

# Statistical Analysis Plan

## Personalized information support for hypertension management (PHM)

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# Statistical Analysis Plan

## SIGNATURE PAGE

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## List Of Abbreviations and Definition of Terms

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PHM	Personalized hypertension management
RCT	Randomized controlled trial
BP	Blood pressure
EQ-5D-5L	Euro Qol-5 Dimension-5 Level
SAP	Statistical analysis plan
SBP	Systolic blood pressure
DBP	Diastolic blood pressure
IQR	Interquartile range
cTTO	Time-trade-off value for Chinese
CONSORT	Consolidated standards of reporting trials
GLMM	Generalized linear mixed model

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## **1. Purpose and scope of the Plan**

This document provides detailed information on the planned statistical analyses for the main papers reporting results from a study funded by the National Natural Science Foundation of China, ensuring transparency of the analysis process.

The results presented in these papers will adhere to the analytical strategy set out here. While subsequent analyses of a more exploratory nature are not strictly bound by this strategy, they are expected to follow the general principles outlined herein. The guidelines are not intended to constrain exploratory analyses (such as determining cut-off points for the categorisation of continuous variables), nor to restrict common practices (such as data transformation prior to analysis). Instead, they aim to establish a clear and consistent framework for conducting, analysing, and reporting trial outcomes. This approach will be followed as closely as possible to ensure consistency and transparency in the interpretation and dissemination of trial findings.

The analysis strategy will be available on request when the principal papers are submitted for publication in a journal. Suggestions for subsequent analyses by journal editors or referees, will be considered carefully, and carried out as far as possible in line with the principles of this analysis strategy; if reported, the source of the suggestion will be acknowledged. Any deviations from the statistical analysis plan will be described and justified in the final report of the trial. The analysis should be carried out by an identified, appropriately qualified and experienced statistician, who should ensure the integrity of the data during their processing. Examples of such procedures include quality control and evaluation procedures.

## 2. Trial overview

Information Type	Details
Study design	Two-arm, double-blind, randomized controlled clinical trial.
Settings	PHM trial was conducted in Jieshou county, Anhui, China, involving a total of 48 administrative villages and all the 48 village clinics in these villages.
Eligibility	Males or females who: were permanent residents in the site villages, aged 18 years or older and accessible during the screening-survey; had already been diagnosed with hypertension; were able to read text messages or living with family member(s) who can read and explain text messages for them; had a mobile phone to receive messages and were able to use the project provided electronic BP monitor device and willing to participate in the study.
Randomization	Jieshou consists of 15 townships which are further divided into 129 administrative villages. Each administrative village has but only one village clinic. Of all the villages, 48 were selected as site-villages through the following steps: acquisition of a complete name-list of all the villages in Jieshou from the local health authority; allocation of the names into site (n= 48) and non-site villages using the Rand function of Excel by an independent statistician with Anhui Medical University; all the village clinics in these selected villages were treated as site clinics and all the clinicians working on hypertension management in the site clinics were invited to participate.
Blinding	The allocation status has been and will continue to be kept blinded to not only the participating patients and practitioners but also field data collectors and statisticians until the quantitative analysis has completed.
Interventions	The intervention group received an intervention-package designed to promote 8 objective behaviors via 6 pragmatic approaches. The objective behaviors included: attending and responding to project messages/contacts; performing self-monitoring and reporting; modifying unhealthy diet habits or practices; maintaining adequate physical exercise/activities; containing tobacco and alcohol consumption; addressing emotion and sleep problems; using clinical checkups and treatment; and facilitating family engagement. While the approaches comprised: support for self-monitoring, supervised machine communication, daily education message, weekly blood pressure notification, quarterly signed feedback; and engagement of clinicians. Despite PHM, decisions about patients' antihypertensive and other drugs remained at the clinicians' discretion at all times.

Trial overview(continued)

Information Type	Details
Control	Participant patients in control arm received usual hypertension care that typically consisted of clinic blood pressure monitoring to titrate drugs, with appointments and drug changes made at the discretion of the clinicians with the local village clinics or higher-level health facilities. They did not receive any of the interventions included in PHM except for provision of provision of an electronic BP monitor.
Sample size	A total of 2392 patients were finally recruited into the trial.
Primary outcome measures	Differences in SBP, DBP and BP control rates between the two arms after 12 and 24 months of intervention initiation, with or without multiple imputation for missing values. Here, BP control rate was defined as SBP <140 mm Hg and/or DBP <90 mmHg.
Secondary outcome measures	Differences, between the two arms after 12 and 24 months of intervention initiation with or without multiple imputation for missing values, in health-related quality of life (assessed on base of the EQ-5D-5L ratings), deaths, admissions and length of stay for all-causes and major complications of hypertension (e.g., cardiovascular heart diseases and cerebrovascular diseases) and 7 standardized (from 0 to 10) scores of objective behaviors including performing self-monitoring and reporting, modifying unhealthy diet practices, maintaining adequate physical exercise/activities, containing tobacco and alcohol consumption, addressing emotion and sleep problems, using clinical checkups and treatment and facilitating family support and engagement.
Duration	The intervention activities of PHM trial took place during August 2021 and August 2022 and the follow-up survey were conducted in August 2022 and August 2023 respectively. In addition, a baseline survey was conducted involving all potential participant patients in August 2021.
Study questions	<ol style="list-style-type: none"> <li>1. Can PHM reduce BP levels and improve BP control rates, enhance quality of life both at the end of the intervention and 12 months after its cessation?</li> <li>2. Can PHM reduce hypertension-related harms, such as hospitalization rates, length of hospital stay, and mortality both at the end of the intervention and 12 months after its cessation?</li> <li>3. Can PHM improve patient behaviors at the end of the intervention?</li> </ol>

### **3. Data cleaning and processing**

#### **3.1 Data checks**

Data collected at the households were first double entered using EPI DATA V3.1 and then checked and cleaned separately by two researchers for mis-recorded, mis-entered and illogical values. Discordances were resolved by discussions between the two researchers and reference to the original completed forms.

#### **3.2 Handling of dropouts**

All data up until the point of patient withdrawal from the trial will be used in analyses unless the patient withdrew consent and does not wish for the data already collected prior to withdrawal to be used for the trial. The patients withdrawn from the study were not replaced but the withdrawal reasons were recorded. All data on patients collected until that point will be used and any patients recruited were followed up in accordance with the trial schedule.

#### **3.3 Handling of missing data**

Missing data will be treated as missing at random and imputed using a chained-equations multiple imputation model. A complete-cases analysis will be presented as a secondary analysis. Missing data will be imputed using a chained equations approach with a model including all outcome variables, baseline prescribing rate, randomization group, clustering by practice and all covariates included in the analysis model.



### **3.4 Handling of outliers**

If outliers are found, the source data will be checked. If the source data is correct, then a sensitivity analysis will be performed excluding them from the analysis. Here, outliers are defined as more than  $1.5 \times$  inter-quartile range (IQR) above upper quartile or less than  $1.5 \times$  IQR below lower quartile.

## **4. Definition and value of variables**

### **4.1 Social-demographics**

- Sex, as specified by the participant's identification card,  $x=1$  for males and 2 for females.
- Age, defined as either the specific value as reported by the participant or grouped into percentile categories as appropriate.
- Education, defined as  $x=1$  if the participant reported no school education, 2 if the participant reported primary school education or higher education.
- Marriage status, defined as  $x=1$  for single, divorced or widowed, 2 for married or cohabiting.

### **4.2 Related health and history**

- Body mass index, defined as either the specific value or grouped into percentile categories as appropriate.
- Waist-to-hip ratio, defined as either the specific value or grouped into percentile categories as appropriate.

- Years since hypertension diagnosis, defined as either the specific value or grouped into percentile categories as appropriate.
- Duration of taking anti-hypertensive drugs, defined as value (of years from the first date when the patient started using antihypertensives) or grouped into percentile categories as appropriate.

### **4.3 Primary outcome measures**

- SBP (systolic blood pressure), defined as the average BP measured by the field data collectors during face-to-face surveys (at the beginning and end of the survey).
- DBP (diastolic blood pressure), defined as the average BP measured by the field data collectors during face-to-face surveys (at the beginning and end of the survey).
- BP control rate, defined as SBP <140 mm Hg and/or DBP <90 mmHg.

### **4.4 Quality adjusted life years (QALYs)**

- Dimensional rating of EQ-5D-5L, defined as  $x$  = the 5-item Likert rating of mobility, self-care, usual activities, pain/discomfort or anxiety/depression given by a patient at baseline and 12 and 24 months after baseline.
- Summed rating of EQ-5D-5L, defined as  $x$  = sum of the 5-dimensional ratings as defined above.
- Quality adjusted life years (QALYs), derived from the cTTO (time-trade-off value for Chinese) of the EQ-5D-5L ratings using published formula. <sup>[1]</sup>

### **4.5 Related symptoms and conditions**

- Hypertension-related symptoms, defined as any of the following symptoms: dizziness, headache/head fullness, transient visual obscuration, floaters in the eye, tinnitus/ear buzzing, chest pain, chest tightness, palpitations, limb numbness, lower limb swelling.
- Occurrence of hypertension-related symptom, defined as  $x=1$  if the patient reported any of the hypertension-related symptoms as defined above, or  $x=0$  if not.
- Number of hypertension-related symptoms, defined as  $x$ =summed count of all the self-reported hypertension-related symptoms as defined above for a patient under concern.
- Mean number of hypertension-related symptoms, defined as  $x = \text{total number of all the self-reported hypertension-related symptoms as defined above among all patients} / (\text{total number of participant patients studied})$ .
- Hypertension complications, defined as any of the following categories of diagnoses given by doctors: cardiac complications (angina pectoris, myocardial infarction, coronary heart disease, heart failure, ventricular hypertrophy, heart disease, myocarditis, tachycardia, bradycardia, and cardiac arrest); cerebral complications (cerebral ischemia, cerebral haemorrhage, cerebral infarction, acute cerebrovascular disease, and brain atrophy); and renal complications (impaired renal function, nephrotic syndrome, renal colic, pyelonephritis, renal failure, chronic glomerulonephritis, hydronephrosis, renal cyst, and renal calculi).

- Mean number of hypertension complications, defined as  $x = \text{total number of all the hypertension complications as defined above among all patients} / (\text{total number of participant patients studied})$ .
- Occurrence of hypertension complications, defined as  $x=1$  if the patient reported any of the above hypertension complications diagnosed by doctors, or  $x=0$  if none of the complications.
- Number of hypertension complications, defined as  $x = \text{summed count of all the hypertension complications as defined above for a patient under concern}$ .
- Hypertension commodity, defined as  $x=1$  if the patient reported that he/she had been diagnosed with diabetes and/or hyperlipidemia by doctors, or 0 if not).

#### **4.6 Use of professional care**

- Outpatient visit, defined as  $x=1$  if the patient under concern reported visit to any outpatient clinic in the past month before the survey because of hypertension or hypertension-related health problems, or  $x=0$  if not.
- Times of outpatient visits, defined as  $x = \text{count of all the outpatient visits as defined above by the patient under concern}$ .
- Hospitalization or hospital admission, defined as  $x=1$  if the patient under concern reported any episode of inpatient care or hospital admission in the past year before the survey because of hypertension or hypertension-related health problems, or  $x=0$  if not.
- Length of stay, defined as  $x = \text{number of days of an inpatient care episode}$ .

- Length of stay per participant for hypertension or hypertension-related health problems, defined as  $x = \text{summed number of days of hospitalization due to hypertension or hypertension-related health problems among all participants in a given time period} / \text{number of participants under concern}$ .
- Length of stay per participant for all causes, defined as  $x = \text{summed number of days of hospitalization due to all causes among all participants in a given time period} / \text{number of participants under concern}$ .
- Length of stay per episode for hypertension or hypertension-related health problems, defined as  $x = \text{summed number of days of hospitalization due to hypertension or hypertension-related health problems among the participants under concern in a given time period} / \text{total number of hospitalization episodes among the same participants}$ .
- Length of stay per episode for all causes, defined as  $x = \text{summed number of days of hospitalization due to all causes among the participants under concern in a given time period} / \text{total number of hospitalization episodes among the same participants}$ .
- Group of length of stay, defined as categories of the value of length of stay divided into quartile or percentile groups.

#### **4.7 Objective behavior scores**

- The objective behaviors in this trial included: attending and responding to project messages/contacts; performing self-monitoring and reporting; modifying unhealthy diet habits or practices; maintaining physical exercise/activities; containing tobacco

and alcohol consumption; addressing emotion and sleep problems; using clinical checkups and treatment; and facilitating family engagement.

- We will compile a specific score for each of the objective behaviors mentioned above except the first one (attending and responding to project messages/contacts) since it was applicable only to the intervention arm.
- Detailed items of the questions consisting the instrument for measuring each of the objective behaviors, value assignment for the responses to each of the question items and algorithms for calculating the behavior scores are given in Appendix 1 to this statistical analysis plan.

## **5. Analysis principles**

The analyses described in this document focus on the pre-specified primary and secondary evaluation measures, with the trial analysis approaches based on an intention-to-treat (ITT) principle and complete case analysis. ITT is defined as analyzing clusters and participants according to their randomized groups, regardless of adherence to the allocated group. Complete data for all participants will be used, based on the imputation model outlined in section 3.3. Complete case analysis refers to the analysis of data from participants who were not lost to follow-up.

The study findings will be reported in line with the Consolidated Standards of Reporting Trials (CONSORT) extension on cluster randomized trials <sup>[2]</sup>.

## **6. Analysis details**

### **6.1 Patient recruitment and attrition**

The CONSORT diagram will be presented for all patients and by randomization group (or communities). The diagram will include:

- The number of communities recruited and randomized;
- The number (%) of patients recruited on schedule;
- The number (%) of patients who had completed the baseline survey;
- The number (%) of patients who had completed the 12-month follow-up survey;
- The number (%) of patients who had completed the 24-month follow-up survey;
- The main reasons for attrition.

## **6.2 Deviations and adverse events**

Full details of protocol deviations will be listed. This includes any unanticipated or unintentional divergence or departure from the protocol, consent documents or other study procedures.

All adverse events reported by participating clinicians and solicited via face-to-face interviews by trained field researchers will be tabulated by allocated group and analysed descriptively. The following medical occurrences will be considered as adverse events:

- Hypertension-related symptoms as defined earlier in section 4;
- Hypertension-related complications as defined earlier in section 4;
- Hospital admissions of all causes and deaths of hypertension-related complications.
- Deaths of all causes and deaths of hypertension-related complications.

### **6.3 Description of participants**

Patients approached and recruited will be tabulated by socio-demographics and other commonly studied co-variables in rows (including age, sex, education, years since hypertension diagnosis, marriage status, and body mass index) and by randomized group.

Continuous data will be summarized in terms of the mean, standard deviation, and number of observations or, where skewed, median and lower & upper quartiles or IQR. Binary and categorical data will be summarized in terms of frequency counts and percentages. Differences in the above statistics between groups will be tested using chi-squared tests, T-tests, or non-parametric tests (or exact tests if appropriate).

### **6.4 Analysis of BP values and control rates**

A generalized linear mixed model (GLMM) will be fitted to address the first study question of PHM, considering SBP, DBP and control rates as response variables. The model will include baseline values, age, sex, marital status, education level, time since diagnosis, and years of taking anti-hypertensive drugs as fixed effects, with practice included as a random effect. Identity or log link functions will be used for the SBP and DBP GLMM models depending on the distribution of the response variable, and results will be reported as mean differences with 95% confidence intervals. Logit link function will be used for the GLMM model of BP control rate, and results will be reported as odds ratios (OR) with 95% confidence intervals. As a sensitive analysis, the above analysis will be repeated in ITT population and complete cases.



We will examine the impact of key subgroups (categorized by median, mean, or percentile as appropriate) that could plausibly modify intervention effectiveness, including age, sex, marital status, education level, baseline SBP, baseline DBP, baseline use of anti-hypertensive drugs, baseline complications, and baseline comorbidities. For this exploratory analysis, estimates of the interaction between subgroups and intervention will be provided with 95% confidence intervals, along with estimates of the intervention effect when specific subgroups are selected.

## **6.5 Analysis of health impacts**

The health impact analysis includes the following in the past year: deaths, hospital admissions, length of hospital stay and quality adjusted life years (QALYs).

The GLMM model will also be used to analyze the effect sizes of the above impacts between the two groups at 12-month and 24-month follow-up. The models will control for clustering (practice) as a random effect and factors such as baseline values, age, sex, marital status, education level, time since diagnosis, and years of taking anti-hypertensive drugs as fixed effects. For binary response variables, a logit link will be used, and model results will be presented as numbers (percentages) and adjusted odds ratios (ORs) with 95% confidence intervals (CIs). For continuous variables, an identity or log link will be used depending on the distribution of the variable, and model results will be presented as means (standard deviations) or medians (interquartile ranges) and adjusted mean differences with 95% CIs.

For the analysis of health impacts, we will not consider the ITT strategy because the death status and admission of all surveyed patients is available.

## 6.6 Analysis of objective behaviors

For the analysis of scores of the 7 objective behaviors, we will first examine the patterns of each of the measures and check for normality of the continuous variables. Necessary transformations will be explored and selected, if necessary, to induce approximate normality. Regarding the numerical variables between two groups, t-test of independent samples for mean comparisons will be carried out. We will also perform GLMM and multivariate linear regression analysis for these measures. Multivariate linear regression analysis will be used to explore the determinants of each behavior and GLMM with a Gaussian link, to analyse the score of each objective behavior among the two arms and at different evaluation time-points. These models will control for clustering and the factors as listed above.

## References

- [1] Nancy Devlin, Bram Roudijk, Kristina Ludwig. Value Sets for EQ-5D-5L: A Compendium, Comparative Review & User Guide. 23 March 2022. <https://doi.org/10.1007/978-3-030-89289-0>.
- [2] Butcher NJ, Monsour A, Mew EJ, Chan AW, Moher D, Mayo-Wilson E, Terwee C B, Chee-A-Tow A, Baba A, Gavin F, Grimshaw JM, Kelly LE, Saeed L, Thabane L, Askie L, Smith M, Farid-Kapadia M, Williamson PR, Szatmari P, Tugwell P, Golub RM, Monga S, Vohra S, Marlin S, Ungar WJ, Offringa M. Guidelines for Reporting Outcomes in Trial Reports: The CONSORT-Outcomes 2022 Extension. JAMA, 2022. 328(22):2252-2264.

## **Appendix 1**

### **Scoring of objective behaviors: items, value assignment and formulae**

#### **Overview**

The intervention package of PHM aimed to promote eight objective behaviors including: attending and responding to project materials/communications; performing self-monitoring and reporting; modifying unhealthy diet practices; maintaining adequate physical activities; containing tobacco and alcohol consumption; addressing emotion and sleep problems; using clinical checkups and treatment; and facilitating family engagement. We will compile a specific score for each of these objective behaviors except the first one (attending and responding to project materials/communications) since it was applicable only to the intervention arm.

This supplementary file specifies detailed items of the questions consisting the instrument measuring each of the objective behaviors, value assignment for the responses to each of the question items and algorithms for calculating the behavior scores. All the scores are designed as: 0 (the worst practice of the behavior under concern) to 10 (the best practice of the behavior under concern). The scoring will use data from three sources including:

- DS1 = self-reported data in face-to-face interview using structured questionnaire.
- DS2 = automatically recorded data from self-monitoring at home using project-provided electronic device.
- DS3 = measured data by trained field data collectors during face-to-face interview.

## Part A: Performing self-monitoring and report

### Score formula:

$$S_a = 10 * (O_{a1} + O_{a2} + O_{a3} + O_{a4} + O_{a5} + O_{a6} + O_{a7} + O_{a8} + O_{a9} + O_{a10} + O_{a11} + O_{a12} + O_{a13} + O_{a14}) / 19$$

### Score items and values:

O<sub>a1</sub> How many times had the patient measured his/her blood pressure in the past month? (DS1)

- ☐ 0 time (O<sub>a1</sub>=0)
- ☐ 1-2 time (O<sub>a1</sub>=1)
- ☐ 3-4 times (O<sub>a1</sub>=2)
- ☐ 5-6 times (O<sub>a1</sub>=3)
- ☐ 7 or more times (O<sub>a1</sub>=4)

O<sub>a2</sub> How many times had the patient measured his/her blood pressure at home in the past month? (DS2)

- ☐ 0 time (O<sub>a2</sub>=0)
- ☐ 1-4 time (O<sub>a2</sub>=1)
- ☐ 5-9 times (O<sub>a2</sub>=2)
- ☐ 10-15 times (O<sub>a2</sub>=3)
- ☐ 15-20 or more times (O<sub>a2</sub>=4)

Had the patient measured his/her blood pressure in the following time of a day in the past month? (DS2)

O<sub>a3</sub> From 4 am to 10 am?

- ☐ No (O<sub>a3</sub>=0)
- ☐ Yes (O<sub>a3</sub>=1)

O<sub>a4</sub> From 10 am to 4 pm

- ☐ No (O<sub>a4</sub>=0)
- ☐ Yes (O<sub>a4</sub>=1)

O<sub>a5</sub> From 4 pm to 10 pm

- ☐ No (O<sub>a5</sub>=0)
- ☐ Yes (O<sub>a5</sub>=1)

O<sub>a6</sub> From 10 pm to 4 am

- ☐ No (O<sub>a6</sub>=0)
- ☐ Yes (O<sub>a6</sub>=1)

What did the patient usually do in measuring his/her blood pressure at home in the past month? (DS1)

O<sub>a7</sub> Refrain from smoking cigarettes and drinking alcohol, coffee, tea etc. for at least 30 minutes before measurement?

- ☐ No (O<sub>a7</sub>=0)
- ☐ Yes (O<sub>a7</sub>=1)

O<sub>a8</sub> Seat quietly and rest for at least 5 minutes before measurement?

- ☐ No (O<sub>a8</sub>=0)
- ☐ Yes (O<sub>a8</sub>=1)

O<sub>a9</sub> Relax the whole body and seat strait right and flat-footed while performing the measurement?

- ☐ No (O<sub>a9</sub>=0)
- ☐ Yes (O<sub>a9</sub>=1)

O<sub>a10</sub> Align the center of the cuff of the blood pressure device with the nipple level and the lower edge of the cuff two-finger-wide above the elbow joint?

☐ No (O<sub>a10</sub>=0)

☐ Yes (O<sub>a10</sub>=1)

O<sub>a11</sub> Tie the cuff of the blood pressure measure device around the arm at right tightness (allowing two fingers to be inserted into the cuff without difficulty)?

☐ No (O<sub>a11</sub>=0)

☐ Yes (O<sub>a11</sub>=1)

O<sub>a12</sub> Had the patient measured his/her body weight in the past six months?

☐ No (O<sub>a12</sub>=0)

☐ Yes (O<sub>a12</sub>=1)

O<sub>a13</sub> Had the patient measured his/her heart-beat increase after “6-minute-fixed-distance-walking”?

☐ No (O<sub>a13</sub>=0)

☐ Yes (O<sub>a13</sub>=1)

## **Part B: Modifying unhealthy diet practices**

### **Score formula:**

$$S_b = 10 * (O_{b1} + O_{b2} + O_{b3} + O_{b4} + O_{b5} + O_{b6} + O_{b7} + O_{b8} + O_{b9} + O_{b10} + O_{b11}) / 11$$

### **Score items and values:**

Had the patient practiced the following intentionally in order to control his/her blood pressure in the past month? (DS1)

O<sub>b1</sub> Eat “light diet”?

☐ No (O<sub>b1</sub>=0)

☐ Yes (O<sub>b1</sub>=1)

O<sub>b2</sub> Contain salt intake under 6 grams a day?

☐ No (O<sub>b2</sub>=0)

☐ Yes (O<sub>b2</sub>=1)

O<sub>b3</sub> Contain intake of fat-meat?

☐ No (O<sub>b3</sub>=0)

☐ Yes (O<sub>b3</sub>=1)

O<sub>b4</sub> Contain intake of “main-food (made of rice, wheat etc.)”?

☐ No (O<sub>b4</sub>=0)

☐ Yes (O<sub>b4</sub>=1)

O<sub>b5</sub> Eat eighty percent full or less each time?

☐ No (O<sub>b5</sub>=0)

☐ Yes (O<sub>b5</sub>=1)

O<sub>b6</sub> Increase intake of vegetables?

☐ No (O<sub>b6</sub>=0)

☐ Yes (O<sub>b6</sub>=1)

O<sub>b7</sub> Eat 3 or more types of vegetables a week?

☐ No (O<sub>b7</sub>=0)

☐ Yes (O<sub>b7</sub>=1)

O<sub>b8</sub> Increase intake of fruits?

☐ No (O<sub>b8</sub>=0)

☐ Yes (O<sub>b8</sub>=1)

O<sub>b9</sub> Eat 2 or more types of fruits a week?

- ☐ No ( $O_{b9}=0$ )  
☐ Yes ( $O_{b9}=1$ )  
 $O_{b10}$  Increase intake of coarse cereals?  
☐ No ( $O_{b10}=0$ )  
☐ Yes ( $O_{b10}=1$ )  
 $O_{b11}$  Eat 2 or more types of coarse cereals a week?  
☐ No ( $O_{b11}=0$ )  
☐ Yes ( $O_{b11}=1$ )

### Part C: Maintaining adequate physical activities

#### Score formula:

$$S_c = 10 * (O_{c1} + O_{c2} + O_{c3} + O_{c4} + O_{c5} + O_{c6} + O_{c7} + O_{c8} + O_{c9} + O_{c10} + O_{c11} + O_{c12} + O_{c13} + O_{c14}) / 30$$

#### Score items and values:

- $O_{c1}$  Had the patient practiced physical exercises in the past month? (DS1)  
☐ No ( $O_{c1}=0$ )  
☐ Yes ( $O_{c1}=1$ )  
 $O_{c2}$  How many days a week did the patient practice physical exercises in the past month? (DS1)  
☐ 0 day ( $O_{c2}=0$ )  
☐ 1-2 days ( $O_{c2}=1$ )  
☐ 3-4 days ( $O_{c2}=2$ )  
☐ 5-6 days ( $O_{c2}=3$ )  
☐ 7 days ( $O_{c2}=4$ )  
 $O_{c3}$  How many minutes a time did the patient practice physical exercises in the past month? (DS1)  
☐ 20 or less minutes ( $O_{c3}=0$ )  
☐ 21-30 minutes ( $O_{c3}=1$ )  
☐ 31-40 minutes ( $O_{c3}=2$ )  
☐ 41-50 minutes ( $O_{c3}=3$ )  
☐ 51 or more minutes ( $O_{c3}=4$ )  
 $O_{c4}$  Had the patient cancelled physical exercises because of weather in the past month? (DS1)  
☐ No ( $O_{c4}=0$ )  
☐ Yes ( $O_{c4}=1$ )  
 $O_{c5}$  Had the patient chosen walking intentionally instead of using automatic vehicles in the past month? (DS1)  
☐ No ( $O_{c5}=0$ )  
☐ Yes ( $O_{c5}=1$ )  
 $O_{c6}$  How many hours a day on average was the patient in sedentary state in the past days? (DS1)  
☐ 12 hours or more ( $O_{c6}=0$ )  
☐ 8-12 hours ( $O_{c6}=1$ )  
☐ 5-8 hours ( $O_{c6}=2$ )  
☐ 3-5 hours ( $O_{c6}=3$ )  
☐ less than 3 hours ( $O_{c6}=4$ )  
 $O_{c7}$  Had the patient exercised his/her joints in the past month? (DS1)  
☐ No ( $O_{c1}=0$ )

