

Trial Description

Title

IT-supported case management to optimize hypertension therapy: a delegation project for trained practice assistants in primary care practices

Trial Acronym

PIA

URL of the trial

[---]*

Brief Summary in Lay Language

Blood pressure therapy is important for patients with elevated blood pressure to prevent myocardial infarction, stroke, or other diseases. Yet, 30 to 45% of patients with hypertension treated in German primary care practices do not reach target blood pressure levels $\leq 140/90$ mmHg. This project aims to overcome this deficit by introducing a physician-guided delegation concept: primary care physicians and practice assistants will be trained to implement an electronic blood pressure management. Patients will be trained on how to obtain valid blood pressure self-readings and transmit their blood pressure electronically to the practice. Based on a physician-defined individualized practice pathway for hypertension treatment the trained practice assistants (so called 'PIA') will suggest medication changes, which will be supervised by the physician. The adjusted and physician-signed medication plan is then sent back to the patient electronically.

Brief Summary in Scientific Language

Longitudinal blood pressure treatment is important for patients with hypertension to prevent cardiovascular events. Yet, 30 to 45% of patients with hypertension treated in German primary care practices do not reach target blood pressure levels $\leq 140/90$ mmHg. This project aims to overcome this deficit by introducing a physician-guided delegation concept: primary care physicians and practice assistants will be trained to realize an IT-supported hypertension management. Patients will be trained on how to obtain valid blood pressure self-readings and transmit their blood pressure electronically to the practice. Based on a physician-defined individualized practice pathway for hypertension treatment the specially trained practice assistants (so called 'PIA') will suggest medication changes, which will be supervised by the physician. The adjusted and physician-signed medication plan is then sent back to the patient.

Organizational Data

- DRKS-ID: **DRKS00012680**
- Date of Registration in DRKS: **2019/05/10**
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Date of Registration in DRKS: **2019/05/10**

Date of Registration in Partner Registry or other Primary Registry: [---]*

- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **156/18 , Ethik-Kommission der Medizinischen Fakultät der Rheinischen Friedrich-Wilhelms-Universität Bonn**

Secondary IDs

Health condition or Problem studied

- ICD10: **I10 - Essential (primary) hypertension**

Interventions/Observational Groups

- Arm 1: **Intervention arm: primary care practices that implement the delegation concept with IT-supported cases management**
- Arm 2: **Control arm: primary care practices without intervention**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: [---]*
- Allocation: **Randomized controlled trial**
- Blinding: [---]*
- Who is blinded: [---]*
- Control: **Active control (effective treatment of control group)**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Change of the blood pressure control rate defined as the amount of patients with office blood pressure <140/90 mmHg (mean value of the 2nd and 3rd blood pressure measurement of three successive office blood pressure readings in a seated position)

Secondary Outcome

Change of systolic and diastolic blood pressure, time needed to reach target blood pressure level, change in antihypertensive drug treatment, cardiovascular events or death from any cause, hospital admissions; satisfaction of patients, practice assistants and physicians

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Doctor's Practice **Nordrhein-Westfalen**

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2019/07/01**
- Target Sample Size: **1020**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **40 Years**
- Maximum Age: **79 Years**

Additional Inclusion Criteria

Insured in statutory health insurance; arterial hypertension (ICD: I10); insufficient blood pressure control after history of at least 6 month non-pharmaceutical therapy with the necessity to prescribe ≥ 1 antihypertensive agent; office blood pressure $\geq 140/90$ mmHg (mean value of the 2nd and 3rd blood pressure measurement of three successive office blood pressure readings in a seated position); sufficient language skills to understand the study documents; internet-enabled terminal or mobile device; sufficient computer competency.

Exclusion criteria

White coat hypertension; critical condition at study inclusion (i.e., hypertensive crisis, blood pressure-related symptoms like dizziness or headache); dialysis for renal failure; pregnancy.

Addresses

■ Primary Sponsor

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Sources of Monetary or Material Support

- **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

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URL: **https://innovationsfonds.g-ba.de/**

Status

- Recruitment Status: **Recruiting planned**
- Study Closing (LPLV): [---]*

Trial Publications, Results and other documents

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Deutsches Register
Klinischer Studien

German Clinical
Trials Register

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**** This entry means that data is not displayed due to insufficient data privacy clearing.*