

# Advanced Practice Nurse Intervention Versus Usual Care For Hypertension Control: Study Protocol For An Open-Label Randomized Controlled Trial

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## Study protocol

**Keywords:** Advanced Practice Nurse, Hypertension, Control, Blood Pressure, Protocol Study

**Posted Date:** June 28th, 2021

**DOI:** <https://doi.org/10.21203/rs.3.rs-38444/v1>

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**Version of Record:** A version of this preprint was published at Trials on July 3rd, 2023. See the published version at <https://doi.org/10.1186/s13063-023-07437-3>.

# Abstract

**Background:** Hypertension is the most frequent chronic pathology in France and in the world. It is one of the main modifiable cardiovascular risk factors. In France, 50% of treated hypertensives are uncontrolled and only 30% of treated patients are fully adherent to their antihypertensive treatment. Poor adherence to drug treatments is considered as one of the main causes of non-control of hypertension. Since 2018, a new profession has entered the French healthcare system: Advanced Practice Nurses (APN). They have many broad skills, at the interface of nursing and medical exercises. The purpose of this interventional study is to assess the impact of APN on blood pressure (BP) control in the context of usual care of hypertension thanks to a better adhesion of patients and a better therapeutic alliance.

**Methods:** The study is designed as prospective, open-label, controlled, randomized 1-to-1 and mono-centric at the Hôtel-Dieu University Hospital, Paris, France. The participants are all hypertensive and recruited during an ambulatory hospitalization (AH) for cardiovascular assessment in the context of the management of their hypertension. Patients are divided into two groups: a control group who keeps a traditional follow-up (AH then consultation with a medical doctor (MD) within approximately two to six months) and an interventional group who will see an APN between the AH and the MD consultation, within 1-3 months. Patients are followed up over six months. The main judgment criterion is BP control (BP < 135/85 mmHg in home BP measurement). The hypothesis formulated is that an individual APN intervention, included in a usual hypertension management, improves BP control.

**Discussion:** This innovative study is a first in France where APNs are at the dawn of their establishment in the healthcare system. It will provide an objective look at this new profession and the impact it can have on the overall management of hypertension.

**Trial registration:** This trial was registered in ClinicalTrials.gov on June 24, 2020: protocol number NCT0448249.

## Background

High blood pressure (BP) is defined by an office blood pressure measure  $\geq 140/90$  mmHg after repeated consultation and/or a BP  $\geq 135/85$  mmHg by home blood pressure measurement (HBPM) regardless antihypertensive drugs use [1–4]. Hypertension is the most prevalent chronic pathology in France and in the world [3]. It is the main modifiable cardiovascular (CV), cerebrovascular, renal and neurodegenerative risk factors and accounts for 13% of the mortality worldwide (more than 10 million deaths) [6].

In France, in 2015, the prevalence of hypertension was 31.3% of people aged between 18 and 74, according to the ESTEBAN study. Among them, 43.7% were unaware of hypertension and only 50.3% of the treated ones had their BP controlled. Only 33.6% of treated hypertensive patients were considered adherent [7]. This rate is similar for all the main CV risk factors, such as type 2 diabetes and dyslipidemia [8,9].

Nearly 200 countries, including France, have joined the World Health Organization Global Plan of Action for the Control of Non-Communicable Diseases 2013–2020. Reducing the prevalence of hypertension is one of the targets of this project thanks to the implementation of policies promoting a healthier lifestyle: weight control, increased physical activities, healthy alimentation, alcohol consumption reduction, tobacco fight strategies [10].

Poor adherence to drug treatments is considered as one of the main causes of uncontrolled hypertension. Non-adherence can affect up to 80% of hypertensive patients [1] and is often defined by taking less than 80% of days covered by a prescribed medication. Early discontinuation of treatments, suboptimal daily use of the prescribed regimens and difficulties to adapt the lifestyle according to the recommendations are the main aspects of non-adherence [1,2]. Lifestyle changes are known to prevent or delay the onset of hypertension and CV complications. Recent recommendations including the 2018 Guidelines for the Management of Arterial Hypertensions of the European Society of Hypertension promotes healthy behaviors [1–3].

These deficiencies in therapeutic adherence and disease objective control can be explained by the person's inabilities to take their treatment, including socioeconomic constraints, hostility, depression and anxiety. Some factors are associated with poor adherence, as low educational level and social isolation [3,11–16]. Widely spaced and shortness of consultations duration, lack of time for health education and for close monitoring are deleterious for both BP control and therapeutic alliance development over the long term [17].

Health education for hypertension management is considered as one of the best ways for CV complications prevention [18]. Hypertension can be asymptomatic; it is necessary to inform that patients about its possible complications to involve them in the monitoring [4]. In addition, the chronic aspect of hypertension complicates its management. It can be difficult for patients to admit their vulnerability, to take long-term daily treatment and to conduct adequate monitoring. For a better BP control, it seems necessary to improve the management and to reinforce the therapeutic alliance. A better communication between caregivers and patients allows accurate diagnosis, treatment choice, adherence and patient's satisfaction [19]. It is possible to improve this aspect of comprehensive care through personalized and in-depth health education.

Since July 2018, a new profession has entered the French healthcare system: advanced practice nurse (APN). This profession exists for several decades in other countries such as Canada, the United States, Australia and the United Kingdom. These countries have already established this profession in their healthcare system, or even several exercises related to advanced nursing practice. The International Council of Nurses defined this exercise in 2002 as follows: "An APN is a State-certified or certified nurse who has acquired the theoretical knowledge, the know-how necessary for making complex decisions, as well as the clinical skills essential to the advanced practice of his profession, advanced practice whose characteristics are determined by the context in which the nurse will be authorized to practice" [20]. This

definition identifies the bases of this exercise while leaving each country free to adapt this practice according to the context and its needs in terms of health [21].

In France, APN training and exercise refer to National Decree No. 2018 – 629 [22]. APNs have many broad skills, at the interface of nursing and medical exercises. These new skills allow them to prescribe and interpret additional exams but also to renew prescriptions already introduced beforehand by a medical doctor (MD). APNs can monitor patients suffering from chronic pathologies, like hypertension, in conjunction with MDs within the framework of an organizational protocol established with them.

This new profession in France appears in a context where it is necessary to respond to several public health challenges, such as the decrease in MD, whereas chronic pathologies increase over the time with aging of the population.

This article introduces the protocol of an interventional study designed to assess the impact of APN on BP control in the context of standardized management of hypertension thanks to a better adherence of patients to their chronic disease and a better therapeutic alliance.

## Methods

### Study design

The study is a prospective, open-label, randomized 1-to-1 and mono-centric trial, conducted at the Diagnosis and Therapeutic Center of the Hôtel-Dieu University Hospital, Assistance Publique – Hôpitaux de Paris, France. This department is one of the labelled European centers of excellence in hypertension.

The study was initially scheduled in the first semester of 2020. With the Covid-19 health crisis, the trial was postponed for several months. It should start during the second semester of 2020.

### Participants

The patients are recruited during their visit at the ambulatory hospitalization (AH) of the Diagnosis and Therapeutic Center of Hôtel-Dieu University Hospital, for hypertension-related complications and CV risk assessment as part of the diagnosis or monitoring of their hypertension.

Participants are eligible if they are at least 18 years of age, have treated or untreated hypertension, and are able to provide a written informed consent. Hypertension is defined by a BP  $\geq$  140/90 mmHg by office blood pressure measurement (OBPM) and/or a BP  $\geq$  135/85 mmHg by HBPM.

The non-inclusion criteria are patients with secondary hypertension, an age under 18 years old, the inability to give a free informed consent and/or to speak or understand French properly.

Written information and oral explanations are provided to patients. To complete inclusion in the study, free informed and written consent is collected from each participant during the day.

# Aim

We assume that individual APN intervention, as part of a usual care management of hypertension, can improve BP control.

The primary outcome is BP control defined by a home BP < 135/85 mmHg.

The secondary endpoints are the smoking habits (continuation, reduction and cessation); weight variations evaluated by both weight and body mass index (BMI) stabilities, reductions, increases; adherence to drug treatment evaluated by Girerd questionnaire; antihypertensive drugs tolerance and the proportion of drugs adjustment during paramedical intervention and medical consultation.

## Experimental Design

After inclusion, eligible patients are randomly assigned to one of the following groups: the control group of patients keeps a traditional follow-up (AH then consultation with a MD within approximately two to six months) and the interventional group meets an APN between the AH and the MD consultation, within one to three months (Fig. 1).

## Randomization

The randomization is performed using Excel software for Windows after the inclusion. A random number (between 1 and 100) is assigned to each patient.

The control group includes odd-numbered patients and the interventional group includes the even-numbered patients.

The patients get their study appointment(s) (MD consultation +/- APN) at the end of AH.

## Sample size

For the primary endpoint, according to French nationally representative data (ESTEBAN), we assume respectively a BP rate control of 50% and 60% in the control and the interventional group.

Assuming an equal number of patients in the two groups, a chi-square test with a two-sided significance level of 5% and a power of 80% with 10% of patients lost to follow-up, 852 patients are needed to be recruited (426 per arm). Sample size calculation is performed with SAS software (version 9.4; Institute Carry, NC).

## Ethical Compliance

The study is registered in the French National Agency for Medicines and Health Products Safety (No. 2020-A00158-31).

## Equipment

During the AH, each patient receives a LS802-B / TensioScreen tensiometer (Terraillon®), whether or not they have one at home and regardless of their group.

The loaned tensiometer meets the recommendations issued by the French Society of Arterial Hypertension [23]. Size of the armband is adapted to the circumference of the arm.

Patients are asked to return the tensiometer during the scheduled medical consultation approximately two to six months after AH.

## **HBPM**

A dedicated HBPM sheet, oral and written explanations for HBPM were given with the loaned tensiometer. All patients are asked to perform a HBPM before their next follow-up consultation(s): MD consultation +/- IPA intervention. To achieve this, they have to measure their BP three times in the morning and three times in the evening over three days after 5 minutes of rest each time, according to the 2020 International Society of Hypertension (ISH) Global Hypertension Practice Guidelines for HBPM (Fig. 2) [1]. The retained home BP is the average of these measurements.

## **The APN and associated competences**

According to the national decree, an APN requires a nurse practice for at least three years and obtain a master's degree.

The APN keeps the skills specific to nursing, but also acquires other specific skills for chronic pathologies management, including hypertension.

The APN are able to take care of patients as part of their stabilized chronic pathologies. The management of acute events or decompensation of chronic conditions are left to the MD.

Decree n ° 2018 – 629 defines APN competences like “carrying out any clinical evaluation and conclusion act or any clinical and paraclinical surveillance act”, performing references monitoring, prevention and technical acts, and renewing medication [22,24].

## **APN Intervention**

APN intervention is divided into five main steps (Fig. 3):

- clinical and paraclinical examinations,
- appraisal of patient's knowledge,
- health education on hypertension and treatments,
- setting a written medication plan with the patient to invest him in his management with adjusting or renewing treatments identically if necessary,

- decision-making balance between the benefits and risks of non-adherence to medication. A time is scheduled at the end of the intervention to let the patient ask questions or express his difficulties if he needs to.

## APN Intervention Design

Each APN intervention lasts approximately 1 hour and are performed by the same hypertension specialist APN.

At the beginning of the interview, the patient is installed for his OBPM. The APN explains the procedure for the OBPM, checks the correct functioning of the sphygmomanometer and leaves the patient in a quiet room to minimize unattended results. The office BP is measured according to the latest recommendations: 5 minutes of rest without speaking or smoking, 3 measurements at one-minute interval in supine position and in standing position, performed with an oscillometric automatic sphygmomanometer [1,2,23]. These OBPM values are compared to the HBPM ones. [1,2]

Then, possible clinical manifestations of hypertension or its complications such as headache, vertigo, syncope, impaired vision, rest or exertion chest pain, dyspnea, palpitations, intermittent claudication, edema, cold extremities are looked for, completed if necessary, with a cardio-pulmonary auscultation and/or an electrocardiogram (ECG). Clinically unstable patients are immediately referred to a MD.

Latest blood tests are checked to assess the control of CV risk factors such as diabetes or dyslipidemia with regard to the latest recommendations [25] and to monitor secondary effects of antihypertensive treatment like dyskaliemia or acute kidney.

These data are used to evaluate patient's therapeutic adherence or an inappropriate antihypertensive treatment, and therefore to insist on certain aspects of self-care during the interview and/or invite the patient to see the attending physician again for overall care for a better management of hypertension and other CV risk factors.

The APN sums up the medical history, assesses patient's knowledge and reminds the patient about the definition, the pathophysiology, the chronic aspect of hypertension, its possible complications.

Then, the lifestyle behavior is evaluated. According to the latest recommendations [1–3,23], the APN advises the patient on:

- salt consumption limitation (about six to eight grams per day),
- weight reduction in the event of overweight or obesity in order to maintain a normal body mass index (BMI) between 18.5 and 24.9.
- practice of a regular physical activity of approximately thirty minutes per day (to be adapted according to the clinical condition of the patient),

- alcohol consumption limitation to less than 14 units per week for men, 8 units per week for women,
- establishment of a diet rich in fiber and low in saturated fat
- smoking cessation.

Drugs knowledge, their indication and mechanisms are evaluated and reminded if necessary. The APN asks the patient about a possible additional prescription or self-medication to estimate the overall risk of drug interaction.

The APN checks eventual side effects of antihypertensive drugs and orthostatic hypotension. Posology adaptation or drug withdrawal in the event of side effects or uncontrolled hypertension is done when necessary but the introduction of new drugs is reserved for MDs.

The APN proposes a decision-making balance between benefits and risks to encourage the patient to improve its therapeutic adherence, promote healthy lifestyle and establish a treatment plan with the patient to improve its adherence.

The end of the interview is dedicated to deepen unmentioned question or subjects with the patient.

The APN gives a new HBPM sheet to the patient with a reminder of the procedure to follow. The patient has to bring the results and the loaned tensiometer to its next MD consultation.

The APN intervention report is digitally available on the patient's electronic medical record.

## **MD Consultation**

The MD consultation is divided into four stages (Fig. 4):

- adherence questionnaire filling,
- nursing care with OBPM and ECG realization,
- MD consult,
- MD prescription.

## **MD Consultation Design**

Before the MD consultation, the APN meets each included patient to complete and collect the Girerd's drug adherence questionnaire (Fig. 5). Validated in 2001, the Girerd questionnaire is currently the benchmark questionnaire for adherence and used by French national health service (NHS) [26]. A succession of 6 close-ended questions estimates the therapeutic adherence of the patient for the last two weeks.

One or two affirmative answers indicate a minor noncompliance, three or more ones indicate a major nonadherence. Otherwise, the patient is considered fully adherent. The completed form is dropped in a box in the nurse office. Questionnaires has to be completed before the MD consultation, in the absence of the MD.

Then, a healthcare giver (usually a nurse) performs an OBPM and an ECG before the MD consultation, according to the same OBPM protocol as for APN intervention.

The MD starts its consultation with a summary of the medical history since the last consultation, an assessment of the CV risk factors, a clinical summary, checks the previously performed paraclinical exams, then proceeds to physical examination, and verifies drug treatments, tolerance, efficacy and eventual modifications since the last appointment.

At the end of the consultation, the MD prescribes medication and paraclinical exams if needed, for the next appointment.

The patient returns the loaned tensiometer to the MD during this consultation.

## **Data collection**

The Fig. 6 illustrates the collected data according to the study stages for the assessment of the APN intervention on drug and healthy lifestyle adherence for BP control.

## **Statistical analysis**

The primary endpoint (difference in BP control rate between interventional and control group) is analyzed using a chi-square test. A p value < 0.05 was considered significant.

For secondary endpoints, difference between average BP at baseline and at follow-up is determined for all the patients and separately for patients in both study groups. Differences between baseline and follow-up are tested for significance within paired-t-tests within each group. Differences in mean BP, weight variations and proportions of drug adjustment between interventional group and control group are tested for significance using a t-test for independent samples. Adherence to drug treatment and smoking status between the two groups are tested for significance by using a chi-square test.

Statistical analyses are performed using SAS software (version 9.4; SAS Institute Carry, NC).

## **Discussion**

### **Progress to date**

APNs are at the dawn of their establishment in the French healthcare system. This study is innovative because it is the first one to assess the impact of an APN intervention on BP control as part of a usual care for hypertension management.

Similar studies, implemented in other countries, have provided positive findings.

In 2014, the study of Dean et al. showed that patients followed-up in a specialist nurse-led hypertension clinic had a significant greater systolic BP reduction compared to usual care provided by general practitioners (144 vs 169 mmHg) [25].

Drevenhorn et al. in 2015, aimed to assess the self-care capacity of hypertensive patients and a possible correlation between their capacity to change their lifestyle with a personalized motivational interview carried out by a nurse as part of their comprehensive care. Motivational nursing interview improved the self-care capacity of these hypertensive patients, in particular through the practice of physical activity [26].

Moreover, another trial in 2018 demonstrated that personalized motivational interview carried out by advanced practice providers on hypertensive patients was associated with improvement of lifestyle changes and increased physical activity. It resulted in better BP management regardless of patient's CV risk evaluated by Framingham risk score [27].

## **Strengths of the study**

This study is conducted in a European center of excellence in hypertension, maximizing the probability that both groups benefit from the latest hypertension standard of care. The centralized one-to-one randomization ensures two equivalent groups to compare and limits the selection bias.

This controlled study highlights all the dimensions of advanced nursing practice in its daily exercise (therapeutic education, clinic, prescription) but includes the both paramedical and medical sides of hypertension monitoring. It provides a good comparison between the actual global management of hypertension and the future global management of hypertension in France which will include APNs.

For the primary outcome, the use of HBPM over OBPM is more relevant for BP control estimation as it reduces the probability of "white coats" and assesses masked hypertension. The use of the same tensiometer for all the participants limits measurement bias.

For the secondary endpoints, the advantages of the Girerd questionnaire are its professional recognition and its speed of completion. Patients have to complete it before the consultation, without the MD, to limit performance bias. Patients need to lose more or less weight according to their BMI. The weight variations are assessed according to the BMI categories for more relevance. We specify if the drugs adjustments are caused by side effects and/or non-control of HTA to emphasize the major APN interventions on medication. The assessment of the proportion of drugs adjustments during the APN intervention and MD consultation highlights the relevance of maximizing the frequency of (para)medical appointments in the global monitoring of hypertension.

## **Limits of the study**

BP measurement can be a difficulty in this study and introduce a measurement bias, especially HBPM, because it remains specific to each person despite the explanations and depends on the environment. It is impossible to control the conditions for HBPM and the OBPM can be nurse dependent. To limit this bias, all participants of the study speak French and are able to understand all the explanations. All nurses follow the same protocol of OBPM.

The open-label character of this study can influence the reactions, the behaviors of the patients and the healthcare givers and introduce a performance bias.

The timeframe for the study is limiting: the patients encounter the APN only once. This can be disadvantageous because a patient's health education for chronic disease may take longer. A similar study over a longer period of time would probably provide a better reflection of APNs management on a chronic pathology such as hypertension for example.

The delay of the study can also be a problem for the choice of the endpoints. It is difficult to obtain usable and significant data for lifestyle modifications on a six-months period. We chose the smoking status and the weight variation according to BMI categories to assess the adherence of lifestyle changes because these quantitative endpoints can evolve on short period and can be more measurable than alimentation or physical activity.

This study is carried out by a recently graduated APN. The level of experience of the professional involved in the study can create a bias. We can suppose that the results would vary with an experienced APN.

The results of the study will be interpreted according to these parameters and compared to the existent literature. It will be interesting to see if APNs are indeed a solution to this major public health problem of uncontrolled hypertension in France.

## **Trial Status**

This trial was registered in ClinicalTrials.gov on June 24, 2020: protocol number NCT0448249. The recruitment began in September 2020. It should be completed about September 2022.

## **Abbreviations**

- AH: Ambulatory Hospitalization
- APN: Advanced Practice Nurse
- BMI: Body Mass Index
- BP: Blood Pressure
- CV: CardioVascular
- HBPM: Home Blood Pressure Measurement

- MD: Medical Doctor
- NHS: National Health Service
- OBPM: Office Blood Pressure Measurement

## Declarations

### Ethics approval and consent to participate

"The study is registered in the French National Agency for Medicines and Health Products Safety (No. 2020-A00158-31). *Written, informed consent to participate will be obtained from all participants*"

### Consent for publication

"Not applicable"

### Availability of data and materials

JVD, AV and JB will have access to the final trial dataset.

### Competing interests

"The authors declare that they have no competing interests with this work."

### Funding

None.

### Authors' contributions

JB is the chief investigator; JVD, AV and JB conceived the study, led the proposal and protocol development. AC contributed to the study design and to development of the proposal. AV was the lead trial methodologist. All authors read and approved the final manuscript.

### Acknowledgements

M. Zerbib Olivier for the editing manuscript.

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## Figures

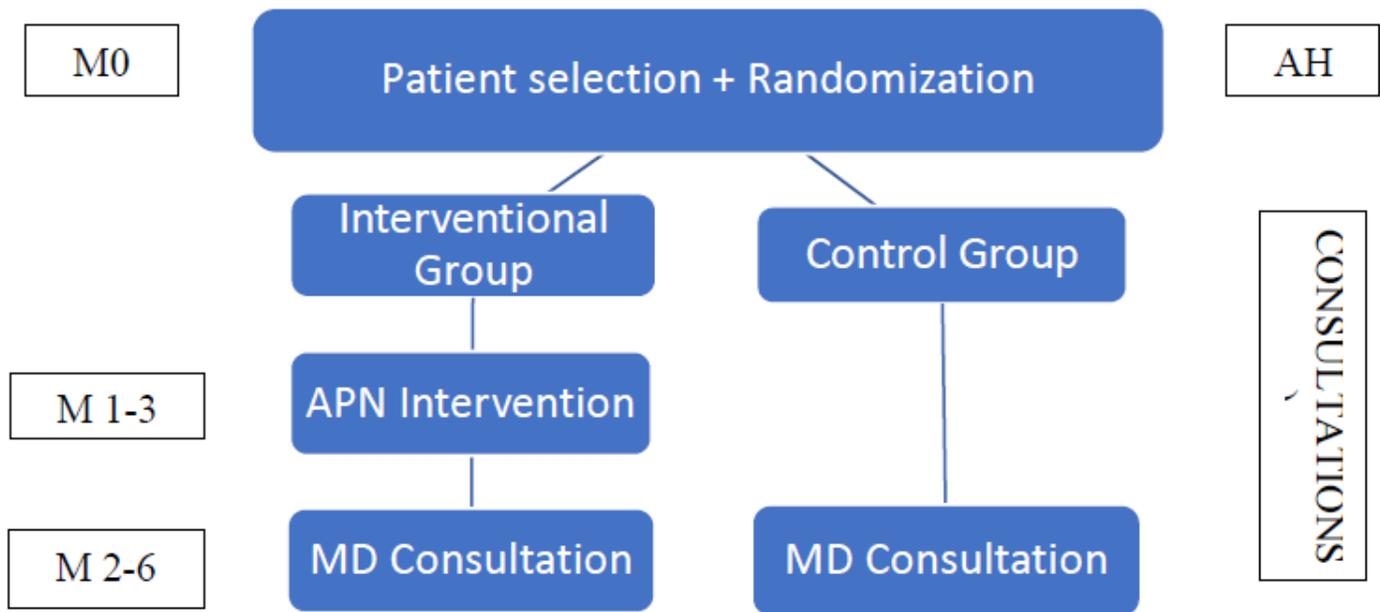


Figure 1

Study process

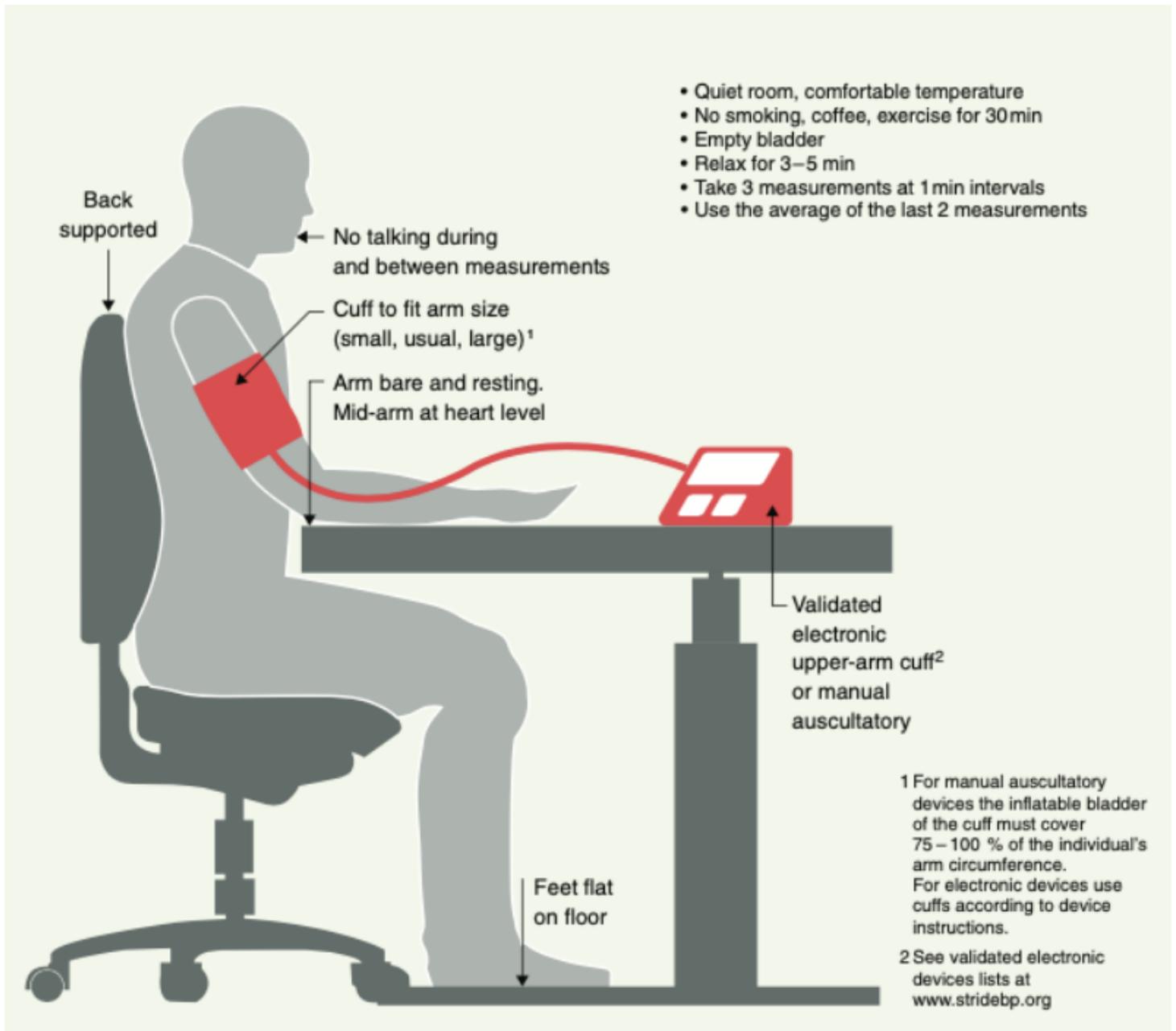
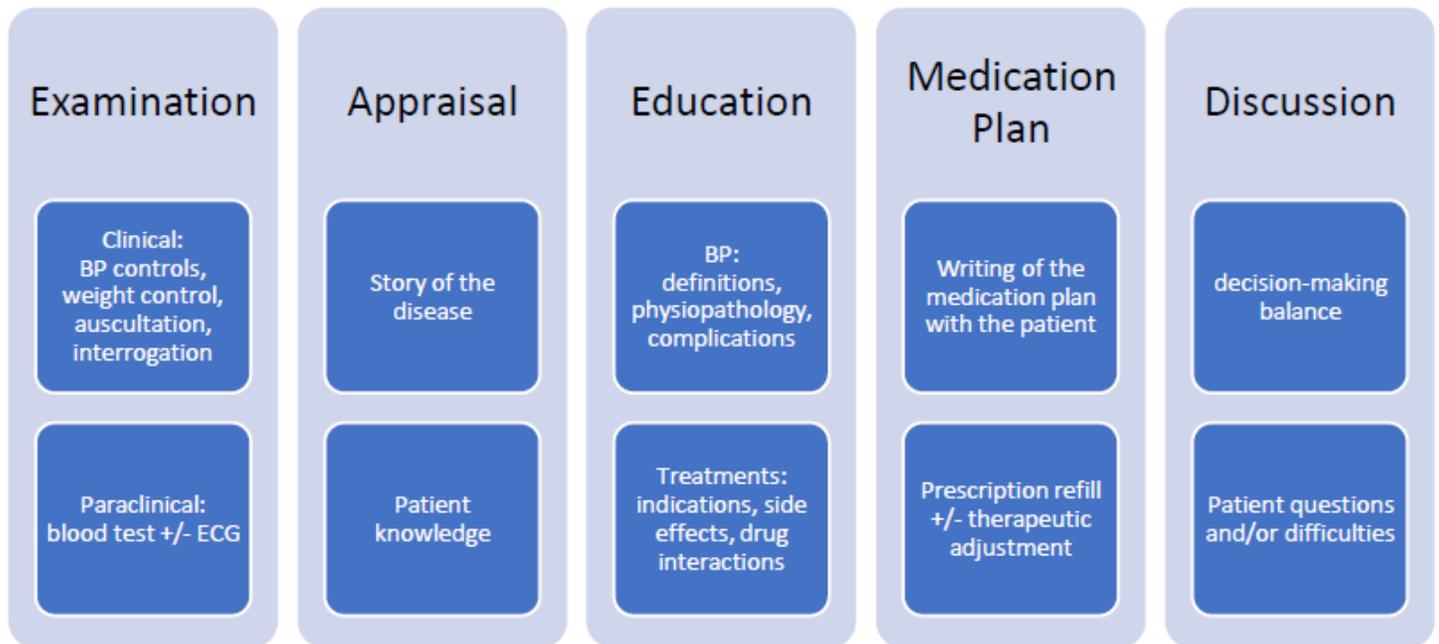


