Study Protocol and Statistical Analysis Plan (version 1.0, 18 November 2025)

1. Title of the Study

The Workplace-Based, Multicomponent Hypertension Management Program in Patients Aged 18-60 Years: A Randomized Controlled Trial

2. Study Identifier

- Organization's Unique Protocol ID: 82404393

3. Background and Rationale

Hypertension remains a major preventable contributor to global cardiovascular morbidity and mortality. Workplace populations represent a critical setting for early intervention among middle-aged adults. Behavioral economics—particularly *nudge theory*—offers promising strategies to address behavioral determinants of hypertension management through subtle modifications of choice architecture. However, limited randomized controlled trial evidence exists within workplace settings.

The Kailuan Cohort, a well-established occupational population in Tangshan, Hebei, provides an ideal platform to test a nudge-based workplace health management model among individuals newly diagnosed with hypertension. This intervention was referred to as the workplace-based multicomponent hypertension management program.

4. Study Objectives

Primary Objective

To evaluate the effectiveness of a workplace-based multicomponent hypertension

management program on blood pressure control at 12 months among newly diagnosed hypertensive adults.

Secondary Objectives

(1) To evaluate improvements in hypertension-related health behaviors (diet, physical activity, medication adherence).

(2) To assess changes in body mass index (BMI) and other cardiometabolic indicators.

(3) To examine quality of life and work productivity outcomes.

5. Study Design

This is a randomized, parallel-group, open-label controlled trial embedded in the Kailuan Cohort. A total of 512 participants (256 per arm) will be enrolled and randomly assigned 1:1.

Study Flow

- Screening and enrollment
- Baseline assessment
- Randomization
- Intervention period: 12 months

Allocation

Participants will be randomly assigned using computer-generated block randomization stratified by sex and age group.

6. Study Setting

Kailuan Group workplace facilities and community health centers (Tangshan, Hebei, China).

7. Study Population

Inclusion Criteria

- Age 18–60 years.
- Newly diagnosed hypertension (per 2024 Chinese hypertension guidelines).
- Employed at Kailuan Group.
- Willing to participate and sign informed consent.

Exclusion Criteria

- Severe cardiovascular or renal disease.
- Psychiatric illness affecting compliance.
- Pregnant or lactating women.
- Participation in other intervention trials.

8. Interventions

Experimental Group: Workplace-based Multicomponent Hypertension Management Program

Includes:

- Default scheduling of blood pressure monitoring and counseling sessions.
- Personalized reminders via workplace digital systems.
- Social comparison feedback using anonymized peer data.

- Small incentives and commitment devices.

Control Group: Standard Workplace Health Management

- Routine health education.
- Standard hypertension counseling.
- Usual workplace health services.

9. Outcome Measures

Primary Outcome

- Change in systolic and diastolic blood pressure from baseline to 12 months.

Secondary Outcomes

- Changes in health behaviors.
- Change in BMI.
- Medication adherence.
- European Quality of Life-5 Dimensions' scores.

10. Sample Size Calculation

Sample size assumes:

- Expected between-group difference in systolic blood pressure (SBP) reduction: 4 mmHg.
- Standard deviation (SD) = 12 mmHg.

- Alpha = 0.05, power = 0.80.
- Allowing 15% attrition. Total sample required: 512 participants (256 per arm).

11. Statistical Analysis Plan

General Principles

- All analyses will follow the intention-to-treat (ITT) principle.
- A secondary per-protocol analysis will be conducted.
- Two-sided tests with $\alpha = 0.05$.

Baseline Analysis

Baseline characteristics will be compared using:

- Mean ± SD or median (interquartile range) for continuous variables.
- Counts and percentages for categorical variables.
- No formal statistical testing will be used for baseline differences.

Primary Outcome Analysis

A mixed-effects linear regression model will be used:

- Dependent variable: SBP/diastolic blood pressure (DBP) change from baseline.
- Fixed effects: intervention group, time, sex, age, baseline blood pressure.
- Random intercepts for participants.

Effect estimates will be reported as mean difference with 95% CI.

Secondary Outcomes Analysis

- Behavior outcomes: logistic or linear regression depending on scale.
- BMI: linear regression or mixed-effects model.
- Quality of life: ANCOVA adjusting for baseline values.
- Cost-effectiveness: the incremental cost-effectiveness ratio between the intervention group and control group during the study period.

Missing Data Management

- Multiple imputation under missing-at-random (MAR) assumption.
- Sensitivity analyses using complete-case analysis.

Subgroup Analyses (Exploratory)

- Sex (male/female)
- Age category (18–44, 45–60)
- Baseline SBP level

Interim Analysis

No interim analyses are planned.

12. Ethical Considerations

The study will comply with:

- Declaration of Helsinki

- Good Clinical Practice (GCP) standards Ethical approval will be obtained from Hebei Medical University Institutional Review Board.

13. Data Management and Monitoring

- Data will be entered into a password-protected electronic data capture system.
- Range and logic checks will be programmed.
- Independent data monitoring committee (DMC) will oversee safety.

14. Dissemination Plan

Findings will be published in peer-reviewed journals and presented at scientific conferences. De-identified individual participant data will be available upon reasonable request following main publication.

15. Timeline

- Start date: January 2026 (planned)
- Primary completion: January 2027
- Study completion: January 2028