Received: 8 May 2023 | Revised: 19 July 2023 | Accepted: 1 August 2023

DOI: 10.1111/jch.14713

ORIGINAL ARTICLE

WILEY

GeogRaphic and socioecoNomic Distribution of real-world Indian data of home blood pressure monitoring (GRAND Study): Study protocol for an observational study in 18 medical centers across India

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Funding information
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Abstract

One-fourth of death in India is attributed to cardiovascular disease (CVD) and more than 80% is related to ischemic heart disease and stroke. The main risk factor for CVD is hypertension. Every third person in India suffers from hypertension and the prevalence increased drastically in the past 20 years, especially among the youngest age group of 20 and 44 years. Regardless of being under anti-hypertension medication, the blood pressure (BP) control rate in the country is still low ranging between 6% and 28% only. Assessing the "true BP control rate" should be performed using both clinic BP measurement and out-of-office BP measurement as the latter shows better prognosis for patients' hypertension and CVD outcomes. Home blood pressure monitoring (HBPM) shows superiority over ambulatory BP measurement as multiple measurements can be collected at the patient's convenience. Only limited evidence on HBPM in India is available and it's either lacking in hypertension participants or of a small sample size. This study will investigate the real BP control status among 2000 hypertensive patients from 18 centers in 12 states across Pan-India. The outcome of this study will emphasize the value of establishing BP control management practice guidelines suitable for physicians and help policymakers in building proper strategies for hypertension management to reduce the CVD burden on the health situation in India.

KEYWORDS
home blood pressure monitoring, hypertension, India, patient knowledge, real blood pressure control

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1 | BACKGROUND

In India, almost one-fourth of all deaths are attributed to cardiovascular disease (CVD), and 52% of CVD death happens before the age of 70 years old.[1–3] More than 80% of CVD mortality is from ischemic heart disease and stroke, and the major risk factor is hypertension.[1,3–6] The prevalence of hypertension in India among adults-general population aged 18 years and above is on average around 30%, meaning that every third person in the country suffers from hypertension, and this prevalence has increased drastically in the past 20 years in both urban and rural areas.[7,8] Despite the area of residency, the affected individuals are mostly among the youngest group between the age of 20 and 44 years as revealed in the national survey, showing that hypertension is not a disease for the older age exclusively.[7,9] Even though efforts are made in the country to diagnose and bring forth awareness of hypertension, the blood pressure (BP) control rate did not improve in the last two decades, ranging between 6% and 28% regardless of being under anti-hypertension medications.[6,7,10–13] From the available national evidence, BP control rate is usually defined using clinic (office) BP (CBP) which is mainly measured on one occasion. There lies the shortcoming to using CBP as an index to BP control as it is impractical for patients to monitor their BP measurement frequently but during their visits to the clinic. Assessing the "true BP control rate" should be deducted not only from a single visit to the clinic but from multiple measurements out of the clinic setting. Using out-of-office BP measurements can relatively provide multiple numbers of BP measurements in the comfortable environment of each individual.[14] Existing global evidence supports the advantages of out-of-office BP measurement for the diagnosis of subtypes of hypertension, contributes to treatment efficacy evaluation, and assists in CVD prevention.[14–15] Among the out-of-office BP measurements, home blood pressure monitoring (HBPM) shows preference over ambulatory blood pressure monitoring (ABPM) from the perspective of the patients and clinical practicality.[16–20] A vast body of international evidence shows HBPM to have a superior prognostic value and as a better predictor over CBP for CVD outcomes and target organ damage.[21] A finding from the India Heart Study which investigated the agreement of two visits CBP and 7 days home blood pressure (HBP) showed poor agreement between the two readings, and stated the conclusion that when it comes to diagnosing hypertension, HBP should be the preferred method.[22] Summarizing the evidence thus far, HBPM appears to provide close to the true value of an individual's BP control better than CBP, while it shows benefit over ABPM as the patient can measure their BP multiple times for long period on several occasions at their own convenience.[19–20] Indian national evidence on HBPM is scarce either due to the limited number of studies conducted with HBPM or having a small sample size.[22,23] In the India Heart Study, they investigated HBPM in the country, however, the participants were of hypertension-naive background and there is only limited evidence on HBPM in hypertensive patients in India.[22] In 2018, Asia BP@Home study determined HBP control status across 11 Asia countries/regions, among the countries involved in this study was India.[23] The limitations of the study were the low sample size ($n = 97$) and the data being collected from one center only. Therefore, there is still a need for nationwide HBPM evidence in India among hypertensive patients and with a larger sample size to show the real BP control rate in the country.

The GeogRaphic And socioecoNomic Distribution of real-world Indian data of home blood pressure monitoring (GRAND Study) aims to create the first massive scale real-world India data of HBPM among hypertensive patients which will answer various pertinent questions about hypertension and BP control, socioeconomic, demographic, and lifestyle factors affecting it, the distribution and variation of data of home and office measurement of BP, and the awareness and behavior of hypertensive patients regarding hypertension and HBPM in India.

2 | METHODS AND STUDY DESIGN

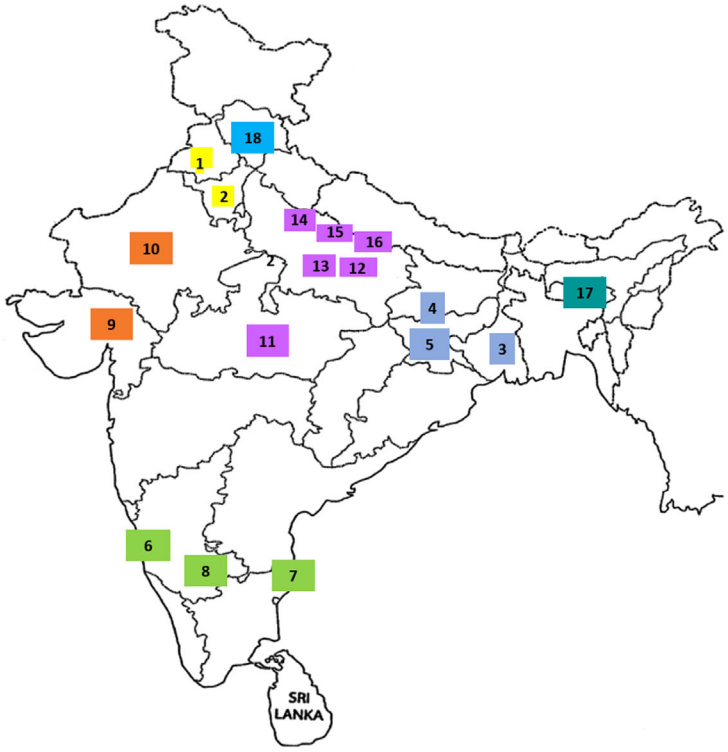
2.1 | Overview

This registry is a multi-center, non-interventional cross-sectional study planned to recruit 2000 hypertensive patients in 18 medical centers across 7 regions and 12 states in India (Figure 1). We will investigate the BP control status and provide Indian real-world data of BP monitoring by CBP and HBP. The study aims to determine the followings: (1) demographic comparison of CBP versus HBP, and BP control; (2)demographic, anthropometric, socioeconomic, medical, and lifestyle factors affecting hypertension subtypes which are white-coat hypertension, masked hypertension, sustained uncontrolled hypertension, controlled hypertension, morning hypertension and evening hypertension in India; (3)BP and heart rate (HR) variability of visit-to-visit CBP and day-by-day HBP, morning HBP, and evening HBP and factors correlated to them; (4)regional differences in BP control; (5)hypertension patients' behavioral association with BP control. The findings from this study will have an impact on filling the gap in the diagnostic dilemma of hypertension management and BP control in India, paving the path to developing guidance for physicians to be used in clinical practice, and building strategies by policymakers to improve the BP control and prevention of CVD outcomes.