- ☐ Yes ( $O_{c1}=1$ )
- Had the patient exercised his/her following joints in the past month? (DS1)
- $O_{c8}$  Cervical joint?
- ☐ No ( $O_{c8}=0$ )
- ☐ Yes ( $O_{c8}=1$ )
- $O_{c9}$  Shoulder joint?
- ☐ No ( $O_{c9}=0$ )
- ☐ Yes ( $O_{c9}=1$ )
- $O_{c10}$  arm joint?
- ☐ No ( $O_{c10}=0$ )
- ☐ Yes ( $O_{c10}=1$ )
- $O_{c11}$  hip joint?
- ☐ No ( $O_{c11}=0$ )
- ☐ Yes ( $O_{c11}=1$ )
- $O_{c12}$  leg joint?
- ☐ No ( $O_{c12}=0$ )
- ☐ Yes ( $O_{c12}=1$ )
- $O_{c13}$  How many days a week had the patient exercised his/her joints in the past month? (DS1)
- ☐ 0 day ( $O_{c13}=0$ )
- ☐ 1-2 days ( $O_{c13}=1$ )
- ☐ 3-4 days ( $O_{c13}=2$ )
- ☐ 5-6 days ( $O_{c13}=3$ )
- ☐ 7 days ( $O_{c13}=4$ )
- $O_{c14}$  Compared with sweeping floor, which of the following best describes intensity of the patient's daily physical activities in the past month? (DS1)
- ☐ much lighter ( $O_{c14}=0$ )
- ☐ moderately lighter ( $O_{c14}=1$ )
- ☐ similar ( $O_{c14}=2$ )
- ☐ moderately heavier ( $O_{c14}=3$ )
- ☐ much heavier ( $O_{c14}=4$ )

#### **Part D: Containing tobacco/alcohol consumption**

##### **Score formula:**

$$S_d = 10 * (O_{d1} + O_{d2} + O_{d3} + O_{d4} + O_{d5} + O_{d6} + O_{d7} + O_{d8}) / 19$$

##### **Score items and values:**

- $O_{d1}$  Had the patient drunk any kind of alcohol in the past month? (DS1)
- ☐ No ( $O_{d1}=1$ ,  $O_{d2}=3$ ,  $O_{d3}=1$ ,  $O_{d4}=4$ , and skip to  $O_{d5}$ )
- ☐ Yes ( $O_{d1}=0$ )
- $O_{d2}$  How many times a week had the patient drunk alcohol in the past month? (DS1)
- ☐ 1-3 times ( $O_{d2}=3$ )
- ☐ 4-7 times ( $O_{d2}=2$ )
- ☐ 8-14 times ( $O_{d2}=1$ )
- ☐ 15 or more times ( $O_{d2}=0$ )
- $O_{d3}$  Had the patient practiced containment of alcohol-drinking in the past month? (DS1)
- ☐ No ( $O_{d3}=0$ )
- ☐ Yes ( $O_{d3}=1$ )

O<sub>d4</sub> Compared with earlier months, had the patient reduced alcohol-drinking in the past month? (DS1)

- ☐ reduced substantially (O<sub>d4</sub>=4)
- ☐ reduced moderately (O<sub>d4</sub>=3)
- ☐ remained similar (O<sub>d4</sub>=2)
- ☐ increased moderately (O<sub>d4</sub>=1)
- ☐ increased substantially (O<sub>d4</sub>=0)

O<sub>d5</sub> Had the patient smoked any kind of cigarette in the past month? (DS1)

- ☐ No (O<sub>d5</sub>=1, O<sub>d6</sub>=4, O<sub>d7</sub>=1, O<sub>d8</sub>=4, and end this part of value assignment)
- ☐ Yes (O<sub>d5</sub>=0)

O<sub>d6</sub> How many cigarettes a day had the patient smoked in the past month? (DS1)

- ☐ 1-5 cigarettes (O<sub>d6</sub>=4)
- ☐ 6-10 cigarettes (O<sub>d6</sub>=3)
- ☐ 11-15 cigarettes (O<sub>d6</sub>=2)
- ☐ 16-20 cigarettes (O<sub>d6</sub>=1)
- ☐ 21 or more cigarettes (O<sub>d6</sub>=0)

O<sub>d7</sub> Had the patient practiced containment of cigarette-smoking in the past month? (DS1)

- ☐ No (O<sub>d7</sub>=0)
- ☐ Yes (O<sub>d7</sub>=1)

O<sub>d8</sub> Compared with earlier months, had the patient reduced cigarette-smoking in the past month? (DS1)

- ☐ reduced substantially (O<sub>d8</sub>=4)
- ☐ reduced moderately (O<sub>d8</sub>=3)
- ☐ remained similar (O<sub>d8</sub>=2)
- ☐ increased moderately (O<sub>d8</sub>=1)
- ☐ increased substantially (O<sub>d8</sub>=0)

## **Part E: Addressing emotion and sleep problems**

### **Score formula:**

$S_e = 10 * (O_{e1} + O_{e2} + O_{e3} + O_{e4} + O_{e5} + O_{e6} + O_{e7} + O_{e8} + O_{e9} + O_{e10} + O_{e11} + O_{e12} + O_{e13} + O_{e14} + O_{e15} + O_{e16}) / 20;$

### **Score items and values:**

O<sub>e1</sub> Had the patient experienced sleep problems in the past month? (DS1)

- ☐ No (O<sub>e1</sub>=1, O<sub>e2</sub>=1, O<sub>e3</sub>=1, O<sub>e4</sub>=1, O<sub>e5</sub>=1, O<sub>e6</sub>=1, O<sub>e7</sub>=1, and skip to O<sub>e8</sub>)
- ☐ Yes (O<sub>e1</sub>=0)

O<sub>e2</sub> Had the patient done anything coping with his/her sleep problems in the past month? (DS1)

- ☐ No (O<sub>e2</sub>=0, O<sub>e3</sub>=0, O<sub>e4</sub>=0, O<sub>e4</sub>=0, O<sub>e5</sub>=0, O<sub>e6</sub>=0, O<sub>e7</sub>=0, and skip to O<sub>e8</sub>)
- ☐ Yes (O<sub>e2</sub>=1)

Which of the following had the patient tried in coping with sleep problems in the past month? (DS1)

O<sub>e3</sub> adjusted sleep environment, e.g., added/changed pillows, bed-room lights etc.?

- ☐ No (O<sub>e3</sub>=0)
- ☐ Yes (O<sub>e3</sub>=1)

O<sub>e4</sub> sought professional care/treatment?

- ☐ No (O<sub>e4</sub>=0)



- ☐ Yes ( $O_{e4}=1$ )
- $O_{e5}$  used hypnotic music?
- ☐ No ( $O_{e5}=0$ )
- ☐ Yes ( $O_{e5}=1$ )
- $O_{e6}$  practiced relax exercises, e.g., mindfulness training?
- ☐ No ( $O_{e6}=0$ )
- ☐ Yes ( $O_{e6}=1$ )
- $O_{e7}$  practiced others?
- ☐ No ( $O_{e4}=0$ )
- ☐ Yes ( $O_{e4}=1$ )
- $O_{e8}$  Compared with earlier months, how were the patient's sleep quality in the past month? (DS1)
- ☐ improved substantially ( $O_{d8}=3$ )
- ☐ improved moderately ( $O_{d8}=2$ )
- ☐ remained similar ( $O_{d8}=1$ )
- ☐ changed for worse ( $O_{d8}=0$ )
- $O_{e9}$  Had the patient experienced emotion problems in the past month? (DS1)
- ☐ No ( $O_{e9}=1$ ,  $O_{e10}=1$ ,  $O_{e11}=1$ ,  $O_{e12}=1$ ,  $O_{e13}=1$ ,  $O_{e14}=1$ ,  $O_{e15}=1$ , and skip to  $O_{e16}$ )
- ☐ Yes ( $O_{e9}=0$ )
- $O_{e10}$  Had the patient done anything coping with his/her emotion problems in the past month? (DS1)
- ☐ No ( $O_{e10}=0$ ,  $O_{e11}=0$ ,  $O_{e12}=0$ ,  $O_{e13}=0$ ,  $O_{e14}=0$ ,  $O_{e15}=0$ , and skip to  $O_{e16}$ )
- ☐ Yes ( $O_{e10}=1$ )
- Which of the following had the patient tried in coping with emotion problems in the past month? (DS1)
- $O_{e11}$  practiced attention distraction, e.g., via outdoor walking etc.?
- ☐ No ( $O_{e11}=0$ )
- ☐ Yes ( $O_{e11}=1$ )
- $O_{e12}$  sought professional care/treatment?
- ☐ No ( $O_{e12}=0$ )
- ☐ Yes ( $O_{e12}=1$ )
- $O_{e13}$  practiced feeling sharing?
- ☐ No ( $O_{e13}=0$ )
- ☐ Yes ( $O_{e13}=1$ )
- $O_{e14}$  practiced feeling venting?
- ☐ No ( $O_{e14}=0$ )
- ☐ Yes ( $O_{e14}=1$ )
- $O_{e15}$  practiced others?
- ☐ No ( $O_{e15}=0$ )
- ☐ Yes ( $O_{e15}=1$ )
- $O_{e16}$  Compared with earlier months, how were the patient's emotion status in the past month? (DS1)
- ☐ improved substantially ( $O_{e16}=3$ )
- ☐ improved moderately ( $O_{e16}=2$ )
- ☐ remained similar ( $O_{e16}=1$ )
- ☐ changed for worse ( $O_{e16}=0$ )

## Part F: Using clinical checkups and treatment

### Score formula:

$$Sf = 10 * (O_{f1} + O_{f2} + O_{f3} + O_{f4} + O_{f5} + O_{f6} + O_{f7} + O_{f8} + O_{f9} + O_{f10} + O_{f11} + O_{f11} + O_{f13} + O_{f14} + O_{f15}) / 18$$

### Score items and values:

O<sub>f1</sub> How many times had the patient consulted doctors for antihypertensive treatment in the past year? (DS1)

- ☐ 7 or more times (O<sub>f1</sub>=4)
- ☐ 5-6 times (O<sub>f1</sub>=3)
- ☐ 3-4 times (O<sub>f1</sub>=2)
- ☐ 1-2 times (O<sub>f1</sub>=1)
- ☐ 0 time (O<sub>f1</sub>=0)

O<sub>f2</sub> Had the patient encountered Grade 3 pressure (systolic pressure >180 mmHg and/or diastolic pressure > 110 mmHg in repeated measurement) in the past year? (DS1)

- ☐ No (O<sub>f2</sub>=1, O<sub>f3</sub>=1, and skip to O<sub>f4</sub>)
- ☐ Yes (O<sub>f2</sub>=0)

O<sub>f3</sub> Had the patient sought professional help for the Grade 3 measurement? (DS1)

- ☐ No (O<sub>f3</sub>=0)
- ☐ Yes (O<sub>f3</sub>=1)

O<sub>f4</sub> Had the patient experienced over-target blood pressure for a week (over half of the self-monitored blood pressure in the week was >140/90 mmHg) in the past year? (DS1)

- ☐ No (O<sub>f4</sub>=1, O<sub>f3</sub>=1, and skip to O<sub>f6</sub>)
- ☐ Yes (O<sub>f4</sub>=0)

O<sub>f5</sub> Had the patient sought professional help for the over-target blood pressure? (DS1)

- ☐ No (O<sub>f5</sub>=0)
- ☐ Yes (O<sub>f5</sub>=1)

O<sub>f6</sub> Had the patient noticed hypertension-related symptoms (e.g., precordial pain, faintness) in the past year? (DS1)

- ☐ No (O<sub>f6</sub>=1, O<sub>f7</sub>=1, and skip to O<sub>f8</sub>)
- ☐ Yes (O<sub>f6</sub>=0)

O<sub>f7</sub> Had the patient sought professional help for the hypertension-related symptoms? (DS1)

- ☐ No (O<sub>f7</sub>=0)
- ☐ Yes (O<sub>f7</sub>=1)

O<sub>f8</sub> Had the patient tested his/her blood sugar in the past year? (DS1)

- ☐ No (O<sub>f8</sub>=0)
- ☐ Yes (O<sub>f8</sub>=1)

O<sub>f9</sub> Had the patient tested his/her blood lipid in the past year? (DS1)

- ☐ No (O<sub>f9</sub>=0)
- ☐ Yes (O<sub>f9</sub>=1)

O<sub>f10</sub> Had the patient omitted/delayed taking antihypertensives because of “too busy” in the past year? (DS1)

- ☐ No (O<sub>f10</sub>=1)
- ☐ Yes (O<sub>f10</sub>=0)

O<sub>f11</sub> Had the patient omitted/delayed taking antihypertensives because of “out from home” in the past year? (DS1)

- ☐ No (O<sub>f11</sub>=1)
- ☐ Yes (O<sub>f11</sub>=0)

O<sub>f12</sub> Had the patient omitted/delayed taking antihypertensives because of “warries about side-effects” in the past year? (DS1)

☐ No (O<sub>f12</sub>=1)

☐ Yes (O<sub>f12</sub>=0)

O<sub>f13</sub> Had the patient omitted/delayed taking antihypertensives because of “purchase delays” in the past year? (DS1)

☐ No (O<sub>f13</sub>=1)

☐ Yes (O<sub>f13</sub>=0)

O<sub>f14</sub> Had the patient omitted/delayed taking antihypertensives because of “unpleasant things or feelings” in the past year? (DS1)

☐ No (O<sub>f14</sub>=1)

☐ Yes (O<sub>f14</sub>=0)

O<sub>f15</sub> Had the patient changed antihypertensive regimen without consulting a doctor in the past year? (DS1)

☐ No (O<sub>f15</sub>=1)

☐ Yes (O<sub>f15</sub>=0)

## **Part G: Facilitating family support and engagement**

### **Score formula:**

$$S_g = 10 * (O_{g1} + O_{g2} + O_{g3} + O_{g4} + O_{g5} + O_{g6} + O_{g7} + O_{g8} + O_{g9} + O_{g10}) / 10$$

### **Score items and values:**

O<sub>g1</sub> Had the patient discussed his/her blood pressure measurement with family member(s) and/or relatives in the past month? (DS1)

☐ No (O<sub>g1</sub>=0)

☐ Yes (O<sub>g1</sub>=1)

O<sub>g2</sub> Had the patient shared experience of consultation with doctor(s) for hypertension-related problems with his/her family member(s) and/or relatives in the past year? (DS1)

☐ No (O<sub>g2</sub>=0)

☐ Yes (O<sub>g2</sub>=1)

O<sub>g3</sub> Had the patient experienced support from his/her family member(s) and/or relatives performing blood pressure measurement at home in the past year? (DS1)

☐ No (O<sub>g3</sub>=0)

☐ Yes (O<sub>g3</sub>=1)

O<sub>g4</sub> Had the patient experienced support from his/her family member(s) and/or relatives using antihypertensive drugs in the past year? (DS1)

☐ No (O<sub>g4</sub>=0)

☐ Yes (O<sub>g4</sub>=1)

O<sub>g5</sub> Had the patient experienced support from his/her family member(s) and/or relatives controlling salt intake in the past year? (DS1)

☐ No (O<sub>g5</sub>=0)

☐ Yes (O<sub>g5</sub>=1)

O<sub>g6</sub> Had the patient experienced support from his/her family member(s) and/or relatives practicing healthy diet in the past year? (DS1)

☐ No (O<sub>g6</sub>=0)

☐ Yes (O<sub>g6</sub>=1)

O<sub>g7</sub> Had the patient experienced support from his/her family member(s) and/or relatives practicing physical exercises in the past year? (DS1)

☐ No (O<sub>g7</sub>=0)

☐ Yes (O<sub>g7</sub>=1)

O<sub>g8</sub> Had the patient experienced support from his/her family member(s) and/or relatives containing smoking and alcohol-drinking in the past year? (DS1)

☐ No (O<sub>g8</sub>=0)

☐ Yes (O<sub>g8</sub>=1)

O<sub>g9</sub> Had the patient experienced support from his/her family member(s) and/or relatives coping sleep/emotion problems in the past year? (DS1)

☐ No (O<sub>g9</sub>=0)

☐ Yes (O<sub>g9</sub>=1)

O<sub>g10</sub> Had the patient experienced support from his/her family member(s) and/or relatives seeking professional help for hypertension and related conditions in the past year? (DS1)

☐ No (O<sub>g10</sub>=0)

☐ Yes (O<sub>g10</sub>=1)