

PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

Hypertension Management in Primary Care: "Getting research into practice"

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

Blood pressure control is important to decrease morbidity and mortality, e.g. due to myocardial infarction and stroke. Scientific studies showed that organizational interventions such as patient recall systems and the combination of non-pharmacological treatment with intensified medication increased blood pressure control and decreased mortality. This cluster randomized trial evaluates the effectiveness of a medical education series for primary care physicians about a modern hypertension management on blood pressure control in patients with high blood pressure.

Brief Summary in Scientific Language

Evaluation of the effectiveness of a physician-centered medical education program about hypertension management on blood pressure control of hypertensive patients in primary care.

Do you plan to share individual participant data with other researchers?

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00006315**
- Date of Registration in DRKS: **2014/07/14**
- Date of Registration in Partner Registry or other Primary Registry: [---]*

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- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **13-5537-BO , Ethik-Kommission der Medizinischen Fakultät der Universität Duisburg-Essen**

Secondary IDs

Health condition or Problem studied

- ICD10: **I10-I15 - Hypertensive diseases**

Interventions/Observational Groups

- Arm 1: **Intervention: Evidence-based three-part medical education program for general practitioners on hypertension management; core elements: 1) training on valid upper arm blood pressure readings, 2) evidence-based information on resistant hypertension, secondary hypertension, and modern pharmacotherapy, and 3) introduction and distribution of practice tools to facilitate the long-term implementation of hypertension management.**
- Arm 2: **Control: Physicians receive the intervention after completion of the follow-up data collection.**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: [---]*
- Allocation: **Randomized controlled trial**
- Blinding: [---]*
- Who is blinded: **patient/subject**
- Control: **Active control**
- Purpose: **Health care system**
- Assignment: **Parallel**
- Phase: **N/A**
-

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Assignment: **Parallel**

Phase: **N/A**

Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Blood pressure control rate measured by 24-hour blood pressure readings (blood pressure is measured before the intervention and three months after the last medical education session)

Secondary Outcome

Changes in average systolic and diastolic 24-hour blood pressure; implemented practice redesign elements such as patient recall systems, standardized sheets, disease-specific information leaflets, predefined practice procedures for hypertension management.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Doctor's Practice **NRW**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2013/09/26**
- Target Sample Size: **100**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

Hypertension according to international guidelines (office readings $\geq 140/90$ mmHg, 24-hour ambulatory measurement $\geq 130/80$ mmHg, and/or mean home measurements $\geq 135/85$ mmHg based on a one week protocol with at least 2 measurements daily), with and without hypertension-related diseases

Exclusion criteria

Unable to give informed consent, not able to read and comprehend the German language

Addresses

■ Primary Sponsor

**Institut für Allgemeinmedizin, Universitätsklinikum Essen, Universität
Duisburg-Essen
Mr. Prof. Dr. med. Stefan Gesenhues
Hufelandstraße 55
45147 Essen
Germany**

Telephone: **0201-877 869-0**

Fax: **0201-877-869-20**

E-mail: [---]*

URL: [---]*

■ Contact for Scientific Queries

**Institut für Allgemeinmedizin, Universitätsklinikum Essen, Universität
Duisburg-Essen
Ms. Priv.-Doz. Dr. med. Birgitta Weltermann, MPH(USA)
Hufelandstraße 55
45147 Essen
Germany**

Telephone: **0201-877 869-0**

Fax: **0201-877-869-20**

E-mail: **Birgitta.Weltermann at uk-essen.de**

URL: **www.uk-essen.de**

■ Contact for Public Queries

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Institut für Allgemeinmedizin, Universitätsklinikum Essen
Ms. Priv.-Doz. Dr. med. Birgitta Weltermann, MPH(USA)
Hufelandstraße 55
45147 Essen
Germany

Telephone: **0201-877-86910**

Fax: [---]*

E-mail: **birgitta.weltermann at uk-essen.de**

URL: **www.uniklinikum-essen.de**

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.)**

**Ministerium für Innovation, Wissenschaft und Forschung des Landes
Nordrhein-Westfalen**
40221 Düsseldorf
Germany

Telephone: [---]*

Fax: [---]*

E-mail: [---]*

URL: [---]*

Status

- Recruitment Status: **Recruiting complete, follow-up continuing**
- Study Closing (LPLV): [---]*

Trial Publications, Results and other documents

* This entry means the parameter is not applicable or has not been set.

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