2.2 | Study design and setting

The protocol and term of consent were approved by Independent Ethical Committee Narayana Diagnostics, Lucknow, Uttar Pradesh, India (Approve number: NIEC/INDT/APP/08/28/22-02). The ethics committee is organized and operates according to the requirements of Good Clinical Practice (GCP), Indian Council of Medical Research (ICMR), and New Drug and Clinical Trial Rule 2019.

The study is designed to include two visits to the study center and at least 7 days of HBPM by the participants. Figure 2 shows the study schedule and data collected at each visit. The investigator or research nurse will recruit the patients and obtain the following list of items during the visit1: (1) written informed consent, (2) relevant background information filled in the registration form, and (3) patient Home BP survey. The patient Home BP survey is composed of 16 questions that



No.	Region	State	Participants
1	North	Punjab	100
2		Haryana	100
3	East	West Bengal	100
4		Jharkhand	100
5		West Bengal	100
6	South	Karnataka	100
7		Tamil Nadu	100
8		Karnataka	100
9	West	Gujarat	100
10		Rajasthan	100
11	Central	Madhya Pradesh	100
12		Uttar Pradesh	100
13		Uttar Pradesh	100
14		Uttar Pradesh	100
15		Uttar Pradesh	100
16		Uttar Pradesh	100
17	North-East	Meghalaya	150
18	Northern Himalaya	Uttarakhand	150

FIGURE 1 GRAND study centers' distribution and the number of participants.

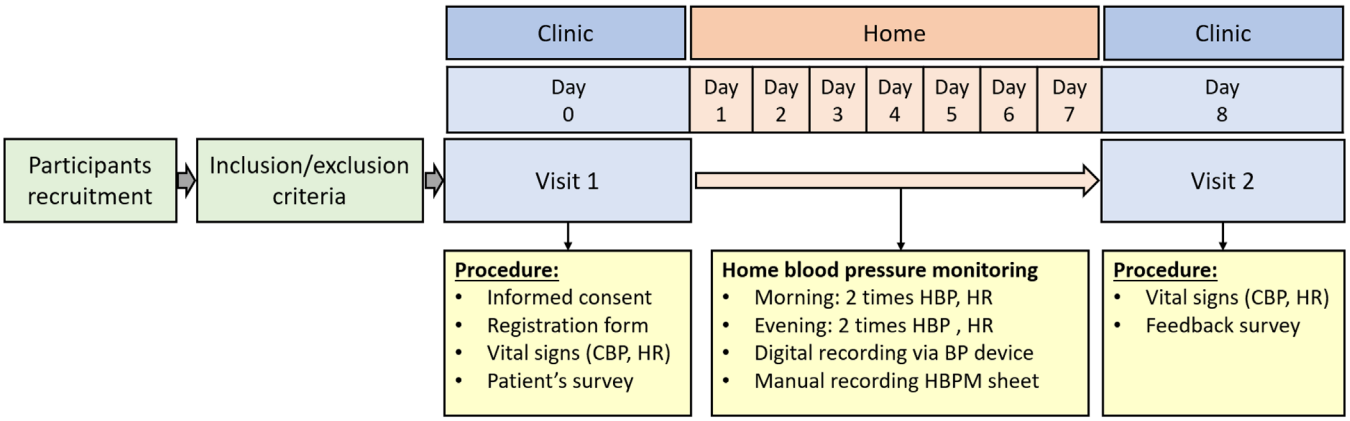


FIGURE 2 The study procedure and flow chart.

will be used to understand the participants' awareness and knowledge of hypertension, the practice of regular BP monitoring, their knowledge of HBP, and the measuring practice of HBP. Each study center will receive minimum 10 validated BP measurement devices (Omron HEM-9210T) and these devices will be used in all the BP measurement data (CBP and HBP) throughout the study. The conditions for measuring CBP and HBP were based on the global instructions from guidelines[18–20] with minor adjustments to the resting time prior to the measurement from the standard 5 min to 2–5 min to accommodate practicality in measuring BP, limited time of consultation, and suitable alteration for the common cultural behavior by patients. The investigator or research nurse will measure CBP and (HR) following the instruction of the patient being in a sitting position in a quiet room without moving or talking while resting for 2–5 min and the cuff wrapped around the upper-arm and positioned at the same level as the heart. The CBP measurement will be observed readings as the investigator or research nurse will operate measuring office BP. For a practical procedure, and to reflect the common practice and accommodate for limited consultation time by the investigators, CBP will be measured only two times within a gap of 1 min without removing the cuff. The two readings of each visit will be used in the analysis without discarding the first reading. The patients then will be provided with the same device used

TABLE 1 HBP morning and evening instructions to the participants.

HBP morning (6:00–12:00)	HBP evening (18:00–24:00)
• Within 1 h after waking up • After urination • Before taking any medications • Before eating breakfast • After 2–5 min resting in a sitting position (lean against the seat back and rest both feet on the floor, no moving or talking)	• Just before going to bed • After 2–5 min resting in a sitting position (lean against the seat back and rest both feet on the floor, no moving or talking)

to measure their CBP along with the patient's Quick Guide on how to measure HBP and HBP measurement sheet. The day the patient will be recruited is considered day 0 in the study format and the next day will be considered day 1 of the HBPM and the participants will record their HBP for at least 7 days. HBP will be measured in the morning and evening; two times each occasion using provided BP device which will automatically store the measurement in the device memory digitally and the patients will also write down the readings manually on the HBP measurement sheet. The instructions for both measurements are described in Table 1.

Prior to CBP measurement, the investigator or research nurse will decide the arm BP will be measured by firstly measuring BP from both arms, starting from the non-dominant upper arm (primarily the left arm). If the BP in the right and left arms differed considerably, the arm with the highest BP will be defined at the visit1 and used throughout the HBP measurements. After the 7 days of HBP measurement, and giving a buffer time, the patients will return within 15 days to the study center to visit2 with the BP device and the filled-out HBP measurement sheet. Patients with less than 3 days of measurement recorded for both morning and evening will be excluded from the further data analysis.

During visit2, the investigator or research nurse upon obtaining the BP device and HBP measurement sheet will measure CBP (two times within a gap of 1 min) and HR following the same method performed in measuring CBP at visit1, and the patients will answer a feedback survey. The feedback survey is composed of 3 questions on the behavior change after experiencing 7 days of HBPM, and knowledge of HBPM benefits. The digitally stored BP recording in the device will be composed of 4 CBP measurements and at least 7 days HBP which will be transferred to a data management system prior to passing the BP device to the next patient.

Each patient's registration form, patient Home BP survey, and BP measurements (manually recorded and digitally) will be logged into a GRAND study data management system.

2.3 | Participant recruitment

The total target sample size is a minimum of 2000 hypertension patients from 18 study centers across 12 states from 7 regions, and 100 patients per center with the exception of two centers in the North-East and Northern Himalaya region which will collect 150 patients per center to balance out the number of patients per region (Figure 1).

In this study, the participants will be hypertensive patients under anti-hypertensive medication treatment for more than 3 months. Eligible patients will be those who have understood, agreed, and signed the informed consent form for this study. The inclusion and exclusion criteria are shown in Table 2.

2.4 | Study withdrawal

Patients may withdraw or decide to discontinue the study at any time at their own request or at the discretion of the investigator for safety, behavioral, or administrative reasons. The investigator will act upon the withdrawal/discontinuation decision by requesting the participant or related family to fill in the proper form. When the patient withdraws from the study, this action will withdraw their consent for disclosure of future information, and no further evaluations nor additional data will be collected.

2.5 | Outcomes

2.5.1 | Primary outcomes/Clinical

Distribution of patients based on BP control status using hypertension diagnosis threshold by the difference in the clinic and home BP thresholds as shown in Figure 3. The BP control status will also be investigated by regions and expressed with graphical bars.

2.5.2 | Secondary outcomes/Clinical

- The distribution of BP control status using target threshold of CBP and HBP as <130/80 mmHg.
- The distribution of BP control status for the population with diabetes mellitus using the target threshold of CBP <130/80 mmHg and HBP <125/75 mmHg.[24]
- The distribution of BP control status for the high-risk population with diabetes mellitus, cardiovascular disease and chronic kidney disease using the target threshold of CBP <130/80 mmHg and HBP <125/75 mmHg.
- To find out the correlation of demographic, anthropometric, socioeconomic, medical condition, medication use, and lifestyle factors

TABLE 2 GRAND study participants' inclusion and exclusion criteria.

Inclusion criteria	Exclusion criteria
1. Patients living in India. 2. Patients diagnosed with hypertension and on stable hypertension medication ≥3 months. 3. Age between ≥20 and ≤70 years. 4. Patients who are thoroughly informed about the study and signed an informed consent form.	1. Patients with Pregnancy-Induced Hypertension. 2. Shift workers or patients working for odd hours (working between 5 pm and 9 am). 3. Patients with arm circumference of <22 cm or >42 cm. 4. Patients deemed unfit to participate in the study due to a health condition.

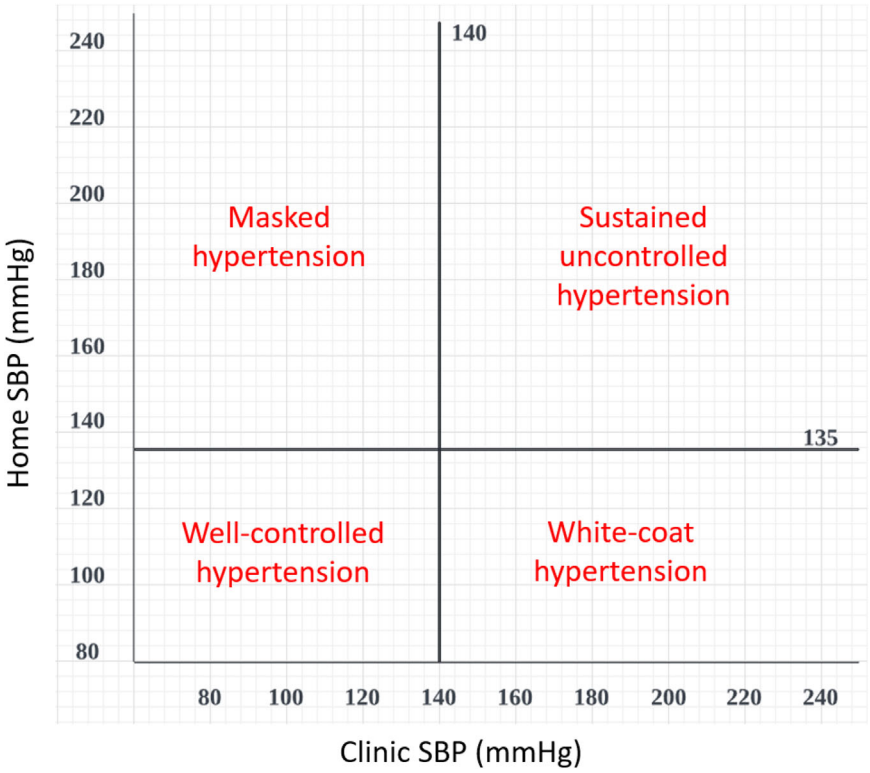


FIGURE 3 A plot template showing the distribution of uncontrolled, well-controlled, masked, and white-coat hypertension according to home and clinic systolic BP measurements. The cut-off of average home SBP 135 and average clinic SBP 140 were assigned as proposed in the IGH-IV 2019 and 2020 ISH Global Hypertension Practice Guidelines.

to BP control status and HR, including data collected from unique demographics in India.

- To examine BP and HR variability for visit-to-visit CBP, day-by-day HBP, morning HBP, and evening HBP.
- Comparison between the digitally recorded BP measurement and manually recorded.

2.5.3 | Secondary outcomes/Behavioral

- To investigate the knowledge, attitude and practice (KAP) of HBPM by hypertensive patients in India.
- Determine the association between KAP, physicians' instructions of HBPM and prescription usage to BP control among hypertensive patients.
- To investigate the change in patient's KAP regarding HBP from visit1 patient Home BP survey and visit two feedback surveys.

2.6 | Data management

All the study-related documents and database hardcopy will be maintained in a locked secured area under the study principal investigator (PI). All digital data will be stored securely under the responsibility of the study PI at King George's Medical University (KGMU), Lucknow, Uttar Pradesh, India. During the data collection, the project coordination, the tracking of study progress, follow-up on the recruitment process, digital data management, and statistical analyses will be under the supervision and responsibility of the study PI and in coordination with TATA Consultancy Services.

2.7 | Statistical method

The data will be collected centrally, and all data processing and statistical analyses will be done by using the software SAS 9.4 (SAS Institute; Cary, NC) and SPSS 21.0 (Release 21.0.0.0, IBM, USA). All the statistical

TABLE 3 GRAND study strength and limitation.

Strength	Limitation
1. Investigate the real BP control rate from the agreement between CBP and HBP among hypertensive patients. 2. Assessing BP control by HBPM which might reflect the real reading of BP. 3. Determine the BP and HR variability (visit-to-visit of CBP, day-by-day, morning and evening of HBP). 4. Comparison between patients' HBP recorded digital and manual readings. 5. Association of BP control with patients' KAP of hypertension and HBPM. 6. Correlation of BP control with patients' characteristics among hypertension in India. 7. Association between physicians' Instructions with BP control and patients' characteristics. 8. Patients' behavior change after experiencing 7 days of HBPM. 9. Prescription usage for hypertension treatment. 10. Provide new evidence of hypertension from unique demographics in India.	1. Selection Bias: participants are under hypertension treatment, and consulting with physicians. The participants are not randomized. 2. HBP measurement for 7 days only. 3. Moderate number of hypertensive patients (2,000 participant), however, the sample will be recruited from across India which might be representative of the country. 4. Recruitment centers are well-distributed by 7 regions, however, in India, there are 29 states and 8 Union territories. This study covers less than half the number of states (12 states).

analyses will be performed for the overall population and by the seven regions. Continuous and categorical variables will be presented as mean ± standard deviation (SD), and number (%), respectively. The average of all HBP readings versus the average of all CBP readings will be plotted to show the hypertension subtypes as in Figure 3. The chi-square will be used to test the prevalence differences among the hypertension subtypes and regression analyses will be performed to describe the association between socio-demographical, lifestyle, and clinical factors and each hypertension condition and hypertension subtype. From the aforementioned factors, determinants influencing each hypertension subtype will be identified. Additionally, the patient's Home BP awareness survey answers will be expressed as descriptive statistics of number (%). Both the demographic/clinical characteristics and the patient Home BP survey answers will be explored for association with hypertension subtypes. The change in patients' behavior between visit 1 and visit 2 will be determined using paired proportions (McNemar's test). To analyze the BP variability of visit-to-visit CBP, day-by-day HBP, morning HBP, and evening HBP, the following parameters will be calculated which are SD, coefficient of variation (CV) calculated as SD divided by the average BP level and multiplying by 100, and average real variability (ARV) calculated as the average of absolute differences between successive measurements. We will also investigate the agreement for the diagnosis of hypertension among the aforementioned variables using the chi-square test and kappa coefficient. Two-sided p values will be presented for all analyses, and the significance of differences will be set at $p < 0.05$.

3 | DISCUSSION

Results from other studies in India show that 42% of patients have a risk of misdiagnosis of hypertension because of the high percentage of masked hypertension and white-coat hypertension.[22] Out-of-office BP measurement is an important tool for physicians to diagnose masked hypertension and white-coat hypertension. Local evidence for ABPM is available in India,[25–27] and there is evidence of HBPM too, however, the available evidence is limited or the sample size is small.[23] National evidence from Longitudinal Ageing Study in India (LASI) explored many variables including hypertension situation. However, BP control was determined on only one occasion during the study, and no measurements at home were collected.[28–30] Data from the Indian Hypertension Control Initiative (IHCI) also lacked HBP measurement.[31] To find out the real BP control rate and medication efficacy, BP value measured at home is needed in India. Another aspect of India is, as a country, it is unique with multiple cultures and habits, and for that variation, it ranges widely in the non-communicable disease (NCD) burden from 47.6% in the state of Bihar to 74.6% in Kerala. The life expectancy also has more than 10 years different with the lowest being in Uttar Pradesh for women (66.8 years old), and Assam for men (63.5 years old) to the highest in Kerala for both women and men, 78.7 years old and 73.8 years old, respectively.[32] Therefore, establishing an effective strategy to mitigate hypertension in the country must be tailored based on the area level of hypertension condition, keeping in mind each particular area's influencing factors to hypertension disease. Herein, the GRAND study will identify the real BP control rate, the factors associated with BP control, and the attitude of hypertensive patients in their hypertension management journey. From this study, addressing all the true factors that associate with hypertension may give a greater insight into how best to allocate resources to reduce the problem of hypertension and alleviate the burden of CVD on India's health situation. The study has notable strengths and limitations which were summarized in Table 3.

3.1 | Impact of study outcome

The study will help in conceptualizing the direction and strategies of policymaking for hypertension management and NCD burden mitigation projects in the country. Additionally, it will highlight the importance of establishing BP control management practice guidelines suitable for physicians and an educational opportunity for patients to practice HBPM in India.

AUTHOR CONTRIBUTIONS

Narsingh Verma conceived the study. Yutaka Imai and Takayoshi Ohkubo Advised on the design of the study. Noriko Matsushita and Ebtehal Salman drafted the manuscript. Narsingh Verma, Yutaka Imai, and Takayoshi Ohkubo reviewed the manuscript. Narsingh Verma and the GRAND Study Research Group are involved in the acquisition of data. All authors contributed to the critical revision of the manuscript for important intellectual content, and all authors read and approved the final manuscript.

ACKNOWLEDGMENTS

This study is supported by research funding by Omron Healthcare Co., Ltd. Technical support for developing the data management system, IT support, and data analysis, by Tata Consultancy Services. The study protocol was developed by Principal Investigator (PI) and reviewed by 2 study advisors (Yutaka Imai, and Takayoshi Ohkubo). The members of the GRAND Study Research Group (not listed individually in the author list of the title page, alphabetically ordered) are as follows: Rituparna, Barooah; Smitha, Bhat; N, Bhavatharini; Arun, Goel; Aloke Kumar, Gupta; Amit, Gupta; Arvind, Gupta; Vitull Kumar, Gupta; Aravinda, Jagadeesha; Anuj, Maheshwari; Rachna, Parashar; Bijay, Patni; Banshi, Saboo; Divya, Saxena; N K, Singh; Ramji, Singh; Ruchi, Singh; Saurabh, Srivastava.

CONFLICTS OF INTERESTS STATEMENT

The authors declare that they have no competing interests. Noriko Matsushita is an employee of Omron Healthcare Singapore Pte. Ltd. Ebtehal Salman is an employee of Omron Healthcare Co., Ltd. Takayoshi Ohkubo has received grants from Omron Healthcare Co., Ltd. Other authors declare that they have no conflict of interest.

TRIAL STATUS

This trial is at the recruitment stage.

CLINICAL TRIAL REGISTRATION STATUS

Registered at Clinical Trials Registry-India (CTRI) under CTRI/2023/02/049486 on 06 February 2023.

CONSENT TO PARTICIPATE

All parties will ensure the protection of patient personal data and will not include patient names on reports, publications, or in any other disclosures, except where required by laws. The informed consent form will be in compliance with local regulatory requirements and legal requirements. The informed consent form used in this study, and any changes made during the course of the study, will be prospectively approved by the IEC. The investigator will ensure that each study patient, or his/her legally acceptable representative, is fully informed about the nature and objectives of the study and possible risks associated with participation. The investigator, or a person designated by the investigator, will obtain written informed consent from each patient or the patient's legally acceptable representative before any study-specific activity is performed. The investigator will retain the original of each patient's signed consent form.

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How to cite this article: Verma N, Matsushita N, Salman E, Ohkubo T, Imai Y. GeogRaphic and socioecoNomic Distribution of real-world Indian data of home blood pressure monitoring (GRAND Study): Study protocol for an observational study in 18 medical centers across India. *J Clin Hypertens*. 2023;25:1105–1134. https://doi.org/10.1111/jch.14713

ADDITIONAL FILES

Additional file 1: Informed consent (PDF 297 kb).

GeogRaphic And SocioecoNomic Distribution of Real world Indian data of Home monitoring
NON-INTERVENTIONAL STUDY INFORMED CONSENT
Version 1.8, June 23, 2022

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[Informed Consent form for patients]

This Informed Consent Form is for patient who attend _____ **hospital/clinic**, and who we are inviting to participate in research on hypertension. The title of our research project is "GeogRaphic And SocioecoNomic Distribution of Real world Indian data of Home monitoring-GRAND Study"

Investigators at _____ hospital/clinic

Name	Title	Roles and Responsibilities

Principal Investigator of the Protocol

Name, degree(s)	Title	Affiliation
Prof. Narsingh Verma (MBBS, MD)	Dean	Department of Physiology, King George Medical University, Lucknow,Uttar Pradesh-India

Advisors

Name, degree(s)	Affiliation
Prof. Yutaka Imai	Tohoku Institute for Management of Blood Pressure
Prof. Takayoshi Ohkubo	Hygiene and Public Health Teikyo University School of Medicine
Dr. C Venkata S Ram	World hypertension league (in partnership with WHO), South Asia region

Coordinating research centers

1. Department of Physiology, KGMU Lucknow, Uttar Pradesh
2. All India Institute of Medical Sciences, Kalyani, West Bengal
3. Department of Medicine, BBDU Lucknow, Uttar Pradesh
4. Jaipur Diabetes Research Centre, Jaipur
5. Wellesley Medical Center, West Bengal
6. Saxena Multi-speciality Hospital, Haryana
7. Diabetes Research & Education Centre, Uttar Pradesh

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8. S.R.C Diabetes Care Centre, Tamil Nadu
9. Kishore Ram Hospital, Punjab
10. Diabetes and Heart Research Centre, Jharkhand
11. Department of Medicine government Institute of Medical Sciences Greater Noida, Uttar Pradesh
12. Diacare Hospital, Gujarat
13. Kevalaya Hospital, Maharashtra
14. Apollo Hospitals New Delhi, Delhi
15. Arvinda Diabetes Center, Karnataka
16. Department of Medicine, Father Muller Medical College, Karnataka
17. Department of Physiology, AIIMS Bhopal, Madhya Pradesh
18. Department of Physiology, AIIMS Rishikesh, Uttarakhand
19. Department of Physiology, North Eastern Indira Gandhi Regional Institute, Meghalaya

This Informed Consent Form has three parts:

- Information Sheet (to share information about the research with you)
- Certificate of Consent (for signatures if you agree to take part)
- Device Security Form (for any damage control)

You will be given a copy of the full Informed Consent Form

PART I: Information Sheet

Introduction

We are doing research on hypertension in India. I am going to give you Information and invite you to be part of this research. You do not have to decide today whether you will participate in the research or not. Before deciding you can talk to anyone you feel comfortable with about the research.

