

# Improvement of primary health care for patients with diabetes

<b>Submission date</b> 10/03/2011	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 17/06/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 15/05/2023	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

The aim of this study is to improve primary healthcare for patients with poorly regulated type 2 diabetes mellitus by improving communication between the patient and the general practitioner (GP). We want to enable participating GPs to identify the needs of patients suffering from poorly regulated type 2 diabetes mellitus, and to foster shared decision-making.

### Who can participate?

We will recruit about 60 GPs in three study centres (Rostock, Düsseldorf and Witten-Herdecke), who will each include about 13 randomly chosen type 2 diabetes mellitus patients (780 in total).

### What does the study involve?

Participating GPs will be randomly allocated into either the intervention or the control group. Patient data, such as HbA1c level and prescribed drugs, will be collected at five different points in time during the study period of 36 months. Patients whose GPs are assigned into the control group will be treated as usual. The GPs assigned to the intervention group will have a conversation with a GP peer, which aims at increasing their motivation to improve poorly regulated blood sugar levels of patients suffering from type 2 diabetes. They will also be trained and equipped with a computer-based communication tool called arriba, which is especially adapted to patients suffering from diabetes. The effect of the intervention will be measured by the changes in the patient's blood sugar level, by their level of participation in the process of shared decision-making, and their quality of life.

### What are the possible benefits and risks of participating?

Patients may benefit from improved management of their type 2 diabetes. There are no risks of participating.

### Where is the study run from?

We will recruit about 60 GPs in three study centres (Rostock, Düsseldorf and Witten-Herdecke). The study is run from the University of Rostock (Germany).

### When is the study starting and how long is it expected to run for?

The study started in March 2011 and will run until August 2015.

Who is funding the study?  
German Federal Ministry of Education and Research (BMBF) (Germany).

Who is the main contact?  
Prof Attila Altiner  
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## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Attila Altiner

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## Additional identifiers

**Protocol serial number**  
01GX1041

## Study information

**Scientific Title**  
Improvement of primary health care of patients with poorly regulated diabetes mellitus type 2 using shared decision-making

**Acronym**  
DEBATE

**Study objectives**  
Changing the communication behaviour of general practitioners to foster shared decision-making (with their patients) utilising developed top decision-aid-diabetes (decision-aid arriba-diabetes) improves health outcomes of patients with poorly regulated diabetes cared for in primary health. HbA1c serves as primary outcome measure.

On 19/05/2014 the overall trial end date was changed from 28/02/2014 to 31/08/2015.

On 30/06/2015 the target number of participants was changed from '60 GPs each with 13 patients; a total of 780 patients' to '108 GPs, each recruiting a consecutive sample of up to 13 patients (on average 7.8 patients per practice), a total of 843 patients'.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Ethics Committee of the Medical Faculty, University of Rostock, 25/05/2011

### **Study design**

Cluster-randomised controlled trial with educative intervention

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Diabetes mellitus type 2

### **Interventions**

1. Cluster-randomised multi-centre controlled trial with an educative intervention (peer-visit and decision-aid arriba-diabetes)
2. Clusters are composed by GPs and patients
3. The GPs in the intervention group will receive an educational peer-visit
4. The peer himself will be a specially trained GP
5. The control group will receive care as usual
6. The study will be performed under real practice conditions

### **Intervention Type**

Behavioural

### **Primary outcome(s)**

Current primary outcome as of 10/01/2012

1. Change of HbA1c at 6, 12, 18, 24 months compared to HbA1c at baseline
2. HbA1c will be measured as routine examination, as the case may be within the scope of the German Disease Management Program performed at GP's medical practice

Previous primary outcome

1. Change of HbA1c at 6, 12, 18, 24 months compared to HbA1c at baseline
2. HbA1c will be measured as routine examination within the scope of the German Disease Management Program performed at GP's medical practice

### **Key secondary outcome(s)**

Current secondary outcome as of 10/01/2012

1. Patient's evaluation of patient-centeredness and life quality (PACIC-D, PEF-FB-9, BÄK-

- questionnaire, EQ-5D, PAID)
2. Cardiovascular risk prognosis
  3. Pharmacotherapy

Previous secondary outcome

1. Patient's evaluation of patient-centeredness and life quality (PACIC-D, PEF-FB-9, SF-36)
2. Cardiovascular risk prognosis
3. Pharmacotherapy

### **Completion date**

31/08/2015

## **Eligibility**

### **Key inclusion criteria**

Current inclusion criteria as of 30/06/2015:

Patients:

1. Diabetes mellitus type 2
2. HbA1c level of 8.0 or above at the time of recruitment
3. Ability to informed consent
4. Fluency in the German language

GPs:

1. General practitioner or internist, working as GP or practitioner with KV admission (Association of Statutory Health Insurance Physicians)

Previous inclusion criteria from 10/01/2012 to 30/06/2015:

Patients:

1. Diabetes mellitus type 2
2. HbA1c level of 8.1 or above at the time of recruitment
3. Ability to informed consent
4. Fluency in the German language

GPs:

1. General practitioner or internist, working as GP or practitioner with KV admission (Association of Statutory Health Insurance Physicians)

Original inclusion criteria until 10/01/2012:

Patients:

1. Diabetes mellitus type 2
2. HbA1c level of 8.5 or above at the time of recruitment
3. Ability to informed consent
4. Fluency in the German language

GPs:

1. General practitioner or internist, working as GP or practitioner with KV admission (Association of Statutory Health Insurance Physicians)
2. Participation on the Disease Management Program diabetes mellitus type 2

### **Participant type(s)**

Mixed

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**Total final enrolment**

833

**Key exclusion criteria**

1. Severe comorbidity
2. Life expectancy of less than 18 months

**Date of first enrolment**

01/03/2011

**Date of final enrolment**

31/08/2015

**Locations****Countries of recruitment**

Germany

**Study participating centre****The Institute of General Practice**

University Medical Center Rostock

Doberaner Strasse 142

P.O. Box 108880

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18057

**Study participating centre****The Institute of General Practice**

Universitätsklinikum der Heinrich-Heine Universität Düsseldorf

Moorenstraße 5

Düsseldorf

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40225

**Study participating centre**  
**The Institute of General Practice and Family Practice**  
Fakultät für Gesundheit  
Universität Witten/Herdecke  
Alfred-Herrhausen-Straße 50  
Witten  
Germany  
58448

## Sponsor information

### Organisation

German Federal Ministry of Education and Research (BMBF) (Germany)

### ROR

<https://ror.org/04pz7b180>

## Funder(s)

### Funder type

Government

### Funder Name

Bundesministerium für Bildung und Forschung

### Alternative Name(s)

Federal Ministry of Research, Technology and Space, Bundesministerium für Bildung und Forschung, Federal Ministry of Education and Research, BMBF

### Funding Body Type

Government organisation

### Funding Body Subtype

National government

### Location

Germany

## Results and Publications

Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	25/06/2019	27/06/2019	Yes	No
<a href="#">Results article</a>		15/05/2021	17/05/2021	Yes	No
<a href="#">Results article</a>	Secondary analysis	13/05/2023	15/05/2023	Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes