaire. Strategies to facilitate medication adherence were offered in cases of involuntary non-adherence, and patients were provided with a HBPM device and instructed to measure their BP. Despite the high baseline adherence rates, Fikri-Benbrahim et al. were able to show a significant increase in the proportion of adherent patients, compared to standard care. However,

this study had a quasi-experimental design, a 20-week intervention program with five follow-up visits, and excluded patients lacking motivation for self-control. This may help explain why we didn't achieve similar results in our study.

This intervention targeted both the intentional and unintentional non-adherence. However, we were only able to decrease unintentional non-adherence in the intervention group, even though the change was not statistically significant. Intentional non-adherence follows an active decision whether or not to take medications and is strongly associated with individuals' beliefs and cognitions (176). Changing such behavior requires time, motivation and a trust relationship between the patients and the provider (134, 177). This intervention consisted in only one face-to-face intervention session with health-care professionals with whom the patients were not familiar. This may have prevented patients from honestly sharing their beliefs and their possible concerns about the medication, hindering the ability to influence the degree of intentional non-adherence.

This intervention was expected to improve BP control through a combination of a patient diary and HBPM intended to improve patients' adherence. However, given that the majority of patients were already adherent to medication and measured their BP frequently, the patients included in the study were likely not the ones who would have benefit the most from this intervention.

C. LIMITATIONS

Volunteer bias may be present in this study as nearly 30% (n=148) of patients contacted refused to participate. According to the literature, the individuals who participate in intervention studies are younger, better educated, and functionally and physically more active than the non-participants (170). This suggests that the patients more likely to benefit from the intervention might have chosen not to participate. The patients that agreed to participate in this study are likely more concerned about their

HTN and BP control and were more motivated to improve their medication adherence and reduce their BP levels.

Given the nature of this intervention, blinding of the participants to their allocation group was not possible, which could explain why we found no differences between the groups. The patients that agreed to participate in the study were likely motivated to control their BP and, therefore, the participants in the control group may have also changed their behavior despite the request to maintain their usual activities. This "contamination" of the control group may have led to a reduction of the power to detect significant differences between the two groups (178). Furthermore, the pharmacists who provided the intervention were not blinded for the study group allocation of patients which may have also contributed for the risk of contamination between the intervention and the control group.

Assessment of HTN control was based on the BP measurements performed in only two interviews (baseline and three-month follow-up). There is a risk that these BP readings may not represent the usual BP levels of the participants and therefore may or may not be representative of the presence/absence of HTN control in these patients. Furthermore, given that we only had one pre-intervention and one post-intervention assessment and given that the subgroup of uncontrolled patients was selected based on their baseline BP values, it is possible that regression to the mean might have influenced the BP reductions in both groups (179, 180). However, the patients were randomly allocated to the study groups and the classification of the patients as uncontrolled was based on three baseline measurements, which might have mitigated the effects of a possible regression to the mean (179, 180).

Even though the interviewers were not blinded to the patients' allocation group, BP was measured with a digital BP monitor with a standard protocol, therefore, the BP readings are unlikely to have been biased.

Loss to follow-up was significant in this study. Approximately 21% of patients did not complete the three-month follow-up which might have reduced the power to show significant changes between the groups. Moreover, compared to the patients lost to follow-up, the patients that completed the study were significantly more educated,

were less intentional non-adherents, and a smaller proportion of patients had dyslipidemia and high waist circumference at baseline. This may indicate that the more severe and less motivated patients might have not completed the study. However, the proportion of lost to follow-up was similar between groups and the ratio of 1:2 (intervention : control), and the balance in terms of age and number of AHT drugs created by randomization, was maintained.

It was challenging for the investigator to meet with the participants three months after the baseline interview. The participants were not available most of the time to go to the health-care center, or were away from Lisbon for long periods of time, making it difficult to schedule the follow-up interview three months after the baseline assessment. The sensitivity analysis showed that when patients with a longer period between baseline and follow-up were excluded, the results favored the intervention group. This indicates that BP control in the intervention group might have deteriorated after the intervention was discontinued, three months after the baseline assessment. To properly portray the effects of the intervention the outcomes should have been measured right after the discontinuation of the intervention.

Medication adherence was measured by the researcher (not blinded), who could have been potentially biased in situations where the patients did not respond with determination to the Morisky Medication Adherence Scale.

D. STRENGTHS

To the best of our knowledge, this is the first RCT to test the effect of a combined intervention to improve HTN control in the primary care setting in Portugal. This was a complex, multifaceted intervention, including a combination of an education session tailored to the patient needs, a medication diary and self-monitoring of BP. According to the literature, the complex combined interventions are more effective as they are more likely to address the multiple barriers of non-adherence (134).

The stratified randomization ensured that the groups were balanced across age and number of AHT medications (as a proxy for HTN severity), characteristics that could have a strong influence on the outcome of the effectiveness of the intervention.

A combination of demographic, social and clinical data was collected allowing a comprehensive assessment of the patients' condition, their needs and their beliefs. This allowed us to tailor the intervention and to control for the variation in baseline characteristics.

Finally, the questionnaires and the intervention protocol were validated by a multi-disciplinary team of cardiologists, GPs, pharmacists, psychologists and sociologists with experience in HTN, epidemiology and public health.

E. CONCLUSION

In summary, it appears that this educational and behavioral intervention failed to produce greater BP control and medication adherence than usual care. While BP was reduced in the population, both patients who received the intervention and patients who did not, benefited.

BP control significantly increased in both the intervention and the control group, however, no differences were observed in the proportion of controlled patients at the end of the study, between the two groups.

From baseline to follow-up, a significant reduction of both SBP and DBP was observed, however, there was no statistically significant difference in the SBP or the DBP reduction in the intervention group compared to the control group at follow-up.

Although an improvement in medication adherence was only observed in the intervention group, no statistical significant differences were found between the two groups in the adherence levels at the end of the intervention.

Despite being unsuccessful in proving the differences between the groups, this study increased awareness about other factors that may strongly affect BP control, namely treatment changes, and that should be taken into account when designing combined interventions.

F. FUTURE RESEARCH

This study provides information about what to avoid and what to pursue in future interventions.

Future interventions should reflect the experiences and realities of the targeted community. Factors associated with uncontrolled BP among the targeted population must be thoroughly investigated and incorporated into the intervention strategies. For instance, interventions aimed at increasing BP control should recognize the importance of optimizing AHT treatment in order to achieve BP goals.

Future similar interventions may wish to investigate the effects of a longer follow-up with more intervention sessions and more frequent follow-up in order to properly achieve behavioral changes. Moreover, future research should avoid classifying patients as uncontrolled based on the clinic BPs alone, due to the risk of misclassification.

The results of the current study indicate that, perhaps the “contamination” of the control group might have spuriously reduced the intervention effect. Future studies of health-care interventions should explore strategies to prevent this “contamination”.

Finally, loss to follow-up was significant in this study. Future efforts should examine techniques to increase retention of the participants.

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ANNEXES

Projeto HiDia

Controlo da hipertensão no dia-a-dia

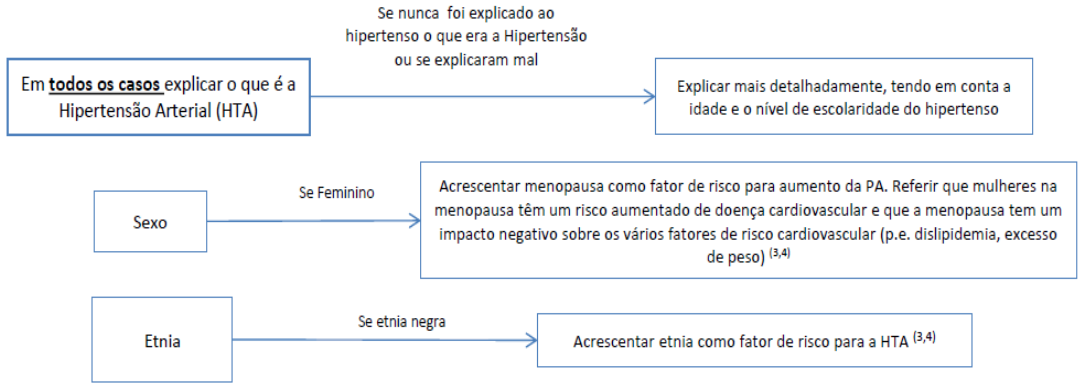
Unidade de Epidemiologia
Instituto de Medicina Preventiva

GUIA DE INTERVENÇÃO

1. MOTIVAÇÃO

Estado de mudança [1,2]	Estratégias de intervenção específicas para cada estado [1,2]
Pré-contemplação para contemplação	Fornecer informação sobre as vantagens e benefícios da adesão (como prevenção de AVC, ataque cardíaco...), personalizar o problema, usar apelos emocionais, transmitindo ao hipertenso que está ativamente envolvido na proteção da sua saúde.
Contemplação a Preparação	Identificar os contras percecionados pelos hipertensos, chamar a atenção para as conceções erradas sobre o uso da medicação, fornecer informação sobre os prós da adesão à terapêutica. Ceder estratégias transmitindo ao hipertenso que está ativamente envolvido na proteção da sua saúde.
Preparação para Ação	Usar estratégias para promover o compromisso: exercícios práticos, planear um dia típico de regime terapêutico e um dia mais desafiante em termos de toma da medicação.
Ação para Manutenção	Sugerir lembretes, suporte social, caixas organizadoras de comprimidos. Sugerir as várias estratégias disponíveis e perguntar ao hipertenso qual acha que pode funcionar com ele.

2. "O QUE É A PRESSÃO ARTERIAL" e "O QUE É A HIPERTENSÃO"



Annex I

Intervention session flowchart

Pergunta	Se responder a uma destas questões
Considera que…	
1. É frequente as pessoas com hipertensão sentirem que têm a tensão arterial elevada?	Sim
2. a Hipertensão é uma doença para toda a vida?	Não
3. uma pessoa hipertensa pode ter melhor saúde quando consegue baixar os seus valores de tensão?	Não
4. ter alguém na família que tenha hipertensão é um fator de risco para a hipertensão?	Não
5. a idade mais avançada é um fator de risco para a hipertensão?	Não
6. uma pessoa que tem sempre a tensão alta, corre um risco maior de ter um AVC (trombose)?	Não
7. uma pessoa que tem sempre a tensão alta, corre um risco maior de ter um enfarte (ataque cardíaco)?	Não
8. uma pessoa que tem sempre a tensão alta, corre um risco maior de ficar cego?	Não
9. uma pessoa hipertensa pode ter que tomar medicação o resto da vida?	Não

Desmistificar estas ideias.
Recomendar falar com o médico

"A partir de que valores acha que a sua tensão está controlada?"

Se referir valores >140/90mm Hg

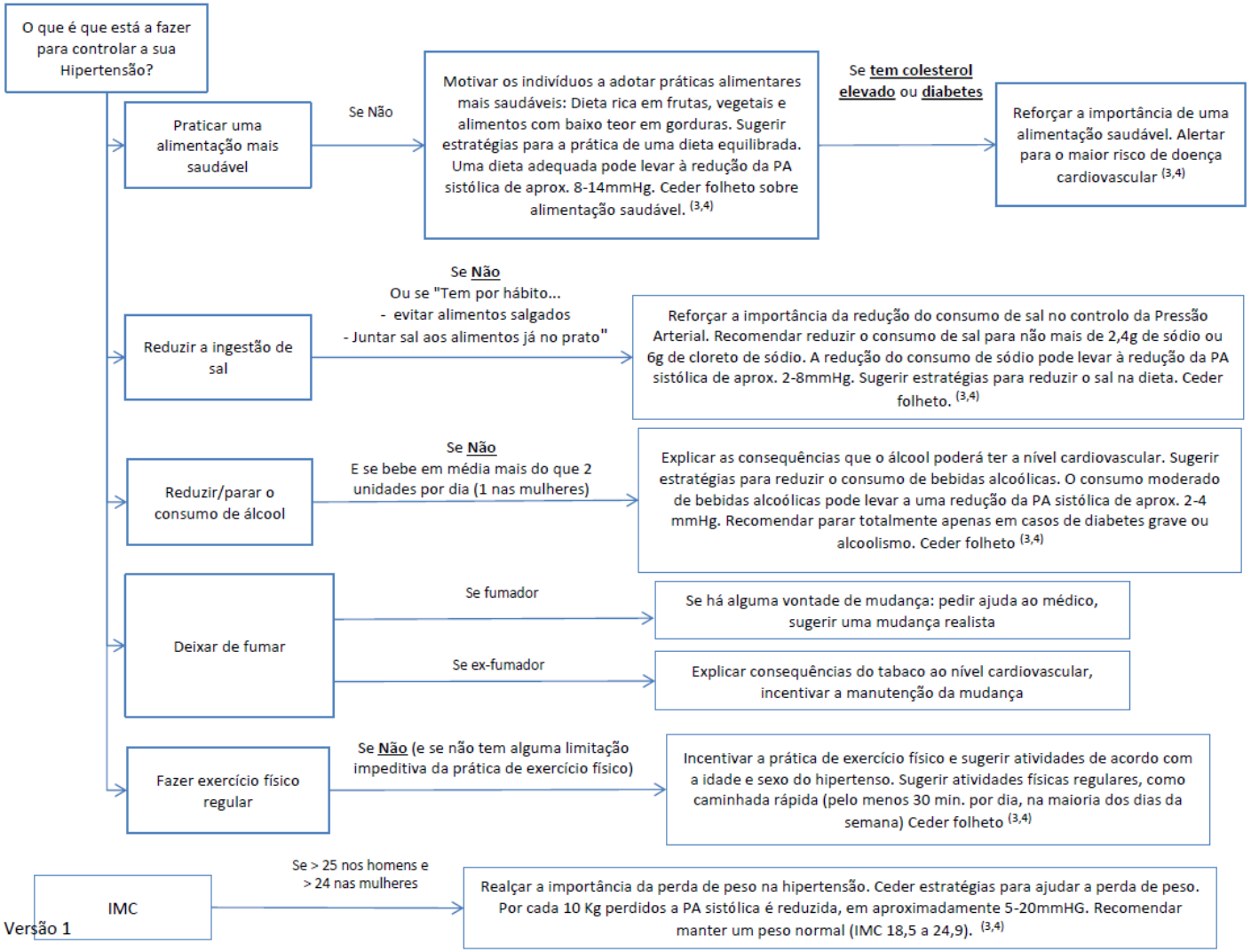
1. Perguntar quais os valores que o médico recomendou
2. Informar que, na maioria das pessoas com hipertensão, é recomendado manter os valores de PA < 140/90

3. "CAUSAS E COMPLICACÕES DA HTA" e "COMO CONTROLAR A HTA"

Pergunta	Se responder
"Até que ponto considera cada um dos seguintes comportamentos como importante para diminuir a tensão alta?"	
1. Deixar de fumar	Nada ou Pouco Importante
2. Perder peso se em excesso	Nada ou Pouco Importante
3. Praticar atividade física regular	Nada ou Pouco Importante
4. Diminuir o consumo de gordura	Nada ou Pouco Importante
5. Consumir mais frutas e vegetais	Nada ou Pouco Importante
6. Diminuir a ingestão de sal	Nada ou Pouco Importante
7. Consumir mais fibras	Nada ou Pouco Importante
8. Consumir bebidas alcoólicas de forma moderada, i.e. no máximo 2 copos de vinho tinto por dia (1 nas mulheres)	Nada ou Pouco Importante

Desmistificar estas ideias.
Recomendar falar com o médico

3.1 Estilos de Vida



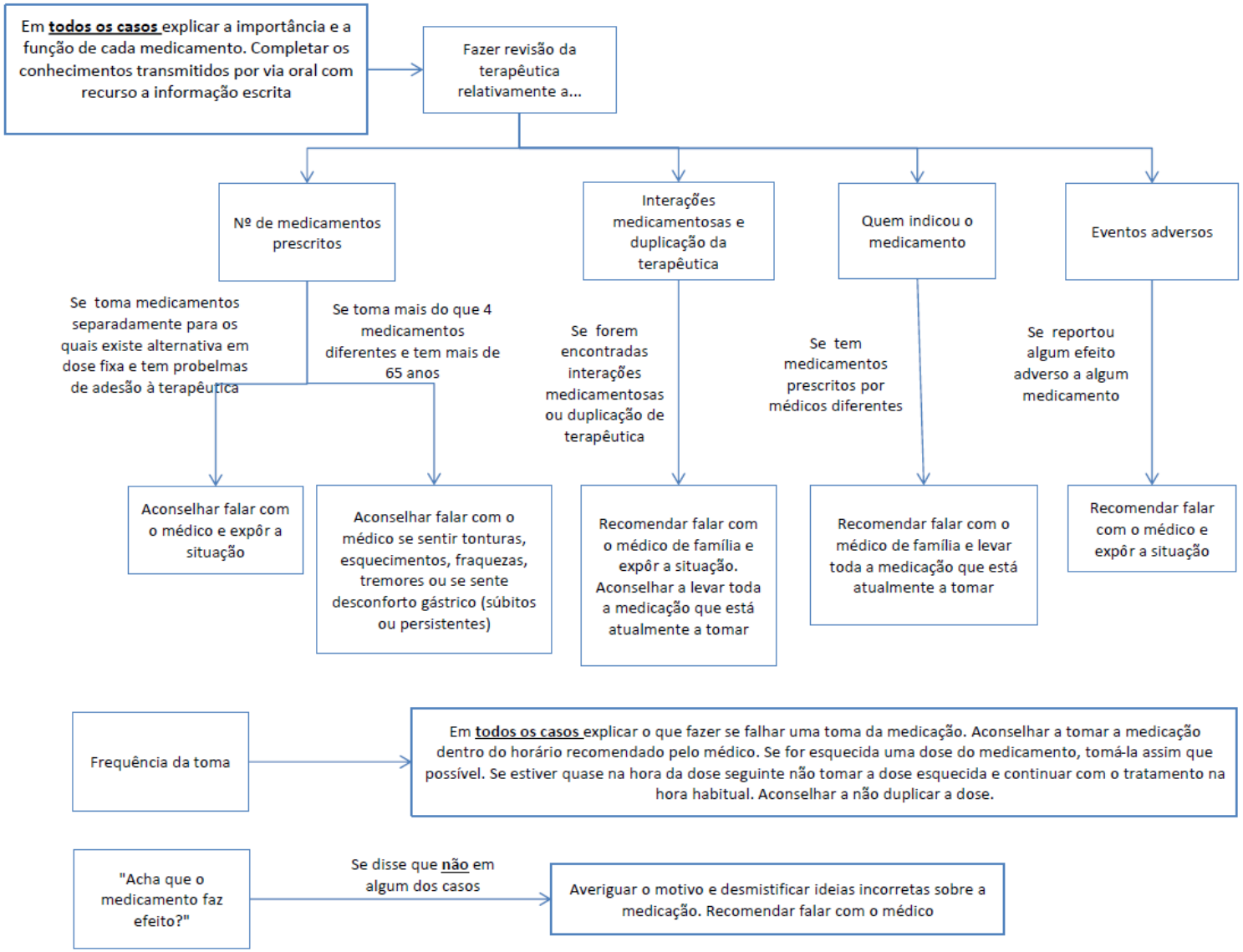
3. MEDICAÇÃO

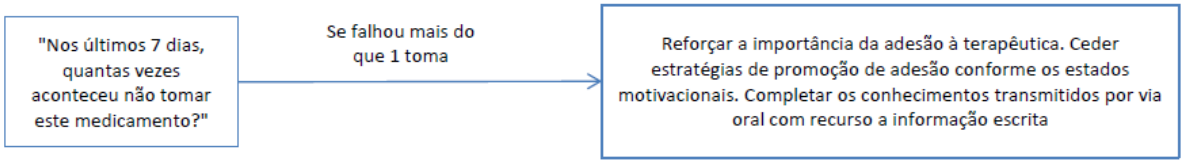
3.1 Crenças sobre a medicação

Pergunta	Se responder
1. As pessoas que tomam medicamentos deveriam parar com o tratamento de vez em quando	Concordo ou "Concordo Plenamente"
2. A maior parte dos medicamentos são aditivos	Concordo ou "Concordo Plenamente"
3. Os remédios naturais são mais seguros do que os medicamentos	Concordo ou "Concordo Plenamente"
4. Os medicamentos fazem mais mal do que bem	Concordo ou "Concordo Plenamente"
5. Todos os medicamentos são venenosos	Concordo ou "Concordo Plenamente"
6. Os médicos depositam demasiada confiança nos medicamentos	Concordo ou "Concordo Plenamente"
7. Se os médicos estivessem mais tempo com os seus doentes, prescreveriam menos medicamentos	Concordo ou "Concordo Plenamente"

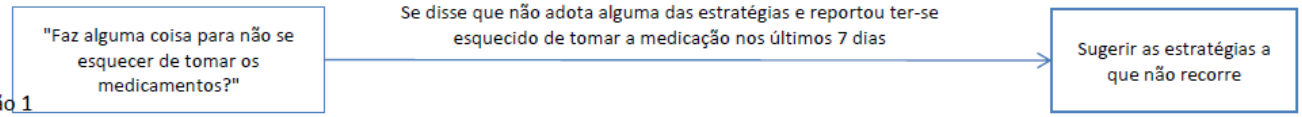
Desmistificar estas ideias. Aconselhar a falar com o médico

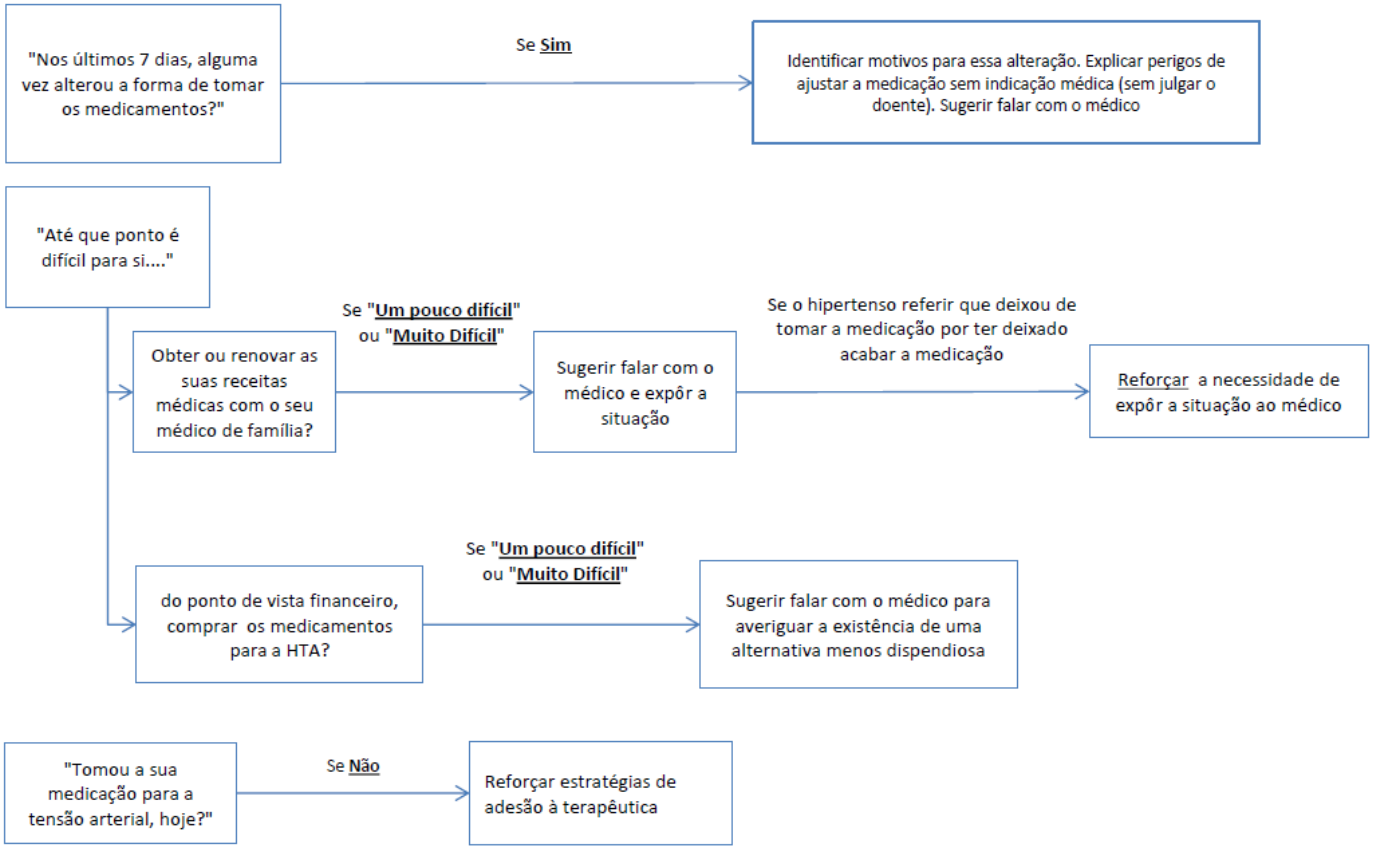
Pergunta	Se responder	Componente educacional
1. Ter que tomar medicamentos para a tensão alta preocupa-me	"Concordo" ou "Concordo Plenamente"	Explicar a importância, a efetividade e a segurança dos anti-hipertensores
2. Sem os meus medicamentos para a tensão alta estaria muito doente	"Discordo" ou "Discordo Plenamente"	Salientar importância da terapêutica e de que forma ela funciona.
3. Por vezes preocupo-me com os efeitos adversos a longo termo dos meus medicamentos para a tensão alta	"Concordo" ou "Concordo Plenamente"	Referir possíveis EA e vantagens a longo prazo dos antihipertensores. Sugerir falar com o médico.
4. Os meus medicamentos para a tensão alta são um mistério para mim	"Concordo" ou "Concordo Plenamente"	Reforçar revisão da terapêutica e possíveis dúvidas
5. A minha saúde no futuro vai depender dos meus medicamentos para a tensão alta	"Discordo" ou "Discordo Plenamente"	Explicar a importância, a efetividade e a segurança dos anti-hipertensores
6. Os meus medicamentos para a tensão alta perturbam a minha vida	"Concordo" ou "Concordo Plenamente"	Estratégias de adesão. Sugerir falar com médico.
7. Por vezes preocupo-me com poder tornar-me demasiado dependente dos meus medicamentos para a tensão alta	"Concordo" ou "Concordo Plenamente"	Explicar a importância, a efetividade e a segurança dos anti-hipertensores
8. Os meus medicamentos para a tensão alta protegem-me de ficar pior	"Discordo" ou "Discordo Plenamente"	Explicar a importância, a efetividade e a segurança dos anti-hipertensores


Em **todos os casos** explicar a importância e a função de cada medicamento. Completar os conhecimentos transmitidos por via oral com recurso a informação escrita
Fazer revisão da terapêutica relativamente a...
Nº de medicamentos prescritos
Interações medicamentosas e duplicação da terapêutica
Quem indicou o medicamento
Eventos adversos
Se toma medicamentos separadamente para os quais existe alternativa em dose fixa e tem probelmas de adesão à terapêutica
Se toma mais do que 4 medicamentos diferentes e tem mais de 65 anos
Se forem encontradas interações medicamentosas ou duplicação de terapêutica
Se tem medicamentos prescritos por médicos diferentes
Se reportou algum efeito adverso a algum medicamento
Aconselhar falar com o médico e expôr a situação
Aconselhar falar com o médico se sentir tonturas, esquecimentos, fraquezas, tremores ou se sente desconforto gástrico (súbitos ou persistentes)
Recomendar falar com o médico de família e expôr a situação. Aconselhar a levar toda a medicação que está atualmente a tomar
Recomendar falar com o médico de família e levar toda a medicação que está atualmente a tomar
Recomendar falar com o médico e expôr a situação
Frequência da toma
Em **todos os casos** explicar o que fazer se falhar uma toma da medicação. Aconselhar a tomar a medicação dentro do horário recomendado pelo médico. Se for esquecida uma dose do medicamento, tomá-la assim que possível. Se estiver quase na hora da dose seguinte não tomar a dose esquecida e continuar com o tratamento na hora habitual. Aconselhar a não duplicar a dose.
"Acha que o medicamento faz efeito?"
Se disse que **não** em algum dos casos
Averiguar o motivo e desmistificar ideias incorretas sobre a medicação. Recomendar falar com o médico

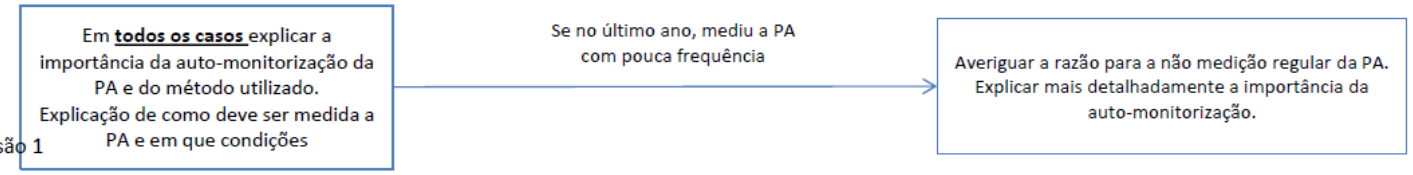


Pergunta		Se responder	Componente educacional
Tendo em conta os últimos 7 dias, pedimos-lhe que nos indique se alguma vez...			*A sugestões recomendadas devem ser debatidas com os doentes, de forma a obter-se um consenso que não prejudique o esquema terapêutico*
Não Intencional	1. se esqueceu de tomar os medicamentos para a HTA?	Sim	Sugerir memorandos para não esquecer a toma da medicação.Caso a pessoa não esteja já a utilizar a estratégia, recomendar: - adaptar o horário da medicação à rotina do utente, através da associação entre a toma da medicação e uma hora diária fixa, uma refeição, uma atividade ou um ritual (incorporar um memorando comportamental a uma atividade, não o transformando numa entidade separada); - Colocar informação visual em locais táticos e visíveis, para relembrar a toma da medicação; - Utilizar embalagens especiais, caixas de contagem e distribuição de comprimidos (1,2,5) [Ceder folheto]
	2. não deu atenção suficiente à toma dos medicamentos para a HTA?	Sim	
Intencional	3. deixou de tomar os seus medicamentos para a HTA por se ter sentido melhor?	Sim	A educação será reforçada em todos os doentes, mas sobretudo naqueles com má adesão intencional.Averiguar se a não adesão intencional de deve a reações adversas aos medicamentos, falhas de comunicação com os profissionais de saúde, poucas instruções ou crenças sobre a medicação. Adaptar as estratégias de acordo com o motivo da não adesão. Explicar perigos de ajustar a medicação sem indicação médica (sem julgar o doente). Sugerir falar com o médico (1,2,5)
	4. deixou de tomar os seus medicamentos para a HTA, por sua iniciativa, após se ter sentido pior?	Sim	
	5. tomou mais comprimidos para a HTA, por sua iniciativa, por se ter sentido pior?	Sim	
	6. interrompeu o tratamento para a HTA por ter deixado acabar os medicamentos?	Sim	
	7. deixou de tomar os medicamentos para a HTA por outra indicação que não fosse a indicação do médico?	Sim	





4. MEDIÇÃO DA PRESSÃO ARTERIAL



Pergunta	Se responder
"Em que situações mede a sua tensão arterial?"	
1. Quando tem dores de cabeça	Sim
2. Quando não se sente bem	Sim
3. Quando tem tonturas	Sim
4. Quando sente cansaço ou sonolência	Sim
5. Quando sente stress ou está nervoso	Sim
6. Se está algum tempo sem tomar medicamentos	Sim
7. Antes da consulta do médico	Sim
8. Na consulta médica	Sim
9. Quando se lembra (de forma irregular)	Sim
10. Rotina/Hábito	Não
11. Para saber como estão os valores de pressão arterial	Não

Salientar que a HTA é uma doença "silenciosa" e que, na maioria dos casos, os doentes não têm sintomas. Importância de medir a PA em condições adequadas.

Tem Diabetes?

Se **Sim**

Sugerir estratégias de auto-monitorização combinada. Ter atenção à frequência com que mede a glicémia para não haver medição excessiva da PA

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Nº questionário: ___-___ ___ ___

NOP: _____

Faculdade de Medicina de Lisboa
Instituto de Medicina Preventiva
Unidade de Epidemiologia

Hora início: ___:___

Hora fim: ___:___

Controlo da Hipertensão no Dia-a-Dia

O Instituto de Medicina Preventiva da Faculdade de Medicina de Lisboa e o seu Centro de Saúde estão a estudar formas de promover melhor controlo da pressão arterial alta (hipertensão).

Para esse fim, pedimos a sua colaboração, respondendo a algumas perguntas sobre o seu estado de saúde, práticas e hábitos relacionados com a hipertensão.

Todas as informações que nos dê através deste questionário são CONFIDENCIAIS e todos os dados serão tratados de forma anónima, sendo apenas utilizados de acordo com as finalidades deste estudo.

Agradecemos, desde já, a sua colaboração!

Patrocínio Financeiro:

Patrocínio Científico:

Preenchimento pelo Investigador			
1-N.º questionário	__-___ ___ ___	**2-Data de hoje**	d___ / m___ / 20___
3-UCSP / USF	_____	**4-Médico**	Dr/a _____
Nome do participante:		_____	

5-Em geral, respondeu às perguntas:

1. Sozinho [ ]
2. Acompanhado [ ] Relação com o inquirido:_____

Esta estrevista irá demorar aproximadamente 1h. Irei colocar-lhe as perguntas oportunamente. Esteja à vontade para interromper caso sinta que as perguntas não são suficientemente claras, eu esclarecerei tudo o que for preciso, tentado não ultrapassar o tempo proposto.

Annex II

Baseline interview questionnaire

B0 – Self-Report de Pressão Arterial

1. Entre que valores costuma variar a sua tensão arterial? S____ a ____ mmHg; D____ a ____ mmHg [ ]
   8. Não sabe
   9. Não responde
2. A partir de que valores acha que a sua tensão está controlada? S____ / D____ mmHg [ ]
   8. Não sabe
   9. Não responde
3. Tomou a sua medicação para a tensão arterial hoje? [ ]
   1. Sim, toda a medicação
   2. Sim, parte da medicação
   3. Não
   8. Não sabe/não se lembra
   9. Não responde

1.ª Medição da PA: *S_____ / D_____ mmHg* *Frequência cardíaca:_____*

Observações: _____

B1 – Estilos de Vida

Atividade Física

Agora vou fazer-lhe algumas perguntas sobre o **tempo gasto em actividades físicas** nos **últimos 7 dias**. Mesmo que não se considere uma pessoa activa, gostaria que pensasse nas actividades feitas no trabalho, em casa, no jardim ou na horta, na deslocação de um lugar para outro e ainda em exercício ou desporto.

4. Em relação aos últimos 7 dias, fez pelo menos 10 min seguidos de...		Se sim: 4.1. Quantos dias?	Se sim: 4.2. Em média, durante QUANTO TEMPO, nesses dias?
a) Atividades físicas vigorosas (Fazem respirar mais forte do que o normal. Ex: levantar cargas pesadas, cavar, ginástica aeróbica ou andar rapidamente de bicicleta. Incluir atividade profissional)	[ ] Sim [ ] Não	___ dias	____ Minutos
b) Atividades físicas moderadas (Fazem respirar um pouco mais forte que o normal. Ex: transportar cargas leves, andar devagar de bicicleta, tarefas domésticas, cuidar do jardim. Não inclui o andar. Incluir a atividade profissional)	[ ] Sim [ ] Não	___ dias	____ Minutos
c) Andar (Andar no trabalho e em casa, deslocar-se de um lugar para outro e ainda o ato de caminhar somente por recreação, desporto, exercício ou lazer)	[ ] Sim [ ] Não	___ dias	____ Minutos
d) Estar sentado/a (Tempo gasto no trabalho, em casa, enquanto faz o trabalho corrente e durante o tempo de lazer. Ex: sentado a uma secretária, visita em casa de amigos, ler ou estar sentado ou em repouso vendo televisão ou ouvindo música. Inclui o tempo gasto estando deitado, mas acordado).	[ ] Sim [ ] Não	___ dias	____ Minutos

Consumo de álcool

1. Sim
2. Não
8. NS
9.NR

5. Em relação aos últimos 7 dias, bebeu vinho, cerveja ou tomou outra bebida alcólica? [ ]
   Se respondeu "Não" → Pergunta 6 (hábitos tabágicos)

5.1. Que tipo de bebida?		5.1.1. Se sim, quantos dias na última semana?	5.1.2. Nos dias em que bebeu, quantos copos, em média?
a) Vinho	[ ] Sim [ ] Não	___ dias	___ copos por dia
b) Cerveja	[ ] Sim [ ] Não	___ dias	___ minis por dia ___ imperiais/cervejas por dia ___ canecas por dia
c) Aguardente, Vinho do Porto, Martini, Licores, Whisky, Gin,...	[ ] Sim [ ] Não	___ dias	___ copos por dia ___ cálices por dia

Hábitos tabágicos

6. Em relação ao consumo de tabaco, como se caracteriza?		6.1. Nº médios cigarros/dia	6.2. Idade - início	6.3. Idade – final
1. Fumador	[ ]	____	___ anos	
2. Ex-fumador		____	___ anos	___ anos
3. Nunca fumou				
9. Não sabe / Não responde				

Qualidade de vida

7. Qual das afirmações melhor descreve o seu estado de saúde hoje?

7.1. quanto à mobilidade *(dar opções)* [ ]
1. Não tenho problemas em andar
2. Tenho alguns problemas em andar
3. Tenho de estar na cama

7.2. quanto aos cuidados pessoais *(dar opções)* [ ]
1. Não tenho problemas com os meus cuidados pessoais
2. Tenho alguns problemas em lavar-me ou vestir-me
3. Sou incapaz de me lavar ou vestir sozinho/a

7.3. quanto às actividades habituais - (ex. trabalho, estudos, actividades domésticas, actividades em família ou de lazer) *(dar opções)* [ ]
1. Não tenho problemas em desempenhar as minhas actividades habituais
2. Tenho alguns problemas em desempenhar as minhas actividades habituais
3. Sou incapaz de desempenhar as minhas actividades habituais

7.4. quanto à dor ou mal-estar *(dar opções)* [ ]
1. Não tenho dores ou mal-estar
2. Tenho dores ou mal-estar moderados
3. Tenho dores ou mal-estar extremos

7.5. quanto à ansiedade ou depressão *(dar opções)* [ ]
1. Não estou ansioso/a ou deprimido/a
2. Estou moderadamente ansioso/a ou deprimido/a
3. Estou extremamente ansioso/a ou deprimido/a

	7.6. Para ajudar as pessoas a definir o seu bom ou mau estado de saúde, desenhámos uma escala (semelhante a um termómetro) na qual o melhor estado de saúde que possa imaginar é marcado por 100 e o pior estado de saúde que possa imaginar é marcado por 0. *(mostrar escala)* Gostaríamos que indicasse nesta escala quão bom ou mau é, na sua opinião, o seu estado de saúde hoje.	[ ]

B2 – Sobre a Hipertensão Arterial

Diagnóstico da HTA	**8.** Que idade tinha quando lhe disseram pela primeira vez que tinha hipertensão? 8. Não sabe /não se lembra 9. Não responde	_____ anos [ ]
	9. Quem lhe disse pela primeira vez que tinha hipertensão? 1. Médico de Família 2. Outro Médico 9.2.1. Especialidade: _____ 3. Enfermeiro 4. Farmacêutico 5. Outra pessoa 9.5.1. Quem?_____ 8. Não sabe /não se lembra 9. Não responde	[ ]
Início da terapêutica farmacológica	**10.** Que idade tinha quando começou a tomar medicamentos para a tensão? 8. Não sabe /não se lembra 9. Não responde	_____ anos [ ]
Conhecimento sobre HTA	**11.** Alguma vez lhe explicaram o que era a hipertensão? 1. Sim, o médico de família 2. Sim, outro médico 11.2.1. Especialidade: _____ 3. Explicaram, mas não foi o médico. 11.3.1. Quem? _____ 4. Não me explicaram → ***pergunta 12.*** 8. Não sabe /não se lembra → ***pergunta 12.*** 9. Não responde → ***pergunta 12.***	[ ]
	11.1. Como diria que lhe explicaram o que era (a hipertensão)? *(dar as opções)* 1. Explicaram mal 2. Explicaram mais ou menos 3. Explicaram bem 8. Não sabe /não se lembra 9. Não responde	[ ]
Opinião sobre Hipertensão	Gostaríamos de conhecer melhor a sua opinião sobre a hipertensão. **12.** Para si, o que significa hipertensão? *(dar as opções)* 1. Elevado nível de stresse 2. Elevado nível de pressão que o sangue aplica às artérias 3. Elevado nível de açúcar no sangue 8. Não sabe 9. Não responde	[ ]
1. Sim 2. Não 8. NS 9. NR	**13.** Considera que... **13.1.** ... baixar a pressão arterial pode melhorar a saúde de uma pessoa hipertensa?	[ ]
	13.2. ... ter alguém na família com hipertensão aumenta a probabilidade de ter hipertensão?	[ ]

	13.3. ... a idade mais avançada aumenta a possibilidade de ter hipertensão?	[ ]
	13.4. ... uma pessoa que tem sempre a tensão alta, corre um risco maior de ter um AVC (trombose)?	[ ]
	13.5. ... uma pessoa que tem sempre a tensão alta, corre um risco maior de ter enfarte (ataque cardíaco)?	[ ]
	13.6. ... uma pessoa que tem sempre a tensão alta, corre um risco maior de ficar cego?	[ ]
	13.7. ... uma pessoa hipertensa pode ter de tomar medicação o resto da vida?	[ ]

Conhecimentos sobre o estilo de vida saudável

14. Numa escala de 1 a 4, até que ponto considera cada um dos seguintes comportamentos como importante para diminuir a tensão alta?