There may be some words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask them to us; the study doctor or the staff.

Purpose of the research

The measurement of blood pressure is an important clinical tool, yet it is being performed in most un-professional manner. Therefore, in the present scenario it is important to compare and validate the data of office blood pressure measurement and home blood pressure measurement. In general practice, it has been observed that most of the research and data collection regarding efficiency of home blood pressure monitoring and office blood pressure monitoring has been done in western countries i.e America or Europe. Currently, no such research has been done in India to assess the efficacy of home blood pressure monitoring versus office blood pressure monitoring. Looking at the huge population and demographic/socio-economic variation in the country, it is imperative to carry out a study to assess the impact of Home Blood Pressure Monitoring (HBPM) in management of blood pressure. The purpose of the study is to conduct India's first multicentric trial to assess the impact of HBPM and hypertension management in general population.

Type of Research Intervention

This research will involve home blood pressure monitoring for at least 7 days.

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Participant selection
We are inviting all adults with hypertension on medication who attend _____ **hospital/clinic** to participate in this research.

Voluntary Participation
Your participation in this research is entirely voluntary. Whether you choose to participate or not, all the services you receive at this hospital/clinic will continue and nothing will change. If you choose not to participate in this research project, you will be offered the treatment that is routinely offered in this hospital/clinic for hypertension, and we will tell you more about it later. You may change your mind later and stop participating even if you agreed earlier.

Procedures and Protocol
The schedule and activities in this registry are the following;

The Schedule of Activities

Observation/test items	**Visit1 (Day0)**	**Visit2 (Day8)**
Allowed time window	-	+7d
Informed consent	X	
Inclusion/exclusion Criteria	X	
Registration Form / Background*	X	
Vital Sign (clinic BP, HR)	X	X
Home BP, HR (at awakening and bedtime: 2 times each occasions)	←→ At least 7 days	

*** Details of Registration Form / Background**
District and town of residency, gender, age, occupation, education level, religion, weight (kg), height (cm), waist (cm), hip (cm), aBSI (you can refer to https://www.absicalculator.eu/), BMI (calculated as weight in kg divided by square of height in m), obesity (definition following the criteria by MoHFW), diet habit (vegetarian/non vegetarian), health insurance, sleep pattern, regional temperature (at clinic- you can refer to https://mausam.imd.gov.in/), investigation center altitude (you can refer to https://en-gb.topographic-map.com/maps/zr8/India/), socioecomic state, marital status, present illness and habit (hypertension [HT], family history of HT, duration of HT, duration of HT therapy, hyperlipidemia [HL], on medication for HL, diabetes mellitus [DM], on medication for DM, liver disease, family history of lipid disorder, family history of DM, family history of CVD, carotid artery disease, thoracic aortic aneurysm, chronic kidney disease, atrial fibrillation [AF], sleep pattern, habitual drinking (in years and frequency), tobacco chewing (in years), current smoking habit (in years and cigarette quantity), physical activity (in intensity and day of activity), any special medications, past history (angina pectoris, myocardial infarction, aortic dissection, heart failure, peripheral artery disease, stroke , ischemic stroke, hemorrhagic stroke, other type of stroke), and medication for HT and type of HT medication.

Study visits will be scheduled at Visit1 and Visit 2.

All information and details in this document are confidential

Visit 1:

The investigator or research nurse who will enrol subjects for study will:

- Obtain written informed consent.
- Obtain written home BP patient's survey.
- Obtain relevant background information (please see above background items).
- Measure height (cm), and weight (kg), waist (cm), and hip (cm).
- Measure Clinic BP (twice with the gap of 1 min) and heart rate (HR).
- Provide home BP measurement device (Omron-HEM-9210T and instruct how to use) along with handbook for patients and home BP measurement sheet.

We would like to ask you to measure your home blood pressure at the following timings (awakening and bedtime; 2 times each occasion for at least 7 days) by using provided BP measurement device and recording on home BP measurement sheet:

[Home BP measurements timing and recording]
We would like to ask you to measure your home BP twice at awakening occasion and twice at bedtime occasion for at least 7 days. Timing for home BP are according to the following methods on each occasion:

- **Morning (awakening):** within 1 hr after waking up, after urination, before taking morning medications, before eating breakfast and after 2-5 min resting in a sitting position
- **Evening (bedtime):** before going to bed and after 2-5 min resting in a sitting position

Interval between the 2 measurements on each occasion is at least 1 minute. You must document and record the BP values onto the home BP measurement sheet and report them to your physician during Visit 2 of the study.

Visit 2:

The investigator or research nurse will:

- Obtain documented sheets for home BP measurement values from you, the patients.
- Measure clinic BP (twice with the gap of 1 min) and HR.
- Receive home BP measurement device returned by you, the patient.

Duration
In total, you will be asked to come 2 times to _____ **hospital/clinic** in 1 to 2 weeks. At Visit 2, the research will be finished.

Patient Survey
This survey consists of 16 questions and is designed to understand the behavior of hypertensive patients. This will help the institution to assess patients' knowledge and their understanding about hypertension.

Risks
There are no anticipated risks to you of participating in this study. The only risk to you of your involvement in this study is the inconvenience of measuring home blood pressure every day for 1 to 2 weeks and giving your time for study scheduled visit.

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Benefits
If you participate in this research, you will have the following benefits: your home blood pressure records will help your physician to provide best treatment for you, you can learn more about the efficacy of your current treatment, you can first-hand learn and practice measuring your own blood pressure at home at your own convenience and without a cost. There may not be obvious benefit for you but your participation is likely to help us find the answer to the research question on blood pressure control. There may not be any benefit to the society at this stage of the research, but future generations are likely to benefit from this study evidence to improve self-measuring blood pressure awareness and control.

Confidentiality
The information that we collect from this research project will be kept confidential. Information about you that will be collected during the research will be put away and no one but the researchers will be able to see it. Any information about you will have a number on it instead of your name. Only the researchers at _____ **hospital/clinic** will know what your number is and we will lock that information up with a lock and key. It will not be shared or given with other investigators in other facilities.

Sharing the Results
The knowledge that we get from doing this research will be shared broadly through conferences. Confidential information will not be shared. After these conferences, we will publish the results in order that other interested people may learn from our research.

Compensation for health damage
No compensation will be provided in this clinical study.

Right to Refuse or Withdraw
You do not have to take part in this research if you do not wish to do so. You may also stop participating in the research at any time you choose.
If you wish to withdraw or stop your participation during any point of the study, you are obliged to return the blood pressure monitoring device to the study center, then sign the withdrawal form and keep a copy of it with you. It is your choice and all of your rights will still be respected.

Alternatives to Participating
If you do not wish to take part in the research, you will be provided with the established standard treatment available at the hospital/clinic.

Who to Contact
If you have any questions, you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact any of the following:

Name of contact person:

Telephone number:

e-mail address:

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This proposal has been reviewed and approved by Independent Ethics Committee (IEC) Narayana Diagnostics, Lucknow, Uttar Pradesh. It is a committee whose task it is to make sure that research participants are protected from harm. If you wish to find more about the IEC, contact [Prof. Narsingh Verma, Address: Department of Physiology-KGMU Lucknow Uttar Pradesh, Tel.: 09839064560].

PART II: Certificate of Consent

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked, have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Signature of Participant_____

Name of Participant _____

Date _____
Day/month/year

A copy of this Informed Consent Form has been provided to participant _____
(participant's initialled by the researcher/assistant)

GeogRaphic And SocioecoNomic Distribution of Real world Indian data of Home monitoring
NON-INTERVENTIONAL STUDY INFORMED CONSENT
Version 1.8, June 23, 2022

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PART III: Device Security Form

I have read the foregoing information, or it has been read to me. I hereby confirm that I have received BP monitor-Omron HEM-9210T. And I assure that I will return it in the very same condition as it was provided to me by hospital/clinic _____

Serial Number of Device_____

Signature of Participant _____

Name of Participant_____

Date _____
Day/month/year

A copy of this Informed Consent Form has been provided to participant _____
(participant's initialled by the researcher/assistant)

Additional file 2: Registration form and feedback survey (PDF 394 kb).

GeogRaphic And SocioecoNomic Distribution of Real world Indian data of Home monitoring
NON-INTERVENTIONAL STUDY REGISTERATION FORM
Version 2.3, August 08, 2022

All information and details in this document are confidential

Center ID: .....
Patient ID:.....
Date:...../...../.....
(Day/Month/Year)

Registration Form

Barcode Sticker:

Patient ID:	**Device ID:**
Do you <u>own BP</u> device at home? **Home blood pressure ownership: ☐Yes ☐No**	**Do you <u>measure BP at home</u>?** **Home blood pressure measuring: ☐Yes ☐No**

<u>Visit 1 Clinic blood pressure measurement (2 times per occasion)</u>

1) Person In-charge for clinic BP measurement: ☐Doctor ☐ Other Healthcare Staff (e.g., Nurse, Pharmacist)
☐Admin Staff ☐Other (please specify: _____)

2) Clinic BP measurement upper arm: 1. ☐Left ☐Right 2. ☐Non-dominant arm ☐Dominant arm

Date (Day/month/year)		**SBP (Systolic Blood Pressure)**	**DBP (Diastolic Blood Pressure)**	**Pulse**
/ /	1st	mmHg	mmHg	beats/min
Time ____:_____	2nd	mmHg	mmHg	beats/min
Reginal Temperature	C°	**Center Altitude**		m

Regional temperature: https://mausam.imd.gov.in/

Center location altitude: https://en-gb.topographic-map.com/maps/zr8/India/

General Information

District of residency		**Village or town of residency**	
Age	year old	**Sex**	☐ Male ☐ Female
Height	cm	**Weight**	kg
Waist	cm	**Hip**	cm
aBSI	This will be calculated by Web-Apps Kg/m^2	**BMI**	This will be calculated by Web-Apps Kg/m^2

GeogRaphic And SocioecoNomic Distribution of Real world Indian data of Home monitoring
NON-INTERVENTIONAL STUDY REGISTERATION FORM
Version 2.3, August 08, 2022

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Obesity Underweight: <18.5 Kg/m^2 Normal: 18.5 – 22.9 Kg/m^2 Overweight: 23.0 – 24.9 Kg/m^2 Obese: ≥25.0 Kg/m^2	☐Yes ☐No	⇒Upon logging the data from this sheet to the online data management system, the above will be calculated automatically. Add the values from the system.	
Religion	☐ Hindu ☐ Sikh ☐ Christian ☐ Muslims ☐ Others_____	**Socioeconomic status**	☐ < 2.5 LPA ☐ 2.5-5 LPA ☐ 5-10 LPA ☐ > 10 LPA
Marital status	☐ Unmarried ☐ Married/divorced/widow without children ☐ Married/divorced/widow/single with children	**Diet Habit**	☐ Vegetarian ☐ Non-Vegetarian
Education Level	☐ None ☐ Primary ☐ Secondary ☐ High school ☐ College/University ☐ Others	**Occupation**	☐ Office Worker ☐ Unskilled Worker ☐ Agricultural workers ☐ Defense worker ☐ Self-Employed ☐ Student ☐ Housewife ☐ Retired ☐ Unemployed
Are you under any health insurance? (multiple answers)	☐ Armed Forces Medical Services (AFMS) ☐ Ayushman Bharat National Health Protection Scheme (PM-JAY) ☐ Central Government Health Scheme (CGHS) ☐ Community Cooperative Health Insurance Schemes (CCHIS) ☐ Employees State Insurance Scheme (ESIS) ☐ Medical reimbursement from an employer/ health insurance through an employer (MRE) ☐ Privately Purchased Commercial Health Insurance (PPCHI) ☐ Rashtriya Swasthya Bima Yojana (RSBY) and allied schemes ☐ I am not under any health insurance scheme ☐ Others, please specify:_____		

GeogRaphic And SocioecoNomic Distribution of Real world Indian data of Home monitoring
NON-INTERVENTIONAL STUDY REGISTERATION FORM
Version 2.3, August 08, 2022

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Present illness and habit

Hypertension condition

Hypertension (HT)	☐Yes ☐No	**Family history of HT**	☐Yes ☐No
Duration of HT	years	**Duration of HT therapy**	years

Other health conditions

Hyperlipidemia (HL)	☐Yes ☐No	**On medication for HL**	☐Yes ☐No
Diabetes mellitus (DM)	☐Yes ☐No	**On medication for DM**	☐Yes ☐No
Liver Disease	☐Yes ☐No	**Chronic Kidney Disease**	☐Yes ☐No
Family history of Lipid disorder	☐Yes ☐No	**Family history of DM**	☐Yes ☐No
Family history of CVD	☐Yes ☐No	**Thoracic aortic aneurysm**	☐Yes ☐No
Carotid artery disease	☐Yes ☐No	**Atrial fibrillation (AF)**	☐Yes ☐No

Life habits

Sleep Pattern	☐Less than 5hrs ☐6-8hrs ☐More than 8hrs	**Habitual drinking**	☐Yes ☐No If yes, for how many years? _____ years Frequency _____days per week
Tobacco chewing	☐Yes ☐No If yes, for how many years? _____ years	**Current smoking habit**	☐Yes ☐No If yes, for how many years? _____ years _____Cigarettes per day
Physical activity	☐High (> 60 minutes a day) ☐Medium (30-60 minutes a day) ☐Low (<30 minutes a day) Number of days _____ per week	**Do you take any medications for special or unusual condition?**	☐Yes, please specify: _____ ☐No

GeogRaphic And SocioecoNomic Distribution of Real world Indian data of Home monitoring
NON-INTERVENTIONAL STUDY REGISTERATION FORM
Version 2.3, August 08, 2022

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Past History

Angina pectoris	☐Yes	☐No	**Myocardial infarction**	☐Yes	☐No
Aortic dissection	☐Yes	☐No	**Heart failure**	☐Yes	☐No
Peripheral artery disease	☐Yes	☐No			
Stroke	☐Yes (Diagnosis by CT or MRI: ☐Yes ☐No) ☐No If yes, please check the type of stroke. ☐ Ischemic stroke ☐ Hemorrhagic stroke ☐ Other type of stroke _____				

Medication

Medication for HT ☐ Yes ☐ No

*Please check multiple boxes if you use a combination drug

Generic name	Classification *	Dose/day	Timing
	☐ARB ☐ACE ☐CCB ☐αblocker ☐βblocker ☐diuretics ☐other		
	☐ARB ☐ACE ☐CCB ☐αblocker ☐βblocker ☐diuretics ☐other		
	☐ARB ☐ACE ☐CCB ☐αblocker ☐βblocker ☐diuretics ☐other		
	☐ARB ☐ACE ☐CCB ☐αblocker ☐βblocker ☐diuretics ☐other		
	☐ARB ☐ACE ☐CCB ☐αblocker ☐βblocker ☐diuretics ☐other		
	☐ARB ☐ACE ☐CCB ☐αblocker ☐βblocker ☐diuretics ☐other		

***Note: remind the patient to bring their medications or prescribed meds during Visit 2 if the above could not be concluded**

Do not forget to assign Visit 2 appointment (on 8th days from the date filling this form)

Visit 2 appointment date:	/ /

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NON-INTERVENTIONAL STUDY REGISTERATION FORM
Version 2.3, August 08, 2022

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Other medication(s)

Generic name	Dose/day	Timing

Memo

GeogRaphic And SocioecoNomic Distribution of Real world Indian data of Home monitoring
NON-INTERVENTIONAL STUDY REGISTERATION FORM
Version 2.3, August 08, 2022

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Visit 2 Clinic blood pressure measurement (2 times per occasion)

1) Person In-charge for clinic BP measurement: ☐Doctor ☐ Other Healthcare Staff (e.g., Nurse, Pharmacist)
☐Admin Staff ☐Other (please specify: _____)

2) Clinic BP measurement upper arm: 1. ☐Left ☐Right 2. ☐Non-dominant arm ☐Dominant arm

Date (Day/month/year)		**SBP** (Systolic Blood Pressure)	**DBP** (Diastolic Blood Pressure)	**Pulse**
/ /	1st	mmHg	mmHg	beats/min
Time ____:_____	2nd	mmHg	mmHg	beats/min
Regional Temperature	C°	Regional temperature: https://mausam.imd.gov.in/		

Feedback survey (visit 2)

1. **Did you feel any difficulty measuring HBPM for 7 days? (multiple answers)**
   - ☐ Yes, it was difficult to measure BP using the device
   - ☐ Yes, it was a burden to measure regularly for 7 days, but if it was for 3 days, I think I can measure regularly
   - ☐ Yes, it was time consuming
   - ☐ Yes, I was confused how to follow the procedure
   - ☐ No, it was smooth

2. **In your opinion, what are the benefits of home blood pressure monitoring? (multiple answers)**
   - ☐ To realize the difference between my clinic blood pressure and usual blood pressure
   - ☐ Helps to know if my hypertension medication is effective
   - ☐ Regular monitoring helps to manage my other health conditions
   - ☐ Good practice for early warning and prevent CVD (e.g., stroke, heart attacks)
   - ☐ Adjust lifestyle habits for better health
   - ☐ I can measure more frequently my blood pressure at home
   - ☐ I can save time going to the clinic/pharmacy for only measuring my blood pressure
   - ☐ I do not think there are any benefits of home blood pressure monitoring

3. **Did you notice any health or lifestyle change in past 7 days after measuring your BP at home? (single answer)**
   - ☐ **Yes**, I noticed the change, and I would like to continue this regularly
   - ☐ **Yes**, I noticed the change, but **I don't want to continue to measure BP at home**
   - ☐ **No**, there were no changes so far, but I want to continue to measure BP at home
   - ☐ **No**, there were no changes so far, so **I will not continue to measure BP at home**
   - ☐ I didn't notice

Additional file 3: Patient's Home BP survey (PDF 322 kb).

GeogRaphic And SocioecoNomic Distribution of Real world Indian data of Home monitoring
NON-INTERVENTIONAL STUDY PATIENT SURVEY
Version 2.6, July 05, 2022

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Center ID: .....
Patient ID: .....
Date:...../...../.....
(Day/Month/Year)

Home Blood Pressure Patient Survey

You will be participating in a study to measure your own blood pressure for 7 days using a home blood pressure device. How confident do you feel about measuring your own blood pressure at home? (multiple answers)

- ☐ I am confident to measure my blood pressure at home using the device
- ☐ I am confident to measure my blood pressure at home, but feel worried to measure it regularly for 7 days
- ☐ I feel worried of time consuming, but I will try to measure my blood pressure at home
- ☐ I feel worried on how to follow the procedure, but I will try to measure my blood pressure at home
- ☐ I am not confident to measure my blood pressure at home, but I will try

1. From your understanding, what is considered high blood pressure value (hypertension)? (multiple answers)
   - ☐ Clinic blood pressure
     Systolic more than (……) mmHg / Diastolic more than (……) mmHg
   - ☐ Home blood pressure
     Systolic more than (……) mmHg / Diastolic more than (……) mmHg
   - ☐ Don't know

2. Under your hypertension treatment, do you have a target blood pressure value recommended by your doctor? (single answer)
   - ☐ Yes, please specify: Systolic (……) mmHg / Diastolic (……) mmHg
   - ☐ No

3. Are you aware of the causes of hypertension? (multiple answer)
   - ☐ Diet rich in salt
   - ☐ Blood type
   - ☐ Smoking/chewing tobacco
   - ☐ Obesity
   - ☐ Lack of physical activity
   - ☐ High alcohol consumption

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- ☐ Stress
- ☐ Vaccination
- ☐ Family history of high blood pressure
- ☐ Association with other health conditions (Chronic kidney disease…etc.)

4. Are you aware about the health risk of uncontrolled hypertension? Please choose from the following options: (multiple answers)
   - ☐ Cancer
   - ☐ Organ Damage
   - ☐ Heart Attack/ Heart Stroke
   - ☐ Heart Failure
   - ☐ Don't know
   - ☐ Others (_____)

5. Do you use prescription sheet when you get your hypertension medication from the pharmacy? (single answer)
   - ☐ Yes
   - ☐ No

6. How often do you get your blood pressure measured outside your home? (single answer)
   - ☐ Daily
   - ☐ Weekly
   - ☐ Monthly
   - ☐ Yearly
   - ☐ When you noticed any symptoms
   - ☐ Only when visit doctor
   - ☐ Not measure at all

7. Do you think regular checking of blood pressure is important? (single answer)
   - ☐ Yes
   - ☐ No
   - ☐ Don't know / not sure

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8. In your opinion, what are the benefits of home blood pressure monitoring? (multiple answers)

- ☐ To realize the difference between my clinic blood pressure and usual blood pressure
- ☐ Helps to know if my hypertension medication is effective
- ☐ Regular monitoring helps to manage my other health conditions
- ☐ Good practice for early warning and prevent CVD (e.g., stroke, heart attacks)
- ☐ Adjust lifestyle habits for better health
- ☐ I can measure more frequently my blood pressure at home
- ☐ I can save time going to the clinic/pharmacy for only measuring my blood pressure
- ☐ I do not think there are any benefits of home blood pressure monitoring

9. Do you have any device to measure blood pressure at home? (single answer)

- ☐ Yes
- ☐ No

10. Do you measure your blood pressure at home? (single answer)

- ☐ Yes ***(continue in the Blue form)***
- ☐ No ***(continue in the Yellow form)***

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Blue form

10.1 If "Yes", please answer why? (multiple answers)

- ☐ White-coat hypertension and masked hypertension identification
- ☐ My doctor recommends me to monitor my blood pressure regularly
- ☐ To monitor if my medication is working regularly
- ☐ To share my blood pressure measurement results with my doctor
- ☐ To let me know if my blood pressure is normal when I feel unwell
- ☐ So that I can adjust my medication if my blood pressure is within normal range
- ☐ My friends / family members recommend monitoring blood pressure regularly
- ☐ Regular monitoring helps to prevent stroke / heart attacks
- ☐ Good practice for early warning / preventative / better health control
- ☐ Adjust lifestyle habits for better health
- ☐ More accurate reading to do it at home
- ☐ I'm getting old
- ☐ Others (_____)

11. How often do you measure your blood pressure at home? (single answer)

- ☐ Daily
- ☐ Weekly
- ☐ Monthly
- ☐ Yearly
- ☐ When you noticed any symptoms

12. At which occasion do you measure your home blood pressure during the day? (single answer)

- ☐ Morning
- ☐ Evening
- ☐ Both morning and evening
- ☐ Others
- ☐ (_____)

All information and details in this document are confidential

Blue form

13. What all steps do you follow to measure your blood pressure at home? (multiple answers)

- ☐ Before breakfast
- ☐ Within one hour of waking up in the morning
- ☐ Before going to bed in the evening
- ☐ Before taking anti-hypertensive drugs
- ☐ No caffeine or alcohol should be consumed 30 minutes before the measurement
- ☐ Resting for 2-5 minutes in a quiet, comfortable place before measurement
- ☐ Sitting body position
- ☐ Each time two readings should be taken
- ☐ I do not know
- ☐ Others (_____)

14. Do you report your recorded home blood pressure value to your doctor? (single answer)

- ☐ Yes
- ☐ No

14.1 If "Yes", which measured value do you report to your doctor? (single answer)

- ☐ All home blood pressure reading
- ☐ Bad reading
- ☐ Good Reading

14.2 If "No", please answer why? (single answer)

- ☐ Doctor did not request me to report the values
- ☐ Never recorded my blood pressure values
- ☐ Worried to report my blood pressure readings to doctor
- ☐ I don't think it's important to report my recoded blood pressure readings to anyone
- ☐ Others (_____)

GeogRaphic And SocioecoNomic Distribution of Real world Indian data of Home monitoring
NON-INTERVENTIONAL STUDY PATIENT SURVEY
Version 2.6, July 05, 2022

All information and details in this document are confidential

Yellow form

10. Do you measure your blood pressure at home? (single answer)

- ☐ Yes ***(continue in the Blue form)***
- ☐ No ***(continue in the Yellow form)***

10.2. If "No", please answer Why? (multiple answers)

- ☐ It is too expensive to buy a home digital blood pressure monitor
- ☐ No recommendation from doctor
- ☐ I do not trust the reading measured by home digital blood pressure monitor
- ☐ I do not know how to measure blood pressure at home
- ☐ Too much burden to measure my blood pressure at home
- ☐ Measuring at home makes me feel like a sick person
- ☐ My blood pressure condition is not serious
- ☐ Medicine recommended by doctor is enough
- ☐ Others (_____)

15. Since you don't measure your blood pressure at home, then what are the alternatives you do to manage and control your blood pressure? (multiple answers)

- ☐ I measure my blood pressure outside my home (clinic, pharmacy…etc.)
- ☐ Monitor my lifestyle (diet, exercise…etc.)
- ☐ Traditional methods (Ayurvedic, acupuncture, homeopathic…etc.)
- ☐ I do not do anything
- ☐ Others (_____)

16. What kind of factors will change your mind for home blood pressure monitoring? (multiple answers)

- ☐ Governmental support (reimbursement for devices, purchase coupons…etc.)
- ☐ Affordable price range for blood pressure devices
- ☐ Easy availability of devices
- ☐ Easy educational material on how to measure blood pressure
- ☐ Self-realization for benefits of home blood pressure monitoring
- ☐ Successful examples from patients of using blood pressure monitor
- ☐ Strong recommendation and clear instructions from healthcare providers
- ☐ Others (_____)

Additional file 4: HBP measurement sheet (PDF 320 kb).

GeogRaphic And SocioecoNomic Distribution of Real world Indian data of Home monitoring
NON-INTERVENTIONAL STUDY HBP MEASUREMENT SHEET
Version 1.7, September 02, 2022

All information and details in this document are confidential

Home blood pressure measurements

Center ID: .....
Patient ID:..... Age.....yrs.
Date:..../...../..... ~ ...../...../.....
(Day/Month/Year)

Your next appointment is on _____/_____/_____
Please bring this home blood pressure sheet filled with your blood pressure recordings with you in your next visit.

How frequently do you usually take your hypertension medications?
☐ Daily ☐ Once every 2 days ☐ Others (please specify: _____)

Duration: blood pressure measurement should be measured for **at least 7 days.**

Please measure your blood pressure before taking any of your medications

Number of days (DD/MM)		1st measurement				2nd measurement				Did you take your hypertension medication today?
		Blood pressure				Blood pressure				
		time	SBP	DBP	Pulse	time	SBP	DBP	Pulse	
Day 1 (/)	Awakening	:				:				☐ Yes, take ☐ No need to take ☐ I forgot
	Bedtime	:				:				☐ Yes, take medicine ☐ No need to take ☐ I forgot
Day 2 (/)	Awakening	:				:				☐ Yes, take medicine ☐ No need to take ☐ I forgot
	Bedtime	:				:				☐ Yes, take medicine ☐ No need to take ☐ I forgot
Day 3 (/)	Awakening	:				:				☐ Yes, take medicine ☐ No need to take ☐ I forgot
	Bedtime	:				:				☐ Yes, take medicine ☐ No need to take ☐ I forgot
Day 4 (/)	Awakening	:				:				☐ Yes, take medicine ☐ No need to take ☐ I forgot
	Bedtime	:				:				☐ Yes, take medicine ☐ No need to take ☐ I forgot
Day 5 (/)	Awakening	:				:				☐ Yes, take medicine ☐ No need to take ☐ I forgot
	Bedtime	:				:				☐ Yes, take medicine ☐ No need to take ☐ I forgot
Day 6 (/)	Awakening	:				:				☐ Yes, take medicine ☐ No need to take ☐ I forgot
	Bedtime	:				:				☐ Yes, take medicine ☐ No need to take ☐ I forgot
Day 7 (/)	Awakening	:				:				☐ Yes, take medicine ☐ No need to take ☐ I forgot
	Bedtime	:				:				☐ Yes, take medicine ☐ No need to take ☐ I forgot

Additional file 5: Withdrawal form (PDF 232 kb).

GeogRaphic And SocioecoNomic Distribution of Real world Indian data of Home monitoring
NON-INTERVENTIONAL STUDY PATIENT WITHDRAWAL FORM
Version 1.2, June 23, 2022

All information and details in this document are confidential

Center ID: .....
Patient ID:.....
Date:...../...../.....
(Day/Month/Year)

Patient Voluntary Withdrawal Form

You have indicated that you would like to withdraw from the study and have communicated this information to your study doctor. You have the right to withdraw fully from this study at any time and you do not have to give a reason. Withdrawing either fully or partly will not prejudice your future medical care.

Ask a member of the study team if you have any concerns and make sure you receive satisfactory answers to your questions before you sign it. Your participation in the study remains confidential and results will only be available as outlined in the main consent form you signed at the start of the study, and all of your collected data thus this point will be permanently deleted.

I declare to confirm my wish to withdraw my consent from all aspects of the study before data collection has been completed and that none of my data will be included in the study.

By signing this form, you confirm that you have had enough time to review this form and all of your concerns and questions have been answered to your satisfaction.

Participant's signature	Date	Participant's name (please print)
Signature of staff reviewing	Date	Name of staff reviewing (please print)

GeogRaphic And SocioecoNomic Distribution of Real world Indian data of Home monitoring
NON-INTERVENTIONAL STUDY PATIENT WITHDRAWAL FORM
Version 1.2, June 23, 2022

All information and details in this document are confidential

Center ID: .....
Patient ID: .....
Date:...../...../.....
(Day/Month/Year)

Patient Involuntary Withdrawal Form

(Only to be completed by study staff or participant's family-related in case of involuntary withdrawal)

The patient is to be withdrawn from the study involuntary for personal reasons not to be disclosed here. The thus far collected data will be bound to one of the following options:

☐ I agree that patient's data can be used for further analysis

☐ I do not permit to use patient's data for further analysis and wish for all the patient's collected data to be deleted permanently from your system

By signing this form, the signer confirms that they have had enough time to review this form and all of their concerns and questions have been answered to their satisfaction.

		/
Signer's signature	Date	Signer's name and relation (please print)
Signature of staff reviewing	Date	Name of staff reviewing (please print)