

# An informed shared decision making programme on the prevention of myocardial infarction for patients with type 2 diabetes in primary care.

<b>Submission date</b> 19/02/2015	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 05/03/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 06/11/2019	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

International and national societies claim a patient-centred approach in diabetes care, including the concept of shared decision making. A shared decision making programme has been developed for the prevention of heart attack. It is called an Informed Shared Decision Making programme (ISDM) and is aimed at supporting patients to make informed decisions on preventive options, to share the decision making process with the health care team and to improve adherence to the chosen treatment. The previous study showed that ISDM can improve patients' knowledge. However, it may not realign power-imbalance between patients and their health care team. Hence, the programme has been augmented by including an additional training module for physicians to facilitate the implementation of shared decision making. The aim of this study is to implement and evaluate this programme in primary care practices. We will investigate if patients allocated to ISDM are more likely to adhere to their chosen anti-hypertensive or statin therapy.

### Who can participate?

Primary care practices are eligible, if they employ at least one diabetes educator or a medical assistant or a nurse with further training in structured diabetes education and if they provide structured teaching and treatment within the Disease Management Programme.

Eligible patients are adults with type 2 diabetes, previous participation in structured treatment and teaching sessions as they are typically provided within the Disease Management Programme, and no previous diagnosis of heart attack.

### What does the study involve?

Two study groups (intervention and control) will be compared. Patients in the intervention group receive ISDM comprising a patient decision aid and a teaching session provided by medical assistants. Patients have a consultation with their general practitioner (sharing information, setting treatment goals and adapting treatment regimens if necessary). Patients in the control group receive standard care.

What are the possible benefits and risks of participating?

The involvement of patients in medical decision making by sharing evidence-based information and discussing benefits and harms of treatment options improves the quality of decision making. Patients set their own treatment goals and may better adhere to their decisions. There are no known risks associated with participating in the study.

Where is the study run from?

The study will take place in Germany, predominantly in the Free State of Thuringia and partly in Saxony-Anhalt and Hamburg. 24 primary care practices will be recruited.

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

From October 2010 to July 2017. Recruitment from December 2014 to July 2017.

Who is funding the study?

European Foundation for the Study of Diabetes on behalf of the European Association for the Study of Diabetes.

Who is the main contact?

Susanne Buhse

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#### **Study website**

<http://www.diabetes-und-herzinfarkt.de/>

## **Contact information**

#### **Type(s)**

Scientific

#### **Contact name**

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## **Additional identifiers**

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

## Study information

### Scientific Title

An Informed Shared Decision Making programme on the prevention of myocardial infarction for patients with type 2 diabetes in primary care: a cluster randomised, controlled trial.

### Acronym

ISDM

### Study objectives

The key hypothesis is that patients who actively participate in decision making show better adherence to their individual treatment goals. We primarily investigate if patients allocated to the ISDM group are more likely to adhere to their antihypertensive or statin medication. We also hypothesise that patients in the Informed Shared Decision Making (ISDM) group less frequently prioritise intensified glucose control and more frequently blood pressure control and statin treatment. Further objectives are to assess if the ISDM group achieves a better understanding and higher levels of realistic expectations regarding heart attack risk and probabilities of benefits and harms of preventive options.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Ethics committee of the Medical Council of the Free State of Thuringia. - Jena, 23/04/2014

### Study design

Parallel group patient- and assessor-blinded cluster randomised controlled trial with six months follow-up. Randomisation of the participating family practices will start not before assessment of the patients' baseline data has been completed.

### Primary study design

Interventional

### Secondary study design

Cluster randomised trial

### Study setting(s)

GP practice

### Study type(s)

Prevention

### Participant information sheet

Not available in web format and in German, please use the contact details below to request a patient information sheet.

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

Type 2 diabetes, prevention of myocardial infarction, patient education, shared decision making

## **Interventions**

Intervention group: ISDM programme comprising (1) an evidence-based patient decision aid on the prevention of myocardial infarction, (2) a structured teaching module provided by medical assistants, (3) a sheet to document the individual treatment goals, (4) a four hours provider training, and (5) an organisational study meeting with the personnel in the participating practice  
Control group: Standard care defined as usual care augmented by a brief extract of the patients' version of the German National Disease Management Guideline on the treatment of patients with type 2 diabetes with a link to the full version of the guideline.

## **Intervention Type**

Other

## **Primary outcome measure**

Primary outcome measure is defined as the adherence to blood pressure drug treatment or if not applicable the adherence to statin treatment. This primary outcome measure is operationalised as adherence to drug prescriptions at six months follow-up. Telephone interviews will be conducted to assess the adherence to the current drug prescriptions.

## **Secondary outcome measures**

1. Informed choice regarding statin treatment, blood pressure control, glucose control, and smoking cessation
2. The achievement of treatment goals regarding statin treatment, blood pressure, HbA1c, and smoking cessation
3. Prioritisation of treatment goals
4. Realistic expectations on the individual heart attack risk and on probabilities of benefits and harms of the available treatment options
5. The level of patient knowledge and understanding relating to the concept of risk, the notion of heart attack risk, and the benefits and harms of preventive treatment

## **Overall study start date**

01/10/2010

## **Completion date**

01/07/2016

## **Eligibility**

### **Key inclusion criteria**

Primary care practices are eligible if they meet the following criteria:

1. Employ at least one diabetes educator or a medical assistant or a nurse with further training in structured diabetes education
2. Provide structured teaching and treatment within the Disease Management Programme for patients with type 2 diabetes

Patients are eligible if they meet the following criteria:

1. Age between 40 and 69
2. Type 2 diabetes
3. HbA1c-value less than 9%
4. Previous participation in structured treatment and teaching sessions as they are typically provided within the Disease Management Programme

**Participant type(s)**

Mixed

**Age group**

Adult

**Sex**

Both

**Target number of participants**

306 participants will be recruited for randomisation, distributed across 24 clusters (practices) with a mean cluster size of 13 participants.

**Total final enrolment**

279

**Key exclusion criteria**

1. Previous diagnosis of ischaemic heart disease (ICD I20-I25),
2. Stroke (ICD I63)
3. Proliferative retinopathy
4. Chronic kidney disease stage 3 or higher
5. Metastatic cancer
6. Addicted to alcohol
7. Cared by a legal guardian

**Date of first enrolment**

16/12/2014

**Date of final enrolment**

15/07/2015

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

Germany

**Study participating centre**

**University of Hamburg, Unit of Health Sciences and Education**

University of Hamburg

Faculty of Mathematics, Informatics and Natural Sciences, Unit of Health Sciences and Education

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**Study participating centre**

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## **Sponsor information**

**Organisation**

European Foundation for the Study of Diabetes

**Sponsor details**

European Foundation for the Study of Diabetes

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**Sponsor type**

Research organisation

**Website**

<http://www.europeandiabetesfoundation.org/>

**ROR**

<https://ror.org/05tgz4m05>

## **Funder(s)**

**Funder type**

Research organisation

**Funder Name**

European Foundation for the Study of Diabetes

**Alternative Name(s)**

The European Association for the Study of Diabetes, EFSD

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Trusts, charities, foundations (both public and private)

**Location**

Germany

## Results and Publications

**Publication and dissemination plan**

We intend to publish all results after analysis of follow-up data. Anticipated date is July 2016.

**Intention to publish date**

31/12/2016

**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Available on request

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>	protocol	31/03/2015		Yes	No
<a href="#">Results article</a>	results	14/12/2018	06/11/2019	Yes	No