	1. Nada importante	2. Pouco importante	3. Importante	4. Muito importante
14.1. Deixar de fumar	[ ]	[ ]	[ ]	[ ]
14.2. Perder peso se em excesso	[ ]	[ ]	[ ]	[ ]
14.3. Praticar atividade física regular	[ ]	[ ]	[ ]	[ ]
14.4. Diminuir o consumo de gordura	[ ]	[ ]	[ ]	[ ]
14.5. Consumir mais frutas e vegetais	[ ]	[ ]	[ ]	[ ]
14.6. Diminuir a ingestão de sal	[ ]	[ ]	[ ]	[ ]
14.7. Consumir mais fibra	[ ]	[ ]	[ ]	[ ]
14.8. Consumir bebidas alcoólicas de forma moderada, i.e. no máximo, 2 copos de vinho tinto por dia (1 copo nas mulheres)	[ ]	[ ]	[ ]	[ ]
14.9. Parar, por completo, de consumir bebidas alcoólicas	[ ]	[ ]	[ ]	[ ]

2.ª Medição da PA: *S_____ / D_____ mmHg* *Frequência cardíaca:_____*

Observações: _____

Crenças sobre a Hipertensão

15. Para cada uma das questões que se seguem, indique qual o número que melhor corresponde à sua maneira de pensar *(cartão)*

15.1. Até que ponto a hipertensão afeta a sua vida?	[ ]
15.2. Quanto tempo pensa que vai durar a sua hipertensão?	[ ]
15.3. Até que ponto sente que controla a sua hipertensão?	[ ]
15.4. Até que ponto pensa que o seu tratamento pode ajudar a sua hipertensão?	[ ]
15.5. Até que ponto sente sintomas da sua doença?	[ ]
15.6. Até que ponto está preocupado com a sua hipertensão?	[ ]
15.7. Até que ponto sente que compreende a sua hipertensão?	[ ]
15.8. Até que ponto a sua hipertensão o/a afeta emocionalmente? (ex. fá-lo/a sentir-se zangado/a, assustado/a, chateado/a ou deprimido/a)	[ ]
15.9. Até que ponto tem a certeza de ser capaz de tomar a medicação da hipertensão tal como foi indicado pelo médico?	[ ]

Crenças sobre a hipertensão – causas

16. Na sua opinião, quais as três principais razões mais responsáveis pela sua hipertensão?

Por favor, ordene-as por ordem decrescente *(da mais importante para a menos importante)*:

A. _____ _____

B. _____ _____

C. _____ _____

B2 – Sobre a Hipertensão Arterial (cont.)

Seguimento médico

1. Sim
2. Não
8. NS
9. NR

17. Habitualmente, qual o médico que o/a segue por causa da hipertensão? *(pode indicar mais do que uma opção)*

17.1. Médico de família		[ ]
17.2. Médico cardiologista		[ ]
17.3. Outro médico especialista	17.3.1. Qual? _____	[ ]
17.4. Nenhum médico em particular		[ ]

Controlo da TA

1. Sim
2. Não
7. NA
8. NS
9. NR

18. O que é que está a fazer para controlar a hipertensão? *(dar opções)*

19. O que é que lhe foi recomendado pelo médico para controlar a hipertensão?

		18	19
a)	Praticar uma alimentação mais saudável	[ ]	[ ]
b)	Reduzir a ingestão de sal	[ ]	[ ]
c)	Reduzir/parar o consumo de álcool	[ ]	[ ]
d)	Deixar de fumar	[ ]	[ ]
e)	Perder peso	[ ]	[ ]
f)	Fazer exercício físico regular	[ ]	[ ]
g)	Outro 18.7.1. Qual? _____ 19.7.1. Qual? _____	[ ]	[ ]

20. Nos últimos 12 meses, a quem pediu conselhos para tratar a hipertensão...

(Dar opções. Pode indicar mais do que uma)

1. Sim
2. Não
8. NS
9. NR

20.1. Médico de família		[ ]
20.2. Médico especialista no hospital	20.2.1. Especialidade: _____ 20.2.2 Hospital _____	[ ]
20.3. Médico privado	20.3.1. Especialidade: _____	[ ]
20.4. Médico do Trabalho (Medicina do Trabalho)		[ ]
20.5. Médico do serviço de urgência	20.5.1 Qual? _____	[ ]
20.6. Enfermeiro no CS / USF		[ ]
20.7. Farmacêutico		[ ]
20.8. Medicinas alternativas	20.8.1. Qual? _____	[ ]
20.9. Outro	20.9.1. Qual? _____	[ ]
20.10.	Não recorreu a nenhuma das opções anteriores nos últimos 12 meses	[ ]

B3 – Sobre a Medição da Pressão Arterial e outros parâmetros

21. Tem diabetes?	[ ]
22. Tem colesterol alto?	[ ]

23. Em média no último ano, com que frequência mediu...

	23.1. a glicemia (açúcar no sangue) em jejum?	23.2. os valores de colesterol?	23.3. a tensão arterial?
1. Uma ou mais vezes por dia 2. Uma ou mais vezes por semana 3. Uma ou mais vezes por mês 4. 4x ano (3 em 3 meses) 5. 2x ano (6 em 6 meses) 6. 1x ano 7. Nunca 8. Outra 23.8.1 Indique: → 9. Não sabe 99. Não responde	[ ]	[ ]	[ ]
	_____	_____	_____

24. Em relação à medição da tensão arterial, onde é que a faz mais frequentemente?

1. Centro de Saúde/USF
2. Farmácia
3. Em casa
4. Hospital
5. Medicina do Trabalho
6. Clínica
7. Outro. 24.7.1 Qual? _____
8. Não sabe
9. Não responde

[ ]

Medição da TA

1. Sim
2. Não
8. NS
9. NR

25. Tem um aparelho para medir a tensão arterial em casa?

Se responde Não → Pergunta 26 [ ]

25.1 De que tipo?

1. Digital de braço
2. Digital de pulso
3. Aneróide (com mostrador de agulha) [ ]
4. De mercúrio (com uma coluna e um nível)
8. Não sabe
9. Não responde

1. Sim
2. Não
8. NS
9. NR

26. Em que situações mede a sua tensão arterial? *(dar opções)*

26.1	Quando tem dores de cabeça	[ ]
26.2	Quando não se sente bem	[ ]
26.3	Quando tem tonturas	[ ]
26.4	Quando sente cansaço ou sonolência	[ ]
26.5	Quando sente stresse ou está nervoso	[ ]
26.6	Se está algum tempo sem tomar medicamentos	[ ]
26.7	Antes da consulta do médico	[ ]
26.8	Quando tem consulta médica, na própria consulta	[ ]
26.9	Quando se lembra (de forma irregular...)	[ ]
26.10	Rotina / Hábito 26.10.1. Como mede (dias da semana, hora): _____	[ ]
26.11	Para saber como estão os valores da sua pressão arterial	[ ]
26.12	Outras. 26.12.1 Indique: _____	[ ]

B4 – Opinião sobre o médico de família e o Centro de Saúde /USF

27. Até que ponto está satisfeito de uma forma geral com o seu médico de família?
    1. Muito insatisfeito
    2. Um pouco insatisfeito
    3. Nem Insatisfeito nem Satisfeito
    4. Satisfeito
    5. Muito Satisfeito
    8. Não Sabe
    9. Não Responde

    [ ]

28. Até que ponto está satisfeito de uma forma geral com o seu Centro de Saúde?
    1. Muito insatisfeito
    2. Um pouco insatisfeito
    3. Nem Insatisfeito nem Satisfeito
    4. Satisfeito
    5. Muito Satisfeito
    8. Não Sabe
    9. Não Responde

    [ ]

29. Recomendaria o seu médico de família a conhecidos seus com hipertensão?
    1. Sim
    2. Não
    8. Não sabe / Tem dúvidas
    9. Não responde

    [ ]

B5 – Suporte social

Suporte Social

1. Sim
2. Não
8. NS
9. NR

30. Tem ajuda de algum familiar ou amigo para controlar a sua tensão arterial, quanto a: *(dar opções, pode assinalar mais do que uma)*

30.1. Relembrar da toma da medicação	[ ]
30.2. Relembrar de ir/marcar consultas médicas	[ ]
30.3. Acompanhá-lo/a quando vai às consultas médicas	[ ]
30.4. Ajudar na medição da tensão arterial	[ ]
30.5. Comprar-lhe a medicação	[ ]
30.6. Explicar-lhe como gerir melhor a doença	[ ]
30.7. Acompanhá-lo/a durante a prática de atividade física	[ ]
30.8. Ajuda-lo a comer de forma mais saudável	[ ]
30.9. Ajuda-lo a acalmar-se, quando fica irritado/a ou nervoso/a	[ ]
30.10. Outra. 30.10.1. Qual?_____	[ ]
30.11. Não tem ajuda de familiar ou amigo para o/a ajudar a controlar a hipertensão	[ ]

30. a) (*se tem alguma* ajuda) **Qual o seu grau de satisfação com essa ajuda?**
1. Muito Insatisfeito
2. Um Pouco Insatisfeito
3. Nem Insatisfeito nem Satisfeito
4. Satisfeito
5. Muito Satisfeito
8. Não sabe
9. Não responde

[ ]

30. b) (*se não tem alguma* ajuda) **Acha que necessita de ajuda?**
1. Sim
2. Não
8. Não sabe
9. Não responde

[ ]

B6 – Medicação Atual

Sabemos que as pessoas com hipertensão tomam, frequentemente, muitos medicamentos (por vezes, para várias doenças).

31. Com a sua autorização, vamos agora registar todos os medicamentos que tomou / está a tomar, de forma regular ou em SOS, no último mês.

31.1. Nome do medicamento (comercial ou titular AIM) Dosagem, Dimensão embalagem (n.º unidades), Apresentação Exemplo: 1. Amlodipina Ciclum, 10 mg, 60, comprimidos	31.2. Preço	31.3. Como toma? Frequência da toma: Regular (Alum – Al; Pequeno-almoço – PA; Almoço – A; Lanche – L; Jantar – J; Deitar – D)	31.3. SOS ou outra freq	31.4. Para o qual? 9. NS/NR	31.5. Quem indicou? 1. Médico família 2. Médico privado 3. Médico hospital 4. Enfermeiro 5. Farmacêutico 6. Familiar 7. Auto-medicação 8. Outro 9. NS / NR	32. Em relação aos medicamentos para a HTA: 32.1. Há quanto tempo toma? 1. <1 mês 2. >= 1 mês e < 6 meses 3. >= 6 meses e < 1 ano 4. 1 a – 5 a 5. > 5 anos 9. NS / NR	32.2. Acha que faz efeito? 1.Sim 2.Não 9.NS/NR	32.3. Tem / Teve algum incómodo relacionado com este medicamento? 1. Sim, qual? 2. Não 9. NS / NR	32.4. É muito frequente as pessoas não tomarem sempre os medicamentos como o médico indicou, por muitas razões: porque se esquecem, fazem "férias dos medicamentos", porque se sentem mal com eles, etc. Nos últimos 7 dias (a terminar ontem), quantas vezes aconteceu não tomar este medicamento? 99.NS/NR
1.					[ ]	[ ]	[ ]	[ ]	
2.					[ ]	[ ]	[ ]	[ ]	
3.					[ ]	[ ]	[ ]	[ ]	
4.					[ ]	[ ]	[ ]	[ ]	
5.					[ ]	[ ]	[ ]	[ ]	
6.					[ ]	[ ]	[ ]	[ ]	
7.					[ ]	[ ]	[ ]	[ ]	
8.					[ ]	[ ]	[ ]	[ ]	

B7 - Sobre os Medicamentos para a Tensão Arterial

Toma da Medicação

Como já foi dito, é muito frequente as pessoas esquecerem-se ou ajustar a forma de tomar os seus medicamentos, por vários motivos

33. Tendo em conta os últimos 7 dias, pedimos-lhe que nos indique se:

1. Sim
2. Não
8. NS
9. NR

33.1.	Alguma vez se esqueceu de tomar os seus medicamentos para a TA?	[ ]
33.2.	Alguma vez não deu atenção suficiente às horas da toma dos medicamentos para a TA?	[ ]
33.3.	Alguma vez deixou de tomar os seus medicamentos para a TA por se ter sentido melhor?	[ ]
33.4.	Alguma vez deixou de tomar os seus medicamentos para a TA, por sua iniciativa, após se ter sentido pior?	[ ]
33.5.	Alguma vez tomou mais comprimidos para a TA, por sua iniciativa, após se ter sentido pior?	[ ]
33.6.	Alguma vez interrompeu o tratamento para TA por ter deixado acabar os medicamentos?	[ ]
33.7.	Ajustou em função do seu dia-a-dia, com as atividades planeadas?	[ ]
33.8.	Ajustou por razões financeiras?	[ ]
33.9.	Alguma vez deixou de tomar os medicamentos para a TA por outra indicação, que não fosse a indicação do médico?	[ ]

1. Sim
2. Não
8. NS
9. NR

34. Faz alguma coisa para não se esquecer de tomar os medicamentos?
(dar as opções, pode assinalar mais do que uma)

34.1.	Sim, tem escrito como tomar num papel ou nas caixas	[ ]
34.2.	Sim, tem uma caixa com divisórias onde guarda os medicamentos	[ ]
34.3.	Sim, trago-os comigo (ex: carteira)	[ ]
34.4.	Sim, segue sempre a mesma rotina	[ ]
34.5.	Sim, tem a ajuda a familiares e/ou amigos	[ ]
34.6.	Sim, coloca os medicamentos em local visível ou "estratégico" (ex: frigorífico)	[ ]
34.7.	Sim, tenho alarme/s no telemóvel e/ou computador	[ ]
34.8.	Não faz nada	[ ]
34.9.	Outra. 34.9.1 Indique_____	[ ]

1. Nada difícil
2. Um pouco difícil
3.Muito difícil
8. NS
9. NR

35. Até que ponto é difícil para si...

35.1.	Obter ou renovar as suas receitas médicas com o seu médico de família?	[ ]
35.2.	Adquirir os seus medicamentos para a HTA quando não tem receita?	[ ]
35.3.	Do ponto de vista financeiro, comprar os medicamentos para a HTA?	[ ]

B8 – Acesso aos cuidados de saúde

Seguro de saúde

1. Sim
2. Não
88. NS
99. NR

36. No que diz respeito aos Cuidados de Saúde, para além do Serviço Nacional de Saúde, o/a Sr/a.... *(dar as hipóteses)*

	36.1 ... é beneficiário/a de que outro/s Seguro/s?	36.2 ... e qual é o seguro a que recorre mais vezes?
1. ADSE (Assist. Doença Serv. Estado)	[ ]	
2. SSMJ (Serv. Minist. Justiça)	[ ]	
3. ADM (Assistência de Doença aos Militares)	[ ]	[ ]

	4. SAD/PSP (Serv. Assist. Doença à PSP)	[ ]
	5. SAD/GNR (Serv. Assist. Doença à GNR)	[ ]
	6. SAMS (Serv. Ação Méd. Soc. Bancários)	[ ]
	7. PT/CTT	[ ]
	8. Sãvida (EDP)	[ ]
	9. SNS (Serv. Nacional de Saúde)	
	10. Outro 36.10.1. Qual?_____	[ ]
	99. Não sabe/Não responde	[ ]
Seguro Privado de saúde	**37. É beneficiário/a de algum seguro privado de saúde?** 1. Sim 2. Não 9. Não sabe / Não responde	[ ]

B9 – Caracterização sócio-demográfica

Para terminar, gostava de lhe fazer algumas perguntas, que depois irão ajudar-nos a caracterizar os participantes no estudo:

Etnia	***38. (não colocar esta questão)*** 1. Caucasiana 2. Africana 3. Outra 38.3.1 Qual?_____	[ ]
Sexo	***39. (não colocar esta questão)*** 1. Masculino 2. Feminino	[ ]
Naturalidade	**40. Nasceu em que país?** 1. Portugal 2. Outro 40.2.1 País: _____ 8. Não sabe 9. Não responde	[ ]
Estado civil	**41. Qual é a sua situação familiar?** 1. Solteiro/a 2. Casado/a ou em união de facto (vive maritalmente há pelo menos 2 anos) 3. Divorciado/a ou separado/a (sem relação marital, atualmente) 4. Viúvo/a (sem relação marital, atualmente) 8. Não sabe 9. Não responde	[ ]
Agregado familiar	**42. Quantas pessoas moram consigo (sem contar consigo mesmo/a)?** 88. Não sabe 99. Não responde	____ pessoas [ ]

Ocupação Principal	**43. Das seguintes categorias, qual a que melhor descreve a sua ocupação principal, nas duas últimas semanas?** 1. Exerce uma profissão 2. Estudante 3. Tarefas domésticas 4. Desempregado/a [ ] 5. Reformado/a 6. Permanentemente Incapacitado/a 7. Outra situação 43.7.1. Qual:_____ 8. Não sabe 9. Não responde

3.ª Medição da PA: *S_____ / D_____ mmHg* *Frequência cardíaca:_____*

Observações: _____

Medições Antropométricas: Peso: ____, ____ *Kg* Altura: _____ *cm* 999. Recusou [ ]

Perímetro da cintura: _____ *cm (ponto médio entre o rebordo inferior da costela e a crista ilíaca)*

- ➔ BMQ Geral e Específico
- ➔ HAD

MUITO OBRIGADO PELA SUA COLABORAÇÃO!

Antes de realizarmos esta entrevista, foi feito um sorteio para determinar em que grupo do estudo o Sr.(a) seria incluído. De acordo com esse sorteio o Sr.(a) será incluído no grupo A / B *(riscar o que não interessa)*.

Deste modo,

(Se Grupo A): iremos contactá-lo novamente para marcar uma entrevista daqui a 3 meses e outra daqui a 6 meses.

(Se Grupo B): iremos marcar uma entrevista de acordo com a sua disponibilidade daqui a aproximadamente uma semana, uma daqui a 3 meses e outra daqui a 6 meses. Iremos pedir-lhe para medir a sua PA e registar os medicamentos que toma durante esses 3 meses. Iremos também telefonar-lhe duas vezes durante esse período para acompanhar o seu processo e esclarecer quaisquer dúvidas que tenha.

Próxima entrevista: _____

BMQ Geral

- Gostaríamos de conhecer **o seu ponto de vista sobre os medicamentos em geral**.
- Para tal, iremos apresentar-lhe algumas **afirmações que outras pessoas fizeram** e pedíamos-lhe o favor de nos **indicar o seu grau de concordância ou discordância para cada afirmação**.
- Não existem respostas certas ou erradas! É a sua opinião pessoal que nos interessa.

AUTO-PREENCHIMENTO? [ ] SIM [ ] NÃO → **apresentar o cartão n.º 4 e colocar as perguntas**

AFIRMAÇÕES QUE OUTRAS PESSOAS FIZERAM SOBRE OS MEDICAMENTOS EM GERAL	CONCORDO PLENAMENTE	CONCORDO	NÃO CONCORDO NEM DISCORDO	DISCORDO	DISCORDO PLENAMENTE
1. *Os médicos usam demasiados medicamentos*	☐	☐	☐	☐	☐
2. *As pessoas que tomam medicamentos deveriam parar com o tratamento de vez em quando*	☐	☐	☐	☐	☐
3. *A maior parte dos medicamentos são aditivos*	☐	☐	☐	☐	☐
4. *Os remédios naturais são mais seguros do que os medicamentos*	☐	☐	☐	☐	☐
5. *Os medicamentos fazem mais mal do que bem*	☐	☐	☐	☐	☐
6. *Todos os medicamentos são venenosos*	☐	☐	☐	☐	☐
7. *Os médicos depositam demasiada confiança nos medicamentos*	☐	☐	☐	☐	☐
8. *Se os médicos estivessem mais tempo com os seus pacientes, prescreveriam menos medicamentos*	☐	☐	☐	☐	☐

MUITO OBRIGADO PELA SUA COLABORAÇÃO!

DATA: ____/____/_____ Nº INQUÉRITO: _____ - _____ _____ _____ **(A PREENCHER PELO INVESTIGADOR)** 0 meses____ 12 meses____

BMQ Específico

- Gostaríamos de conhecer **o seu ponto de vista sobre os medicamentos que toma para a tensão arterial**.
- Para tal, iremos apresentar-lhe algumas **afirmações que outras pessoas fizeram** e pedíamos-lhe o favor de nos **indicar o seu grau de concordância ou discordância para cada afirmação**.
- Não existem respostas certas ou erradas! É a sua opinião pessoal que nos interessa.

AUTO-PREENCHIMENTO? [ ] SIM [ ] NÃO → apresentar o cartão n.º 4 e colocar as perguntas

AFIRMAÇÕES QUE OUTRAS PESSOAS FIZERAM SOBRE OS MEDICAMENTOS PARA A TENSÃO ARTERIAL	CONCORDO PLENAMENTE	CONCORDO	NÃO CONCORDO NEM DISCORDO	DISCORDO	DISCORDO PLENAMENTE
1. A minha saúde, neste momento, depende dos medicamentos que tomo para a tensão alta	☐	☐	☐	☐	☐
2. Ter que tomar medicamentos para a tensão alta preocupa-me	☐	☐	☐	☐	☐
3. A minha vida seria impossível sem os meus medicamentos para a tensão alta	☐	☐	☐	☐	☐
4. Sem os meus medicamentos para a tensão alta estaria muito doente	☐	☐	☐	☐	☐
5. Por vezes preocupo-me com os efeitos adversos a longo termo dos meus medicamentos para a tensão alta	☐	☐	☐	☐	☐
6. Os meus medicamentos para a tensão alta são um mistério para mim	☐	☐	☐	☐	☐
7. A minha saúde no futuro vai depender dos meus medicamentos para a tensão alta	☐	☐	☐	☐	☐
8. Os meus medicamentos para a tensão alta perturbam a minha vida	☐	☐	☐	☐	☐
9. Por vezes preocupo-me com poder tornar-me demasiado dependente dos meus medicamentos para a tensão alta	☐	☐	☐	☐	☐
10. Os meus medicamentos para a tensão alta protegem-me de ficar pior	☐	☐	☐	☐	☐

MUITO OBRIGADO PELA SUA COLABORAÇÃO!

DATA: ____/____/_____ Nº INQUÉRITO: _____ - _____ _____ _____ 0 MESES____ 12 MESES___ (A PREENCHER PELO INVESTIGADOR)

Este questionário foi construído para ajudar a saber como se sente. **HAD**

- Pedimos-lhe que leia cada uma das perguntas e **faça uma cruz (X)** no espaço que se segue à **resposta que melhor descreve a forma como se tem sentido na última semana.**
- Não demore muito tempo a pensar nas respostas. A **sua reacção imediata** a cada questão será provavelmente **mais correcta do que uma resposta muito ponderada.**

POR FAVOR FAÇA APENAS UMA CRUZ EM CADA PERGUNTA!

1. Sinto-me tenso/a ou nervoso/a

1. Quase sempre [ ]
2. Muitas vezes [ ]
3. Por vezes [ ]
4. Nunca [ ]

2. Ainda sinto prazer nas coisas que costumava gostar

1. Tanto como antes [ ]
2. Não tanto agora [ ]
3. Só um pouco [ ]
4. Quase nada [ ]

3. Tenho uma sensação de medo, como se algo terrível estivesse para acontecer

1. Sim e muito forte [ ]
2. Sim, mas não muito forte [ ]
3. Um pouco, mas não me aflige [ ]
4. De modo algum [ ]

4. Sou capaz de me rir e ver o lado divertido das coisas

1. Tanto como antes [ ]
2. Não tanto como antes [ ]
3. Muito menos agora [ ]
4. Nunca [ ]

5. Tenho a cabeça cheia de preocupações

1. A maior parte do tempo [ ]
2. Muitas vezes [ ]
3. Por vezes [ ]
4. Quase nada [ ]

6. Sinto-me animado/a

1. Nunca [ ]
2. Poucas vezes [ ]
3. De vez em quando [ ]
4. Quase sempre [ ]

7. Sou capaz de estar descontraidamente sentado/a e sentir-me relaxado/a

1. Quase sempre [ ]
2. Muitas vezes [ ]
3. Por vezes [ ]
4. Nunca [ ]

8. Sinto-me mais lento/a, como se fizesse as coisas mais devagar

1. Quase sempre [ ]
2. Muitas vezes [ ]
3. Por vezes [ ]
4. Nunca [ ]

9. Fico de tal forma apreensivo/a (com medo) que até sinto um aperto no estômago

1. Nunca [ ]
2. Por vezes [ ]
3. Muitas vezes [ ]
4. Quase sempre [ ]

10. Perdi o interesse em cuidar do meu aspecto físico

1. Completamente [ ]
2. Não dou a atenção que devia [ ]
3. Talvez cuide menos que antes [ ]
4. Tenho o mesmo interesse de sempre [ ]

11. Sinto-me de tal forma inquieto/a que não consigo estar parado/a

1. Muito [ ]
2. Bastante [ ]
3. Não muito [ ]
4. Nada [ ]

12. Penso com prazer nas coisas que podem acontecer no futuro

1. Tanto como antes [ ]
2. Não tanto como antes [ ]
3. Bastante menos agora [ ]
4. Quase nunca [ ]

13. De repente, tenho sensações de pânico

1. Muitas vezes [ ]
2. Bastantes vezes [ ]
3. Por vezes [ ]
4. Nunca [ ]

14. Sou capaz de apreciar um bom livro ou um programa de rádio ou TV

1. Muitas vezes [ ]
2. De vez em quando [ ]
3. Poucas vezes [ ]
4. Quase nunca [ ]

MUITO OBRIGADO PELA SUA COLABORAÇÃO!

Unidade de Epidemiologia
Instituto de Medicina Preventiva
Faculdade de Medicina de Lisboa

Projeto HiDia

Controlo da Hipertensão no Dia-a-Dia

Seguimento presencial

Intervenção

A preencher pelo investigador:

N.º quest		NOP	
Data	___/___/___		
Hora Início	___ : ___	Hora Fim	___ : ___
UCSP/USF		Médico	Dr.
Nome		Contacto	

1. Tomou a sua medicação para a tensão arterial hoje? [ ]
   1. Sim, toda a medicação
   2. Sim, parte da medicação
   3. Não
   8. Não sabe/não se lembra
   9. Não responde

1.ª Medição da PA: *S_____ / D_____ mmHg* *Frequência cardíaca:_____*

Observações: _____

1.Sim
2.Não
8. NS

2. "Nos últimos 30 dias", foi ao médico, por um motivo relacionado com a sua Tensão? [ ]

SE FOI AO MÉDICO

2.1. Qual foi o médico? *(se não responder logo, dar as hipóteses)*		2.2. Datas das consultas?
1. Médico de Família	[ ]	___/___/___ ___/___/___
2. Médico Especialista no Hospital Especialidade: _____	[ ]	___/___/___ ___/___/___
3. Médico Privado Especialidade: _____	[ ]	___/___/___ ___/___/___
4. Urgência Hospitalar	[ ]	___/___/___ ___/___/___

2.3. Conversou com o médico sobre o seu Diário da Hipertensão? [ ]

SE SIM 2.3.1. Mostrou o Diário da Hipertensão ao médico? [ ]

O que lhe disse? O que o médico respondeu?

_____

_____

3. Até que ponto o Diário o/a ajudou na conversa com o médico, sobre a sua hipertensão?

Muito	Bastante	Pouco	Não ajudou	Não preenchi	Não sei
[ ]	[ ]	[ ]	[ ]	[ ]	[ ]

4. Nestes últimos 3 meses (desde a primeira entrevista), foi-lhe diagnosticado...

4.1. Insuficiência cardíaca? [ ]
4.2. Angina de peito? [ ]
4.3. Insuficiência renal? [ ]
4.4. Perda de visão? [ ]
4.5. Outra doença? [ ]
SE SIM 4.5.1. Qual?_____ [ ]

SE SIM 4.1. Foi internado/a por algum problema de saúde, nestes últimos 3 meses? [ ]
Se sim 4.1.1.Insuficiência cardíaca? [ ]
4.1.2. Angina de peito? [ ]
4.1.3. Insuficiência renal? [ ]
4.1.4. Perda de visão? [ ]
4.1.5. AVC (trombose) ou derrame cerebral? [ ]

Annex III

Follow-up interview questionnaire

4.1.6. Ataque cardíaco? [ ]

4.1.7. Outra doença? [ ]

SE SIM 4.5.1. Qual?_____ [ ]

1.Sim
2.Não
7. NA

Pedimos-lhe que nos indique

5. O que fez de novo nestes últimos 30 dias para controlar a sua tensão arterial alta... *(dar as hipóteses)*

SE FOI AO MÉDICO

5.1. O que se encontra atualmente a fazer, que seja uma recomendação nova do(s) médico(s)?

	5.	5.1.
1. Alterar a alimentação	[ ]	[ ]
2. Fazer exercício físico	[ ]	[ ]
3. Deixar de fumar	[ ]	[ ]
4. Tomar medicamentos	[ ]	[ ]
5. Outro. Qual?	[ ]	[ ]

6. E recorreu a outra ajuda para controlar a sua tensão? *(dar as hipóteses)*		**6.1. Quando?**
1. Farmacêutico	[ ]	d___ / m___ / 20__
2. Medicinas alternativas	[ ]	d___ / m___ / 20__
3. Outro. Qual?	[ ]	d___ / m___ / 20__

7. Acha que a sua hipertensão está controlada (atualmente)? [ ]

Questionar sobre a medicação para a HTA

8. Nos últimos 30 dias, mudou de medicamentos da tensão? [ ]

Vamos agora registar **todos os medicamentos** que tomou / está a tomar, **de forma regular ou em SOS, no último mês**.

8.1.Quais os medicamentos que está a tomar? *(verificar o nome)* Nome do medicamento (comercial ou titular AIM) Dosagem Dimensão embalagem (n.º unidades) Apresentação *NOTA: preencher antes com elementos da entrevista anterior e atualizar para os eventuais medicamentos novos*	8.2. Nos últimos 30 dias, alterou a forma de tomar? 1. Não alterou 2. Medicamento Novo 3. Deixou de tomar 4. Alteração da frequência da toma 5. Outra. Qual? 9. Não sabe / Não responde	*(se alterou)* 8.2.1. Quais foram os motivos? 1. Indicação médica 2. Esquecimento 3. Sentia-se pior 4. Não estava a fazer efeito 5. Para não criar dependência 6. Pelos efeitos adversos 7. Por questões económicas 8. Por preferir tomar um medicamento genérico 9. Outro. Qual? 99. Não sabe / Não responde	*Não perguntar para os que deixou de tomar* 8.3. Como toma? *NOTA: preencher antes com elementos da entrevista anterior e atualizar quando necessário* Frequência da Toma: Regular (Jejum – JJ; Pequeno-almoço – PA; Almoço – A; Lanche – L; Jantar – JT; Deitar – D)	SOS ou outra freq	31.4. Para o quê? 9. NS/NR	*Perguntar apenas para os medicamentos novos* 8.4. Quem indicou? 1. Médico família 2. Médico privado 3. Médico hospital 4. Enfermeiro 5. Farmacêutico 6. Familiar 7. Auto-medicação 8. Outro 9. NS / NR	*Só para medicamentos para HTA* 8.5. Acha que o medicamento faz efeito? 1.Sim 2.Não 8. NS / NR	*Não perguntar para os que assinalou motivo "pelos efeitos adversos"* 8.6. Tem / Teve algum incómdo com este medicamento nestes meses? 1. Sim. qual? 2. Não 9. NS / NR	8.7. É muito frequente as pessoas não tomarem sempre os medicamentos como o médico indicou, por muitas razões. Nos últimos 7 dias (a terminar ontem), quantas vezes não tomou este medicamento? 99. NS/NR	Se Sim 8.7.1.Motivo?	*Não perguntar para os que deixou de tomar*
1.												
2.												
3.												
4.												
5.												
6.												
7.												
8.												

Toma da Medicação

1. Sim
2. Não
8. NS
9. NR

Como já foi dito, é muito frequente as pessoas esquecerem-se ou ajustar a forma de tomar os seus medicamentos, por vários motivos

9. Tendo em conta os últimos 7 dias...

9.1. Alguma vez se esqueceu de tomar os seus medicamentos para a TA?	[ ]
9.2. Alguma vez não deu atenção suficiente às horas da toma dos medicamentos para a TA?	[ ]
9.3. Alguma vez deixou de tomar os seus medicamentos para a TA por se ter sentido melhor?	[ ]
9.4. Alguma vez deixou de tomar os medicamentos da TA, por sua iniciativa, após se ter sentido pior?	[ ]
9.5. Alguma vez tomou mais comprimidos para a TA, por sua iniciativa, após se ter sentido pior?	[ ]
9.6. Alguma vez interrompeu o tratamento para TA por ter deixado acabar os medicamentos?	[ ]
9.7. Ajustou em função do seu dia-a-dia, com as atividades planeadas?	[ ]
9.10 Ajustou por razões financeiras?	[ ]
9.11. Alguma vez deixou de tomar os medicamentos da TA por outra indicação que não do médico?	[ ]

Vou-lhe agora fazer algumas perguntas iguais às do questionário que preencheu antes, sabermos a sua opinião atual sobre a HTA

Opinião sobre HTA

1. Sim
2. Não
8. NS
9. NR

10. Para si, o que significa hipertensão? *(dar as opções)*

1. nível elevado de stress
2. nível elevado de pressão que o sangue aplica às artérias
3. nível elevado de açúcar no sangue

8. Não sabe
9. Não responde

[ ]

11. Considera que...

11.1. ... baixar a tensão arterial pode melhorar a saúde de uma pessoa hipertensa?	[ ]
11.2. ... ter alguém na família com hipertensão aumenta a probabilidade de ter hipertensão?	[ ]
11.3. ... a idade mais avançada aumenta a possibilidade de ter hipertensão?	[ ]
11.4. ... uma pessoa que tem sempre a tensão alta, corre um risco maior de ter um AVC (trombose)?	[ ]
11.5. ... uma pessoa que tem sempre a tensão alta, corre um risco maior de ter enfarte (ataque cardíaco)?	[ ]
11.6. ... uma pessoa que tem sempre a tensão alta, corre um risco maior de ficar cego?	[ ]
11.7. ... uma pessoa hipertensa pode ter de tomar medicação o resto da vida?	[ ]

2.ª Medição da PA: *S_____ / D_____ mmHg* *Frequência cardíaca:_____*

Observações: _____

Conhecimentos sobre o estilo de vida saudável

12. Numa escala de 1 a 4, até que ponto considera cada um dos seguintes comportamentos como importante para diminuir a tensão alta?

	1. Nada importante	2. Pouco importante	3. Importante	4. Muito importante
12.1. Deixar de fumar	[ ]	[ ]	[ ]	[ ]
12.2. Perder peso se em excesso	[ ]	[ ]	[ ]	[ ]
12.3. Praticar atividade física regular	[ ]	[ ]	[ ]	[ ]
12.4. Diminuir o consumo de gordura	[ ]	[ ]	[ ]	[ ]
12.5. Consumir mais frutas e vegetais	[ ]	[ ]	[ ]	[ ]
12.6. Diminuir a ingestão de sal	[ ]	[ ]	[ ]	[ ]
12.7. Consumir mais fibra	[ ]	[ ]	[ ]	[ ]
12.8. Consumir bebidas alcoólicas de forma moderada, i.e. no máximo, 2 copos de vinho tinto por dia (1 copo nas mulheres)	[ ]	[ ]	[ ]	[ ]
12.9. Parar, por completo, de consumir bebidas alcoólicas	[ ]	[ ]	[ ]	[ ]

Crenças sobre a HTA

13. Para cada uma das questões que se seguem, indique qual o número que melhor corresponde à sua maneira de pensar *(cartão)*

13.1. Até que ponto a hipertensão afeta a sua vida?	[ ]
13.2. Quanto tempo pensa que vai durar a sua hipertensão?	[ ]
13.3. Até que ponto sente que controla a sua hipertensão?	[ ]
13.4. Até que ponto pensa que o seu tratamento pode ajudar a sua hipertensão?	[ ]
13.5. Até que ponto sente sintomas da sua doença?	[ ]
13.6. Até que ponto está preocupado/a com a sua hipertensão?	[ ]
13.7. Até que ponto sente que compreende a sua hipertensão?	[ ]
13.8. Até que ponto a sua hipertensão o/a afeta emocionalmente? (ex. fá-lo/a sentir-se zangado/a, assustado/a, chateado/a ou deprimido/a)	[ ]
13.9. Até que ponto tem a certeza de ser capaz de tomar a medicação da hipertensão, tal como foi indicado pelo médico?	[ ]

14. Na sua opinião, quais as três principais razões por que tem hipertensão?

Por favor, ordene-as por ordem decrescente *(da mais importante para a menos importante)*:

A. _____ _____

B. _____ _____

C. _____ _____

Opinião sobre o médico de família e o Centro de Saúde/USF

15. Até que ponto está satisfeito/a, de uma forma geral, com o seu médico de família?
1. Muito insatisfeito/a
2. Um pouco insatisfeito/a
3. Nem Insatisfeito nem satisfeito/a
4. Satisfeito
5. Muito satisfeito
8. Não Sabe
9. Não Responde
[ ]

16. Até que ponto está satisfeito/a, de uma forma geral, com o seu Centro de Saúde?
1. Muito insatisfeito/a
2. Um pouco insatisfeito/a
3. Nem Insatisfeito nem satisfeito/a
4. Satisfeito/a
5. Muito satisfeito/s
8. Não Sabe
9. Não Responde
[ ]

17. Recomendaria o seu médico de família a conhecidos seus com hipertensão?
1. Sim
2. Não
8. Não sabe / Tem dúvidas
9. Não responde
[ ]

Análise Custo-Efetividade – Recursos usados pelo participante

Custos diretos não médicos

1. Sim
2. Não
9. NS

Vou fazer-lhe algumas perguntas para poder estimar os custos da deslocação que o/a senhor/senhora faz até ao centro de saúde

18. Do local onde mora (ou do local onde habitualmente se encontra) até aqui, sabe dizer-me quantos Km são? [ ]

SE SIM 18.1. São _____ Km

SE NÃO 18.2. Pode dizer-me quanto demora, normalmente, a chegar ao centro de saúde? [ ]

SE SIM 18.2.1. Demorei _____ minutos

19. Como veio hoje para cá?
1. A pé
2. De carro (próprio ou não)
3. De autocarro
4. Outro. Qual? _____
Não responde
[ ]

Caracterização Sócio-Demográfica

Para terminar..

Estado civil

20. Qual é a sua situação familiar?
1. Solteiro/a
2. Casado/a ou em união de facto (vive maritalmente há pelo menos 2 anos)
3. Divorciado/a ou separado/a (sem relação marital, atualmente)
4. Viúvo/a (sem relação marital, atualmente)
9. Não sabe
10. Não responde
[ ]

Agregado familiar

21. Quantas pessoas moram consigo (sem contar consigo mesmo/a)? _____ pessoas
88. Não sabe
99. Não responde
[ ]

Ocupação Principal

22. Das seguintes categorias, qual a que melhor descreve a sua ocupação principal, nas duas últimas semanas?
1. Exerce uma profissão
2. Estudante
3. Tarefas domésticas
4. Desempregado/a
5. Reformado/a
6. Permanentemente Incapacitado/a
7. Outra situação 43.7.1. Qual:_____
8. Não sabe
9. Não responde
[ ]

3.ª Medição da PA: *S*_____ / *D*_____ *mmHg* *Frequência cardíaca:*_____

Observações: _____

Medições Antropométricas: Peso: ____, ____ *Kg* Altura: _____ *cm* 999. Recusou [ ]

Perímetro da cintura: _____ *cm (ponto médio entre o rebordo inferior da costela e a crista ilíaca)*

- Gostaríamos de conhecer o seu ponto de vista sobre os medicamentos que toma para a tensão arterial.
- Para tal, iremos apresentar-lhe algumas afirmações que outras pessoas fizeram e pedíamos-lhe o favor de nos indicar o seu grau de concordância ou discordância para cada afirmação.
- Não existem respostas certas ou erradas! É a sua opinião pessoal que nos interessa.

BMQ Específico

AUTO-PREENCHIMENTO? [ ] SIM [ ] NÃO → apresentar o cartão n.º 4 e colocar as perguntas

AFIRMAÇÕES QUE OUTRAS PESSOAS FIZERAM SOBRE OS MEDICAMENTOS PARA A TENSÃO ARTERIAL	CONCORDO PLENAMENTE	CONCORDO	NÃO CONCORDO NEM DISCORDO	DISCORDO	DISCORDO PLENAMENTE
1. A minha saúde, neste momento, depende dos medicamentos que tomo para a tensão alta	☐	☐	☐	☐	☐
2. Ter que tomar medicamentos para a tensão alta preocupa-me	☐	☐	☐	☐	☐
3. A minha vida seria impossível sem os meus medicamentos para a tensão alta	☐	☐	☐	☐	☐
4. Sem os meus medicamentos para a tensão alta estaria muito doente	☐	☐	☐	☐	☐
5. Por vezes preocupo-me com os efeitos adversos a longo termo dos meus medicamentos para a tensão alta	☐	☐	☐	☐	☐
6. Os meus medicamentos para a tensão alta são um mistério para mim	☐	☐	☐	☐	☐
7. A minha saúde no futuro vai depender dos meus medicamentos para a tensão alta	☐	☐	☐	☐	☐
8. Os meus medicamentos para a tensão alta perturbam a minha vida	☐	☐	☐	☐	☐
9. Por vezes preocupo-me com poder tornar-me demasiado dependente dos meus medicamentos para a tensão alta	☐	☐	☐	☐	☐
10. Os meus medicamentos para a tensão alta protegem-me de ficar pior	☐	☐	☐	☐	☐

MUITO OBRIGADO PELA SUA COLABORAÇÃO!

DATA: ____/____/_____ Nº INQUÉRITO: ____-____ ____ ____ 0 MESES___ 12 MESES___ (A PREENCHER PELO INVESTIGADOR)

Opinião sobre a Intervenção - Aplicar apenas ao Grupo Intervenção

Usabilidade do Diário

1.Sim
2.Não
8. NS
9. NR

*O seu Diário da Hipertensão tinha uma parte inicial com **informação sobre Hipertensão**.*

24. Voltou a ler essa informação durante o estudo? [ ]

SE SIM

24.1. Como classifica essa informação quanto a

	Excelente	Bom	Razoável	Mau	Não Sei
a) Clareza?	[ ]	[ ]	[ ]	[ ]	[ ]
b) Interesse?	[ ]	[ ]	[ ]	[ ]	[ ]
c) no Geral?	[ ]	[ ]	[ ]	[ ]	[ ]

25. Chegou a preencher o seu Diário da Hipertensão,

	Sim, sempre	Sim, quase sempre	Sim, às vezes	Sim, mas raramente	Não preenchi	Não Sei
a) para o registo da Medicação?	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
b) para o registo da PA?	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]

SE NÃO PREENCHEU (no geral ou uma das partes)

25.1. Qual o motivo?_____

_____

26. Como classifica o Diário, quanto à clareza das instruções?

	Muito Claro	Claro	Pouco Claro	Nada Claro	Não preenchi	Não sei
a) para o registo da Medicação?	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
b) para o registo da PA?	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]

27. Como classifica o Diário, quanto à facilidade de preenchimento e em cumprir as instruções?

	Muito fácil	Fácil	Difícil	Muito difícil	Não preenchi	Não sei
a) para o registo da Medicação?	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
b) para o registo da PA?	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]

28. Como classifica o Diário, quanto ao tempo que demorou a preencher?

	Pouco tempo	Algum tempo	Bastante tempo	Muito tempo	Não preenchi	Não sei
a) para o registo da Medicação?	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
a) para o registo da PA?	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]

29. No Geral, até que ponto o Diário o/a ajudou a não se esquecer de tomar os seus medicamentos para a HTA?

Muito	Bastante	Pouco	Não ajudou	Não preenchi	Não sei	Não se aplica
[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]

30. No Geral, até que ponto o Diário o ajudou a medir regularmente a PA?

Muito	Bastante	Pouco	Não ajudou	Não preenchi	Não sei	Não se aplica
[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]

31. Alguma das partes do Diário lhe foi particularmente útil? [ ]

SE SIM Qual?_____

32. Se fosse possível gostaria de continuar a usar o Diário? [ ]

33. Tem alguma sugestão acerca do Diário? [ ]

SE SIM Qual?_____

Sobre a medição da PA

1. Sim
2. Não
8. NS
9. NR

34. Nos últimos 30 dias, teve algum problema com o medidor de tensão arterial que lhe foi entregue? [ ]

SE SIM Qual?_____

35. Foi fácil fazer a medição conforme indicado? [ ]

SE NÃO Porque motivo?_____

36. Houve algum dia em que não tivesse conseguido medir? [ ]

SE SIM Porque motivo?_____

37. Nos últimos 30 dias, mediu alguma vez a PA sem ser em casa? [ ]

SE SIM Onde? [ ]

1. USCP/USF
2. Farmácia
3. Outro. Onde?_____
8. NS/NR

38. De uma forma geral qual é a sua opinião sobre a utilização do diário?

_____
_____
_____
_____
_____
_____
_____
_____
_____

39. Indique o que mais lhe agradou na participação neste estudo?

_____
_____
_____
_____
_____
_____
_____
_____
_____

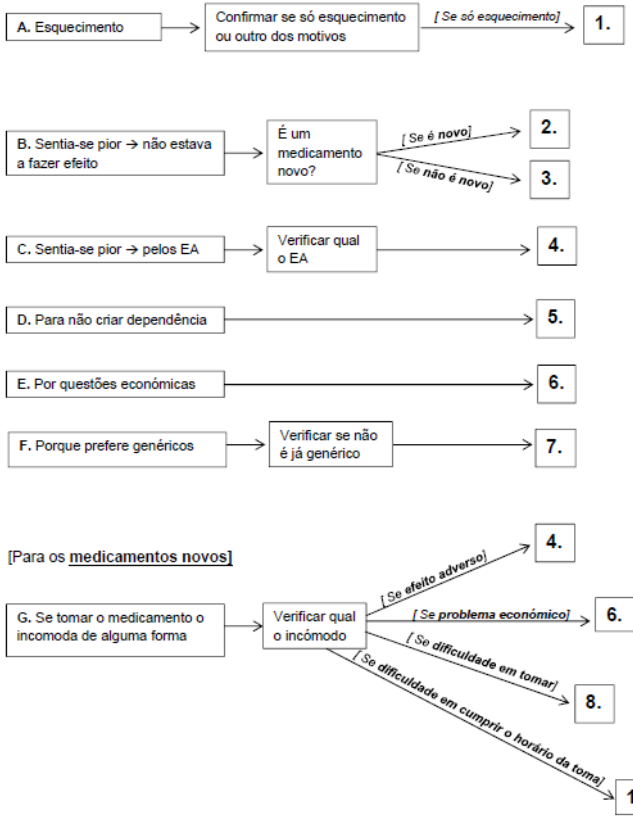
Reforço da Adesão à Terapêutica - Aplicar apenas ao Grupo Intervenção

Após pergunta 9 (pág. 5)

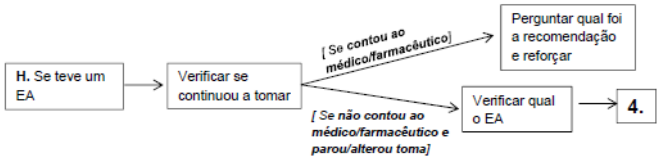
De acordo com a informação dada pelo participante, o entrevistador deve realizar o seguinte aconselhamento:

[Para **todos os medicamentos**]

Se deixou de tomar
ou alterou a forma de tomar por:



[Para os **medicamentos novos**]



I. Se não tomou pelo menos uma vez nos últimos 7 dias

Ver recomendações de **A** a **F**

1. Esquecimento:
Caso a pessoa não esteja já a utilizar, sugerir as seguintes estratégias: Tente manter os medicamentos perto de si, à vista (por exemplo, na mesa de cabeceira ou junto à escova dos dentes). Tente criar uma rotina, por exemplo, associe a uma refeição ou ao deitar ou levantar. Utilize caixas organizadoras de medicamentos. Não deixe acabar os medicamentos, renove as receitas antecipadamente. Mantenha o tratamento para manter a tensão arterial mais baixa e continuar protegido.

2. Medicamento novo – não estava a fazer efeito
Os medicamentos para a tensão precisam normalmente de 2 a 4 semanas para se perceber o seu efeito. Se acha mesmo que não estão a funcionar fale com o seu médico, mas até lá continue a tomar para baixar a tensão e ficar mais protegido.

3. Medicamento antigo – não estava a fazer efeito
Se acha que não está a fazer efeito, fale com o seu médico para que ele possa ajustar o tratamento. Mas não páre a medicação recomendada pelo médico sem ele saber. É importante que continue a tomar os medicamentos para manter a tensão arterial baixa e continuar protegido.

4. Efeitos adversos
Alguns desses efeitos acontecem mais no início do tratamento mas desaparecem ao continuar. Outros efeitos (tonturas, dores de cabeça, etc.) podem ser resolvidos sem precisar de parar a medicação. Fale com o seu médico, assim que puder, para ele mudar o tratamento se achar que é preciso. Até lá, continue a tomar os medicamentos para manter a tensão mais baixa e continuar protegido.
Se Tonturas / Hipotensão ortostática – incluir na informação anterior. Levante-se ou mude de posição com mais cuidado e calma para evitar que isso aconteça.

5. Para não criar dependência
Os medicamentos para a tensão não provocam dependência, como acontece com alguns medicamentos para outras doenças. Tem que os tomar sempre para continuar protegido. Pode falar com o médico se continuar com dúvidas, mas até lá não páre de tomar os medicamentos, para a tensão continuar baixa.

6. Questões económicas
Todos os dias há alterações de preços e aparecem medicamentos mais baratos. Fale com o seu médico para saber se há alternativas mais baratas. É importante que não deixe de tomar os medicamentos para manter a tensão baixa e continuar protegido.

7. Porque prefere genéricos
Fale com o seu médico para perceber se existem genéricos dos seus medicamentos. Mas até lá não deixe de tomar, para manter a tensão baixa e continuar protegido.

8. Dificuldade em tomar
Existem muitos comprimidos ou cápsulas, todos com formas e sabores diferentes, e alguns poderão ser mais fáceis de tomar. Se continuar com dificuldades, fale com o seu médico. Até lá, tente não parar de tomar os medicamentos, para manter a tensão mais baixa e continuar protegido.

Questionário telefónico – a realizar por outra entrevistadora que não a farmacêutica que aplicou a intervenção

Data: ___/___/___ Hora: ____ : ____ Entrevistadora: _____

As perguntas que lhe vou fazer de seguida dizem respeito a toda a intervenção que foi feita: tanto à sessão de esclarecimento, como à utilização do diário e medição da tensão.