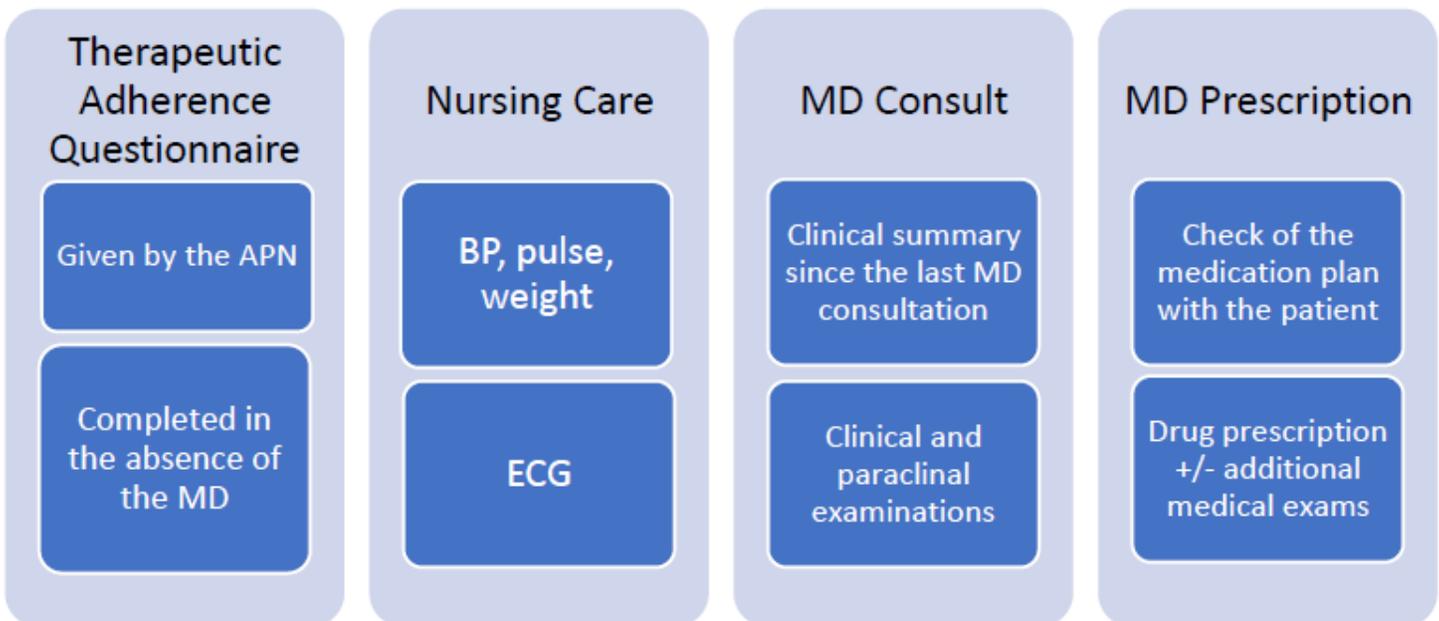
Figure 2

HBPM Protocol according to the 2020 ISH Guidelines



**Figure 3**

Plan of the APN intervention



**Figure 4**

Plan of the MD consultation

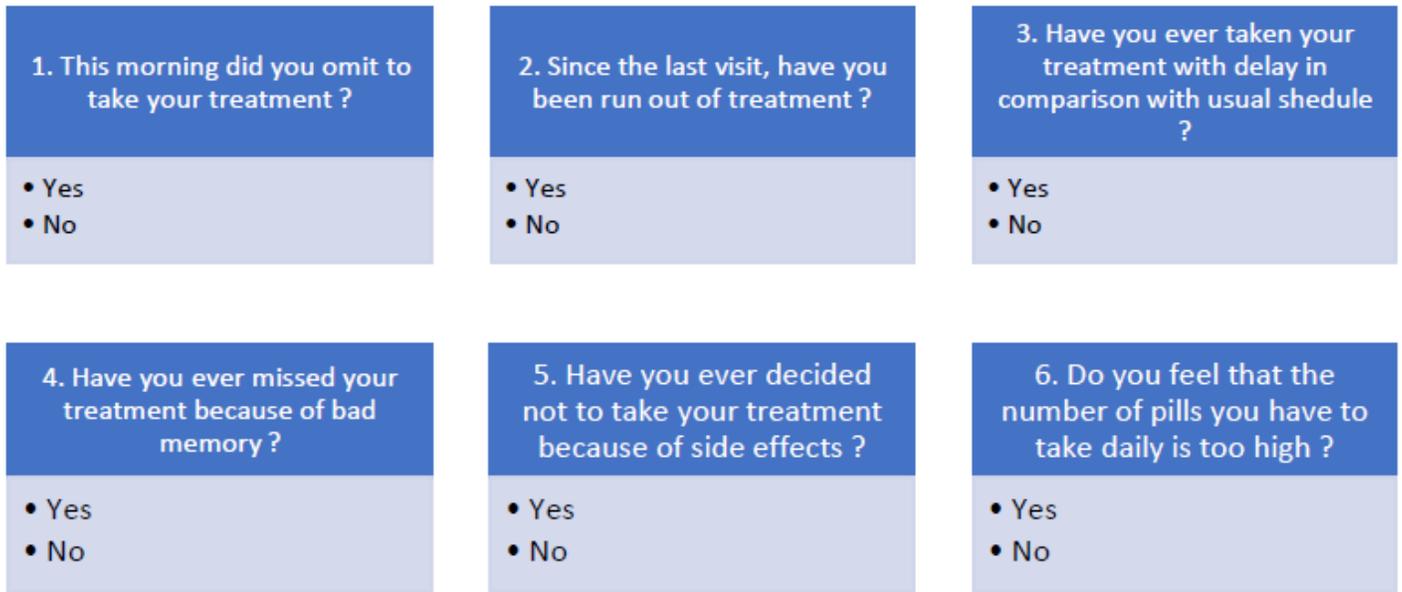


Figure 5

Girerd Questionnaire

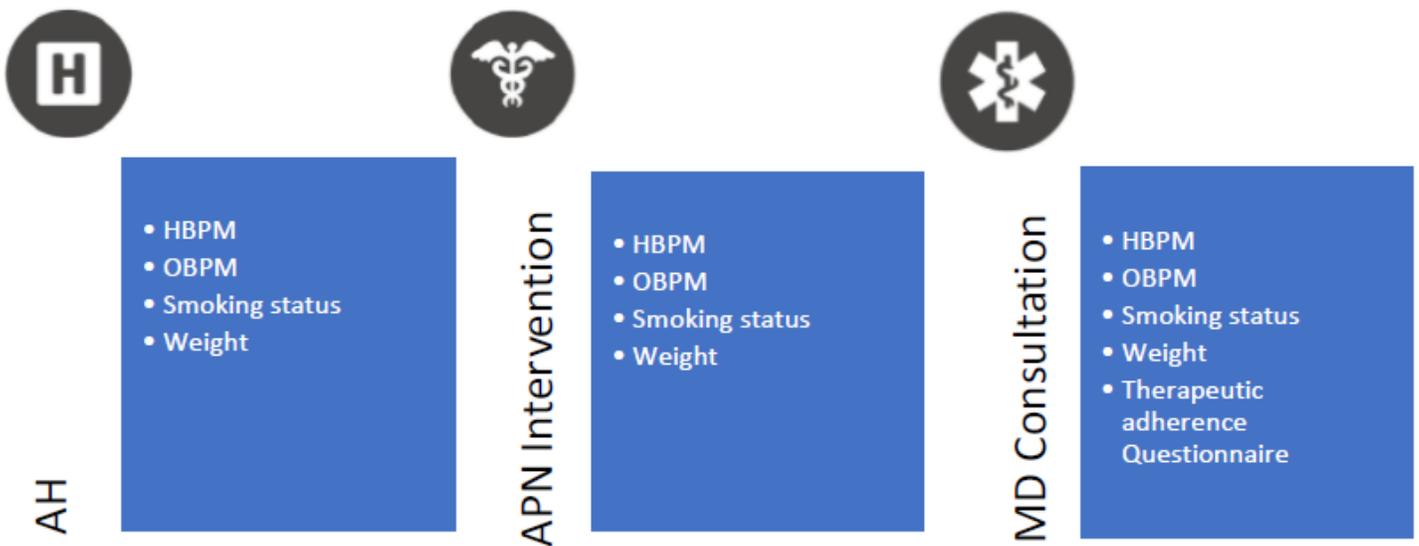


Figure 6

Data collection according to the study stages

## Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

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