四川大学华西医院生物医学伦理委员会
Biomedical Research Ethics Committee，West China Hospital of Sichuan University
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基于信息化的等级-社区医院高血压一体化管理模式临床研究知情同意书

Consent Form

方案名称(Research name)：

An Internet-based patient–primary care physician–cardiologist integrated management model of hypertension in China

尊敬的高血压患者

Dear hypertensive patient:

我们邀请您参加四川大学华西医院批准开展的“基于信息化的高血压管理模式及防治策略”项目。本项目将在南充市中心医院、甘孜州人民医院等医院共同开展，估计将有 1000 多名受试者自愿参加。

We invite you to participate in a clinical study "An Internet-based patient – primary care physician – cardiologist integrated management model of hypertension in China" approved by the Biomedical Research Ethics Committee, West China Hospital of Sichuan University. The study will also be carried out in Nanchong Central Hospital, People's Hospital of Ganzi Tibetan Autonomous Prefecture, and so on. It is estimated that more than 1000 subjects will participate voluntarily.

1.研究目的

我国高血压控制率较低，仅 16.8%，尤其是农村、西部和少数民族地区。这与初级保健机构医生的医疗技能和患者之间的信任度有关。然而，基层医疗卫生机构是防治高血压的主战场。如何最有效地整合三级医院的患者、基层医生、心脏病专家，构建高血压防治的长效机制，值得探讨。本研究旨在评估在中国四川不同社会经济水平地区进行的高血压患者-初级保健医生-心脏病专家（PPC）综合管理模式的临床效果，并进行健康经济评价。

1. Research purpose：The control rate of hypertension is low in China (16.8%), especially in rural, western, and minority areas. This is related to poor medical skills among physicians in primary care institutions and low levels of trust among patients. However, primary health care institutions are the main battleground for the prevention and treatment of hypertension. It is worth exploring how to most effectively integrate patients, primary care physicians, and cardiologists in tertiary hospitals, to build a long-term mechanism for the prevention and treatment of hypertension. In this study, we aim to evaluate the clinical effectiveness and conduct a health economic evaluation of an Internet-based patient–primary care physician– cardiologist (PPC) integrated management model of hypertension in areas of China with different socioeconomic levels.

2.研究过程

（1）参与本项目的患者，您可能会被随机分为常规管理组和干预组，常规管理组于社区进行日常高血压随访，干预组患者将扫描二维码进入管理程序，由社区医师和等级医院医师进行专门管理，并通过该管理程序上传家庭血压数据，与社区医师交流病情等。

（2）本项目将持续开展 12 个月，根据血压达标情况，每月或者每三个月于社区医院随访。我们将收集您的病史信息，您需要提供血标本和尿标本进行免费的实验室检查，如血常规、尿常规、血糖、肝酶、肌酐，以及血脂水平，包括甘油三酯、总胆固醇、低密度脂蛋白胆固醇，以及高密度脂蛋白胆固醇在基线、6 个月和 12 个月时的变化。在基线、1 个月和 12 个月时进行动态血压监测。您需要配合初级保健医生和心脏病专家进行血压测量、治疗和随访。

2. Research process: If you agree to participate in this study,

(1) You will be randomly divided into a traditional care group or an intervention group. The traditional care group will receive routine hypertension follow-ups in the community. The intervention group will be managed by the primary care physicians and cardiologists through the Red Shine Chronic Disease Management System (RSCDMS). You can upload your home blood pressure values and communicate with physicians using the system.

(2) The study will last for 12 months, and follow-ups will be conducted in the community hospital every month or every three months according to the blood pressure. we will collect your medical

information, and you need to provide blood and urine samples for free laboratory tests such as blood routine, urine routine, blood glucose, liver enzymes, creatinine, and the serum levels of lipids including triglycerides, total cholesterol, low-density lipoprotein cholesterol, and high-density lipoprotein cholesterol at baseline, 6-month, and 12-month. Free ambulatory blood pressure monitoring will be conducted at baseline, 1-month, and 12-month. You need to cooperate with the primary care physicians and cardiologists for blood pressure measurement, treatment, and follow-ups.

3. 可供选择的诊疗方案

本项目不涉及提供药物干预，将结合患者病情和目前指南给予治疗建议。

3.Treatment options: This study does not involve drug intervention. Treatment recommendations will be given in combination with the patient's condition and current Chinese guidelines.

4. 哪些人不宜参加项目

如果您患有继发性高血压，在过去 6 个月内因急性心肌梗死住院，心力衰竭，严重的肝肾疾病，计划在 6 个月内接受手术，有恶性肿瘤病史，认知功能障碍或不能自理，正参与其他临床试验，则不宜参加本项目。

4. Who is not suitable to participate in the program: If you have secondary hypertension, hospitalized for acute myocardial infarction within the past 6 months, heart failure, severe hepatic or renal disease, planned to undergo surgery within 6 months, history of malignant tumors, cognitive dysfunction or unable to take care of self, or you are participating in other clinical trials, you are not suitable to participate in this program.

5. 参加项目有哪些风险

参加本项目将根据患者病情，为患者提供高血压治疗方案，助力患者血压达标。但不排除部分患者为难治性高血压或合并其他疾病致血压控制欠佳。因此，本项目不能保证患者参与后均能将血压控制达标。若研究期间，患者出现与研究相关的损害（包括因诊疗方案引起的不良反应等），社区医师将会和等级医院医师及时采取措施，为患者提供新的诊治方案。因本

研究主要目的为为患者提供基于互联网的远程管理，不涉及药物及器械研究，因此出现治疗相关不良反应，可能为药物副作用，我们将及时采取措施，但不包含经济补偿。另，因近期新型冠状病毒肺炎影响，患者往返医院时应注意防护，注意安全，我们也会采用互联网手段，减少患者往返医院次数。

5. Risks: Participating in this study will provide you with hypertension treatment plan, and help you control hypertension. However, it is not ruled out that some patients with refractory hypertension or combined with other diseases lead to poor blood pressure control. Therefore, this study will not guarantee that your blood pressure will reach the standard after participating in the program. If there is any research-related damage (including adverse reactions caused by the treatment plan) during the study period, the primary care physicians and cardiologists will take timely measures to provide a new treatment plan for you. The main purpose of this study is to provide telemedicine for patients, and does not involve drug and device research. Thus, when treatment-related adverse reactions occur, it may be drug side-effects. We will take measures in time, but do not include economic compensation. In addition, due to the COVID-19, patients should pay attention to protection when you going to and from the hospital. We will also use the Internet means to reduce the times of patients going to and from the hospital.

6. 参加本项目有哪些可能的好处

参加本项目，您的血压可能得到控制，从而降低高血压引起的远期心脑血管疾病风险。

6.Benefits: By participating in this study, your blood pressure may be controlled, thus reducing the long-term risk of cardiovascular and cerebrovascular diseases caused by hypertension.

7. 参加项目需要支付有关费用吗

参加本项目，研究相关血生化、血常规、尿常规、动态血压监测检测为免费项目，经费来源为四川省科技厅重点研发项目。其他高血压相关靶器官损伤检查结果患者可自行提供，供医生判断病情。

7.About fees: Participating in this study, you will receive free ambulatory blood pressure

monitoring, blood routine, urine routine, blood glucose, liver enzymes, creatinine, and the serum levels of lipids including triglycerides, total cholesterol, low-density lipoprotein cholesterol, and high-density lipoprotein cholesterol at baseline and follow-ups. The fund is supported by Science and Technology Pillar Programs in Sichuan Province (Grant number 2017SZ0008). Other results of hypertension-related target organ damages can be provided by yourself for doctors to judge your condition.

8. 个人信息是保密的吗

您的项目资料将保存在社区卫生服务中心和四川大学华西医院，项目者、项目主管部门、伦理委员会可查阅您的医疗记录。任何有关本项项目结果的公开报告将不会披露您的个人身份。我们将在法律允许的范围内，尽一切努力保护您个人医疗资料的隐私和个人信息。

8.Privacy issue: Your information will be kept in the community health service center and West China Hospital of Sichuan University. The project manager, the project authority and the ethics committee can have access to your medical records. Any public report on the results of this study will not disclose your personal identity. We will make every effort to protect the privacy and your personal medical data to the extent permitted by law.

9. 我必须参加项目吗？

参加本项项目是完全自愿的，您可以拒绝参加项目，或在任何阶段随时退出本项目而不会受到歧视和报复，其医疗待遇与权益不受影响。如果您决定退出本项目，请与您的医生联系，以便妥善诊疗疾病。

9.Voluntariness: You may choose not to participate in this study, or at any time inform the researcher to request a withdrawal from the study. Your data will not be included in the study results, and any medical treatment and benefits will not be affected. If you decide to quit the program, please contact your doctor for proper diagnosis and treatment.

受试者声明：我已经阅读了上述有关本项目的介绍，我的项目人员已向我充分解释和说明了本项目的目的、操作过程以及参加本项目可能存在的风险和潜在的获益，并回答了我所有相关问题。自愿参加本项目。

Subject statement: I have read the above introduction of this study. My project personnel have fully explained the purpose, process, possible risks, and potential benefits of participating in the study, and answered all my relevant questions. I volunteer to participate in this study.

我同意□ 或拒绝□ 除本项目以外的其他项目利用我的项目资料和生物标本。

I agree □ or refuse □ to use my study data and biological specimens for other projects except for this study.

受试者正楷姓(Patient's name)：_____

受试者签名(Signature of patient)：_____

日期(Date)：__ __ __ __ 年(Year) __ __ 月(Month) __ __ 日(Day)

受试者的联系电话(Tel)：_____

法定代理人正楷姓名(legal representative's name)：_____

（如适用, If applicable）

与受试者关系(Relationship with subject)：_____

法 定 代 理 人 签 名 (Signature of legal representativ) ：

日期(Date)：__ __ __ __ 年(Year) __ __ 月(Month) __ __ 日(Day)

见证人正楷姓名(Witness's name)：_____ (如适用,If applicable）

见证人签名(Signature of witness)：_____

日期(Date)：__ __ __ __ 年(Year) __ __ 月(Month) __ __ 日(Day)

（注：如果受试者不识字时尚需见证人签名，如果受试者无行为能力时则需代理人签名）

(note: if the subject is illiterate, it requires the signature of the witness; if the subject is incompetent, the signature of the representative is required.)

医生声明：我已对上述参加本项目的自愿者说明了该项项目的有关细节，并且为他/她提供一份签署过的知情同意书的原件。我确认已向受试者详细解释了本项目的情况，特别是参

加本项目可能产生的风险与受益、免费与补偿、损害与赔偿、自愿与保密等伦理原则和要求。

Doctor's statement: I have explained the details of the study to the volunteers and provided him/her with an original signed informed consent form. I confirm that I have explained the situation of this study to the subjects in detail, especially the ethical principles and requirements such as risks and benefits, free of charge and compensation, damage and compensation, voluntariness, and confidentiality.

医生签名(Signature of doctor)：_____

日期(Date)：__ __ __ __ 年(Year) __ __ 月(Month) __ __ 日(Day)

联系电话(Tel)：_____

伦理批准机构：四川大学华西医院生物医学伦理委员会

Ethical approval authority: Biomedical Research Ethics Committee of the West China Hospital of Sichuan University

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