Sobre a Intervenção

40. Qual a disponibilidade da farmacêutica para responder às suas perguntas?

Excelente	Muito Bom	Bom	Razoável	Mau	NS/NR
[ ]	[ ]	[ ]	[ ]	[ ]	[ ]

41. Fui encorajado/a a fazer perguntas sobre o meu estado de saúde e tratamento.

Concordo Plenamente	Concordo	Nem Concordo nem Discordo	Discordo	Discordo Plenamente	NS/NR
[ ]	[ ]	[ ]	[ ]	[ ]	[ ]

42. Durante a intervenção, fui sempre encorajado a dizer tudo o que pensava ser importante

Concordo Plenamente	Concordo	Nem Concordo nem Discordo	Discordo	Discordo Plenamente	NS/NR
[ ]	[ ]	[ ]	[ ]	[ ]	[ ]

43. Foram respondidas todas as minhas questões sobre o papel dos medicamentos.

Concordo Plenamente	Concordo	Nem Concordo nem Discordo	Discordo	Discordo Plenamente	NS/NR
[ ]	[ ]	[ ]	[ ]	[ ]	[ ]

44. Como classifica os esforços da farmacêutica para o/a ajudar a controlar a sua HTA?

Excelente	Muito Bom	Bom	Razoável	Mau	NS/NR
[ ]	[ ]	[ ]	[ ]	[ ]	[ ]

45. A intervenção respondeu às minhas necessidades, preocupações e questões.

Concordo Plenamente	Concordo	Nem Concordo nem Discordo	Discordo	Discordo Plenamente	NS/NR
[ ]	[ ]	[ ]	[ ]	[ ]	[ ]

46. Tenho um melhor conhecimento do papel da medicação no tratamento da minha HTA

Concordo Plenamente	Concordo	Nem Concordo nem Discordo	Discordo	Discordo Plenamente	NS/NR
[ ]	[ ]	[ ]	[ ]	[ ]	[ ]

47. No geral, a intervenção ajudou-me a controlar melhor a minha hipertensão.

Concordo Plenamente	Concordo	Nem Concordo nem Discordo	Discordo	Discordo Plenamente	NS/NR
[ ]	[ ]	[ ]	[ ]	[ ]	[ ]

48. De uma forma geral, como classifica a intervenção?

Excelente	Muito Bom	Boa	Razoável	Má	NS/NR
[ ]	[ ]	[ ]	[ ]	[ ]	[ ]

49. Recomendaria a intervenção a conhecidos seus com hipertensão? [ ]

50. Autoriza que o seu médico de família tenha acesso à informação de todos os medicamentos que está a tomar neste momento? [ ]

51. Autoriza que o seu médico de família tenha acesso aos valores das medições de tensão arterial que realizámos nas entrevistas deste estudo? [ ]

Annex IV

Authorization from the FML Ethics Committee

Exmo Senhor
Prof. Doutor Evangelista Rocha
Coordenador da Unidade de Epidemiologia
Instituto de Medicina Preventiva

Assunto: Parecer da Comissão de Ética da FMUL
Data: 7 de Maio de 2010

A Comissão de Ética da Faculdade de Medicina da Universidade de Lisboa, na reunião do dia 6 de Maio de 2010, apreciou o projecto "HiDia - Hipertensão Dia-a-Dia: projecto de controlo da hipertensão em doentes hipertensos medicados não controlados, integrado no estudo DIMATCH-HTA " submetido por Vª Ex.ª.
Foi dado parecer favorável à realização do estudo.

Com os nossos melhores cumprimentos,

Prof. Doutor João Lobo Antunes
Presidente da Comissão de Ética
da Faculdade de Medicina da Universidade de Lisboa

Annex V

Authorization from the National Data Protection Authority

COMISSÃO NACIONAL
DE PROTECÇÃO DE DADOS

Processo n.º 1410/2010

AUTORIZAÇÃO N.º 1119 /2010

A AIDFM – Associação para a Investigação e Desenvolvimento da Faculdade de Medicina de Lisboa notificou à CNPD um tratamento de dados pessoais com a finalidade de elaborar um estudo para avaliar a efectividade de uma intervenção combinada (comportamental e educativa) no controlo da Hipertensão Arterial em hipertensos medicados não controlados, ao nível dos cuidados primários.

O estudo está integrado no estudo DIMATCH-HTA, já autorizado pela CNPD (Autorização nº 3860/2009), e visa complementar os dados recolhidos nesse estudo com base num diário de hipertensão com registo da toma da medicação hipertensora e dos valores de pressão arterial obtidos em auto-monitorização em casa. Serão feitas duas entrevistas telefónicas e duas entrevistas presenciais ao longo de 6 meses.

Serão incluídos no estudo os participantes no estudo DIMATCH-HTA, aos quais é solicitado novo consentimento, para a participação neste estudo. O médico assistente, investigador no estudo, solicitará consentimento informado, cuja declaração deverá ser arquivada no processo clínico do doente.

Os dados serão recolhidos num caderno de recolha de dados em formato papel.

No "caderno de recolha de dados" não há identificação nominal do titular, sendo aposto um código de doente. A chave desta codificação só pode ser conhecida do profissional de saúde participante.

Os destinatários deverão ser ainda informados sobre a natureza facultativa da sua participação e garantida confidencialidade no tratamento da informação.

A CNPD já se pronunciou na sua Deliberação n.º 227 /2007 sobre o enquadramento legal, os fundamentos de legitimidade, os princípios orientadores para o correcto cumprimento da Lei de Protecção de Dados, bem como as condições gerais aplicáveis ao tratamento de dados pessoais para esta finalidade.

COMISSÃO NACIONAL
DE PROTECÇÃO DE DADOS

A informação tratada é recolhida de forma lícita (art.º 5º, n.º1 al. a) da Lei 67/98), para finalidades determinadas, explícitas e legítimas (cf. al. b) do mesmo artigo) e não é excessiva.

O fundamento de legitimidade é o consentimento expresso do titular dos dados.

Assim, tendo em atenção o disposto nas disposições combinadas dos artigos 28º, n.º1, alínea a) e 30º da Lei n.º 67/98, de 26 de Outubro, e as condições e limites fixados na referida Deliberação, que se dão aqui por reproduzidos e que fundamentam esta decisão, autoriza-se o tratamento de dados pessoais nos seguintes termos:

Responsável pelo tratamento: AIDFM – Associação para a Investigação e Desenvolvimento da Faculdade de Medicina de Lisboa
Finalidade: estudo para avaliar a efectividade de uma intervenção combinada (comportamental e educativa) no controlo da Hipertensão Arterial em hipertensos medicados não controlados, ao nível dos cuidados primários.
Categoria de Dados pessoais tratados: código do doente, centro de saúde participante, médico, valores da PA sistólica e diastólica, registo de toma de medicação, avaliação da entrevista telefónica, informação da consulta (a preencher pelo médico), questionário de satisfação.
Entidades a quem podem ser comunicados: Não há.
Formas de exercício do direito de acesso e rectificação: junto do médico assistente.
Interconexões de tratamentos: Não há.
Transferências de dados para países terceiros: Não há
Prazo de conservação: o código do titular deve ser destruído um mês após o fim do estudo.

Dos termos e condições fixados na presente Autorização decorrem obrigações que o responsável deve cumprir. Deve, igualmente, dar conhecimento dessas condições a todos os intervenientes no circuito de informação.

Lisboa, 15 de Março de 2010

Ana Roque, Luís Paiva de Andrade, Vasco Almeida, Helena Delgado António (Relatora), Carlos Campos Lobo, Luís Barroso

Luís Lingnau da Silveira (Presidente)

Annex VI

Authorization from the Health Regional Administration of Lisbon and Tagus Valley

ARSLVT
Administração Regional de Saúde de Lisboa e Vale do Tejo, I. P.
Ministério da Saúde

Exmº Senhor
Dr. Paulo Nicola
Unidade de Epidemiologia
Instituto de Medicina Preventiva da
Faculdade de Medicina de Lisboa
Edifício Egas Moniz
Avª Prof. Egas Moniz
1649-028 Lisboa

Sua Referência	Sua Comunicação	Nossa Referência	Data
		CD-SEC-2010 12256	

Assunto: **Pedido de colaboração no projecto de investigação "HiDia: Controlo da Hipertensão no Dia-a-Dia".**

Relativamente ao projecto de investigação mencionado em epígrafe, acusamos a recepção do Parecer da Comissão Ética da Faculdade de Medicina da Universidade de Lisboa.

Por despacho do Senhor Presidente do Conselho Directivo, Dr. Rui Portugal, cumpre-nos informar V.Exª de que foi autorizada a realização do projecto "HiDia: Controlo da Hipertensão no Dia-a-Dia".

Com os melhores cumprimentos.

O Presidente do Conselho Directivo

Rui Portugal

LUÍS AFONSO
Vice-Presidente do Conselho Directivo
ARSLVT, I.P.

Annex VII

Baseline characteristics of all the patients with baseline assessment

Variable	Total (n=248)	Control Group (n=165)	Intervention Group (n=83)	*p-value*
Sociodemographic variables				
Male sex, n (%)	126 (50.8)	85 (51.5)	41 (49.4)	0.753
Age (years), mean±sd	68.02±9.84	68.23±9.34	67.63±10.79	0.797
Main occupation, n (%)				0.561
Have a job/student/ Housekeeping	65 (26.2)	40 (24.2)	25 (30.1)	
Unemployed	8 (3.2)	6 (3.6)	2 (2.4)	
Retired/ with illness/ permanently Incapacitated	175 (70.6)	119 (72.1)	56 (67.5)	
Marital status, n (%)				0.643
Married/common-law marriage	175 (70.6)	118 (71.5)	57 (68.7)	
Unmarried	73 (29.4)	47 (28.5)	26 (31.3)	
Education, n (%)				0.810
Primary education not completed	17 (7.1)	12 (7.5)	5 (6.3)	
Basic education – 1st cycle	93 (39.1)	62 (39.0)	31 (39.2)	
Basic education – 2nd and 3rd cycles	34 (14.3)	20 (12.6)	14 (17.7)	
Secondary/post-secondary education	46 (19.3)	33 (20.8)	13 (16.5)	
Higher education	48 (20.2)	32 (20.1)	16 (20.3)	
missing, n (%)	*10 (4.0)*	*6 (3.6)*	*4 (4.8)*	
Ethnicity, n (%)				0.178
Caucasian	241 (97.2)	162 (98.2)	79 (95.2)	
Other	7 (2.8)	3 (1.8)	4 (4.8)	
No. people in the household, median (IQR)	1.0 (1.0-2.0)	1.0 (1.0-2.0)	1.0 (1.0-2.0)	0.565
Clinical variables				
Time since diagnosis, mean±sd (years)	16.18±11.86	16.60±11.84	15.38±11.94	0.708
missing, n (%)	*30 (12.1)*	*22 (13.3)*	*8 (9.6)*	
Time since AHT drugs, mean±sd (years)	14.74±11.13	15.04±10.99	14.18±11.44	0.716
missing, n (%)	*28 (11.3)*	*20 (12.1)*	*8 (9.6)*	
Number of AHT drugs, n (%)				0.724
1	126 (50.8)	80 (48.5)	46 (55.4)	
2	82 (33.1)	57 (34.5)	25 (30.1)	
3	35 (14.1)	25 (15.2)	10 (12.0)	
4	5 (2.0)	3 (1.8)	2 (2.4)	
Number of total drugs, median (IQR)	5.0 (4.0-7.0)	5.0 (4.0-7.0)	5.0 (3.0-6.0)	**0.034**
BMI (Kg/m^2), n (%)				0. 104
Non-Obese (<30)	145 (59.9)	90 (56.3)	55 (67.1)	
Obese (≥30)	97 (40.1)	70 (43.8)	27 (32.9)	
missing, n (%)	*6 (2.4)*	*5 (3.0)*	*1 (1.2)*	
Diabetes, n (%)	86 (35.0)	63 (38.7)	23 (27.7)	0.089
missing, n (%)	*2 (0.8)*	*2 (1.2)*	*0 (0.0)*	
Dyslipidemia, n (%)	150 (60.5)	106 (64.2)	44 (53.0)	0.088

High waist circumference, n (%)	147 (63.6)	100 (64.9)	47 (61.0)	0.562
missing, n (%)	*17 (6.8)*	*11 (6.7)*	*6 (7.2)*	
BP measurement routine, n (%)				0.604
At least once a week	97 (39.1)	63 (38.2)	34 (41.0)	
At least once a month	79 (31.9)	56 (33.9)	23 (27.7)	
Every three months or less	72 (29.0)	46 (27.9)	26 (31.3)	
Have a BP monitor	180 (72.6)	117 (70.9)	63 (75.9)	0.405
Mean arterial pressure*, mean±sd	102.60±11.43	101.56±11.97	104.57±10.11	0.165
Lifestyle and knowledge about HTN				
Regular physical exercise, n (%)	69 (27.8)	43 (26.1)	26 (31.1)	0.383
Excessive alcohol use, n (%)	29 (11.7)	20 (12.1)	9 (10.8)	0.768
Follow healthy diet, n (%)	182 (73.7)	118 (71.5)	64 (78.0)	0.272
missing, n (%)	*1 (0.4)*	*0 (0.0)*	*1 (1.2)*	
Smoking habits, n (%)				**0.009**
Smoker	23 (9.3)	21 (12.7)	2 (2.4)	
Ex-smoker	80 (32.3)	46 (27.9)	34 (41.0)	
Never smoked	145 (58.5)	98 (59.4)	47 (56.6)	
knowledge about meaning of HTN	154 (62.1)	105 (63.6)	49 (59.0)	0.481
Health services variables				
To treat HTN, during last year, has resorted to, n (%)				
Physician	96 (38.9)	64 (38.8)	32 (39.0)	0.971
Health care professional other than physician	11 (4.5)	9 (5.5)	2 (2.4)	0.279
Satisfaction with primary care physician, n (%)				
Very satisfied, satisfied	229 (95.5)	153 (96.2)	76 (93.8)	0.400
Neither satisfied or dissatisfied, dissatisfied and very dissatisfied	11 (4.5)	6 (3.8)	5 (6.2)	
missing, n (%)	*8 (3.2)*	*6 (3.6)*	*2 (2.4)*	
Satisfaction with primary care health center, n (%)				0.145
Very satisfied, satisfied	235 (96.3)	154 (95.0)	81 (98.8)	
Neither satisfied or dissatisfied, dissatisfied and very dissatisfied	9 (3.7)	8 (5.0)	1 (1.2)	
missing, n (%)	*4 (1.6)*	*3 (1.8)*	*1 (1.2)*	

sd – standard deviation
IQR – interquartile range