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

Submission date
19/02/2015

Recruitment status
No longer recruiting

Registration date
05/03/2015

Overall study status
Completed

Last Edited
06/11/2019

Condition category
Circulatory System

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 aimof this study is to implemented 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
Susanne.Buhse@uni-hamburg.de

Study website
http://www.diabetes-und-herzinfarkt.de/

Contact information

Type(s)
Scientific

Contact name
Dr Susanne Buhse

Contact details
University of Hamburg, Faculty of Mathematics, Informatics and Natural Sciences, Unit of Health Sciences and Education, Martin-Luther-King-Platz 6, 20146 Hamburg.
Hamburg
Germany
20146
+ 49 40 42838 3528
Susanne.Buhse@uni-hamburg.de

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 Menagement 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
Martin-Luther-King-Platz 6
Hamburg
Germany
20146

Study participating centre

University Hospital Jena
University Hospital Jena
Department of Internal Medicine III, Endocrinology and Metabolic Diseases
Bachstraße 18
Jena
Germany
07740

Sponsor information

Organisation
European Foundation for the Study of Diabetes

Sponsor details
European Foundation for the Study of Diabetes
Rheindorfer Weg 3
Düsseldorf
Germany
40591
+49 211 7584690
Foundation@easd.org

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?
Protocol article	protocol	31/03/2015		Yes	No
Results article	results	14/12/2018	06/11/2019	Yes	No