Remote Blood Pressure Management Clinical Application Research
A 24-month multicenter randomized controlled trial

study protocol

Affiliated Cardiovascular Hospital of Qingdao University

Qingdao, Shandong, China

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Research on Clinical Application of Remote Blood Pressure Management study protocol

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Technology Field: Population and Health

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1. Main research content

①Project research objective

Remote blood pressure management for patients with hypertension,

②Project research content and task breakdown

Recruit of essential hypertension patients who are randomly divided into three groups. One group uses the remote blood pressure management platform to realize automatic upload of patient measurement data, intelligent analysis, and early warning reminders; one group distributes electronic sphygmomanometers, and patients record blood pressure by themselves; one group performs routine community hypertension management. For 24 months follow-up, observe the patient's blood pressure level, blood pressure compliance rate, risk assessment, etc.

③The main technical difficulties and problems to be solved

A large-scale popularization of the remote blood pressure management mode based on the "cloud sharing smart cabinet".

④Innovation point

Provide a smart, simple and efficient innovative tool for chronic disease management of residents for primary hospitals, and promote the improvement of chronic disease management in my country .Use smart terminal equipment to realize automatic data collection and transmission to ensure that patient blood pressure data timely and continuously .Provide data reference and basis for academic research and chronic disease prevention and control, and promote the transformation of scientific research results of chronic disease prevention and treatment in my country.

2. Project acceptance content and assessment indicators

①Main technical indicators

Subject papers and reports: Four English papers, Four Chinese papers, Four international conference reports, and Six domestic conference reports

②Talent team construction

The project is committed to building an intelligent hypertension comprehensive detection and management network system from department-in-hospital-superior hospitals to promote the integration and shared utilization of resources in medical

institutions. Improve the scientific research ability and level of primary medical staff by participating in research projects. Cultivate a group of backbone forces for the prevention and treatment of hypertension and related diseases for the grassroots.

③**Social and economic benefits**

Through the continuous collection of blood pressure data and cloud storage of wearable devices, the patient-related monitoring data is transformed from single-point data to time-based data. Analyze and observe the law of data fluctuations, combine the analysis of related data trends in the cloud and a large number of related characteristics, evaluate the risk of illness, and provide suggestions for changing the corresponding living habits. It is expected that the blood pressure compliance rate of patients with hypertension and chronic diseases will be increased by about 15%.The risk score of patients will be reduced, and medical expenses will be saved. Through the "Cloud Sharing Smart Cabinet", the electronic sphygmomanometers that have been certified for clinical accuracy will be better popularized, and patients with hypertension will be more aware of importance of family blood pressure monitoring. The remote blood pressure management of the "Cloud Sharing Smart Cabinet" has the feasibility of large-scale promotion, which is transformed into products for promotion through scientific research projects.

④**Other evaluation indicators**

Compile the researcher's manual and CRF tables; customize the cloud sharing smart cabinet; determine the subject center unit, project training, complete the baseline survey; follow-up and intervene patients as planned; mid-term summary of the subject; monitoring at any time; conclusion and recall CRF tables, complete statistical analysis, write final report; write academic papers and conference reports

3. Project mid-term evaluation indicators

①**Main technical indicators**

Subject papers and reports: one English paper, two Chinese papers, and one international conference report, two domestic conference report:

②**Application demonstration indicators**

The number of using cloud sharing smart cabinets accounts for about 50% of the total number. The number of blood pressure patients enrolled in the remote group, non-remote group and routine group is no less than 1050; All the patients have completed the cardiovascular risk assessment, completed the baseline survey and are enrolled in the group for treatment .The blood pressure compliance rate of patients at the remote group with hypertension and chronic diseases will be increased by about 15% compared with the routine group.

4. Project annual plan and assessment indicators

2020

2020.06-2020.08

Compile researcher's manual and complete the printing of 1050 CRF tables; customize the cloud sharing smart cabinet (maximum matching according to the funding situation).

2020.09-2020.12

Determine the subject center unit, project training, implement the cloud sharing smart cabinet and other equipment to be put in place, enroll patients and complete baseline survey, conduct risk assessment.

2021

2021.01-2020.03

At least 1050 patients in the remote group, non-remote group, and routine group were enrolled in the group.

2021.04-2021.12

Follow up and intervene patients as planned. Blood pressure measurement in the office will be performed every 3 months, and CRF tables will be entered in time. It is expected to be carried out around mid-term summary of the subject at December 2020.

2022

2022.01-2022.12

Follow-up and intervene patients as planned, perform office blood pressure measurement every 3 months, and CRF tables will be entered in time.

2023

2023.01-2023.03

Follow up and intervene patients as planned, and measure blood pressure in the office every 3 months, and CRF tables will be entered in time. By the end of March 2023, all patients will complete follow-up and risk assessment will be performed again.

2023.04-2023.06

Finish the project, collect the CRF tables, complete the statistical analysis, write the final report, write the academic paper and conference report.