**Remote Blood Pressure Management Clinical Application Research**

**A 24-month multicenter randomized controlled trial**

# Informed Consent

Affiliated Cardiovascular Hospital of Qingdao University

Qingdao, Shandong, China

May 1, 2020

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Subject name: Age: Gender: Male/Female

Dear patient:

You are invited to participate in the "Remote Blood Pressure Management Clinical Application Research" organized by the Affiliated Cardiovascular Hospital of Qingdao University .Please read the following information carefully, and then decide whether to participate in this project. If you have any questions, please consult the researchers.

**Introduction of the research**

1. A total of 1050 hypertensive patients participated in this project. The project cycle is 24 months .You need to go to the hospital on the 3, 6, 9, 12, 15, 18, 21, and 24 months to participate in follow-up. All enrolled patients will be randomly divided into three groups of remote, non-remote and routine blood pressure management.
The remote and non-remote groups will receive an electronic blood pressure monitor at the beginning of the study, and the remote function will be activated at the remote group, the non-remote group will not activate the remote function, and the routine group will follow the routine treatment.

2. The blood pressure data of patients in the remote group will be uploaded through the remote data transmission function of the blood pressure monitor .The data analysis platform performs analysis and manages blood pressure through smart management methods such as mobile APP .The blood pressure of the non-remote group and the routine group was managed by conventional routine methods. Finally, the blood pressure management effect is compared and evaluated at the remote group, non-remote group and routine group.

**Purpose of the research**

Evaluate the clinical effects of remote blood pressure management based on "Doctors-Cloud Sharing Smart Cabinet" and the feasibility of popularizing remote blood pressure management through the "medical doctor-cloud sharing smart cabinet". By building more effective blood pressure management model, it provides better blood pressure management services for hypertensive patients.

**Possible risks**

1. The remote electronic sphygmomanometers used in this research are all approved by relevant national departments. Using qualified products will not cause any substantial personal injury caused by the experimental equipment.

2. If the events of substantial personal injury related to the research happen, we will provide corresponding compensation according the relevant provisions of national laws and regulations.

**Probable benefits of research**

Every patient participating in the research of this subject will receive a doctor’s systematic hypertension diagnosis and treatment. Both the remote blood pressure

management group and the non-remote blood pressure management group will get a value of 799Yuan’s remote electronic sphygmomanometer being used for three years for free. Routine management group will receive routine diagnosis and treatment at office.

**Voluntary participation and withdraw**

At any stage of the research, you can propose to withdraw from this research project. After you withdraw, your other conventional treatments will not be affected in any way.

**Confidentiality**

The results and data obtained in this research are owned by the project implementers and medical institutions and are used freely, but your legal rights will not be violated .We will use your personal data and not disclose its content. The research results will be published for scientific purposes under the premise of disclosing your personal information.

This informed consent form is in duplicate, one for the doctor and one for the subject.

**Signing of informed consent**

**Researcher's statement:**

I have asked subjects and/or his/her family or authorized representative to introduce purpose, methods, procedures, risks and benefits of the research and answer all the questions .During the research process, if the risks and benefits change and may affect the subject's decision whether to continue participating in the study, I will notify the subject and/or his/her family member or authorized representative.

**Subject statement:**

I have fully understood the purpose, methods, procedures and styles of the research that may bring me risks and benefits. I know that my participation in this research is voluntary and can withdraw at any time without affecting my current and future treatments .My personal information is confidential. I will try my best to cooperate with the medical treatment .I voluntarily sign an informed consent form.

Subject's signature:
Date of signature:
Home address:
Contact number:

Signature of family member or authorized representative:
Date of signature:
Home address:
Contact number:

Witness Signature:
Date of Signature: