# Improvement of primary health care for patients with diabetes

Submission date	Recruitment status  No longer recruiting	<ul><li>Prospectively registered</li></ul>		
10/03/2011		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
17/06/2011	Completed	[X] Results		
<b>Last Edited</b> 15/05/2023	Condition category Nutritional Metabolic Endocrine	[] 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 ifa.sekretariat@med.uni-rostock.de

# Contact information

## Type(s)

Scientific

#### Contact name

Prof Attila Altiner

#### Contact details

University of Rostock
Medizinische Fakultät
Institut für Allgemeinmedizin
POB 100888
Rostock
Germany
18055
+49 (0)38 1494 2481
ifa.sekretariat@med.uni-rostock.de

# 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 arribadiabetes) 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 examinaton, 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 Rostock Germany

18057

# Study participating centre

#### The Institute of General Practice

Universitätsklinikum der Heinrich-Heine Universität Düsseldorf Moorenstraße 5 Düsseldorf Germany 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 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?
Results article	results	25/06/2019	27/06/2019	Yes	No
Results article		15/05/2021	17/05/2021	Yes	No
Results article	Secondary analysis	13/05/2023	15/05/2023	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes