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Efficacy of an evidence-based Informed Shared Decision Making program for prevention of myocardial infarction in type 2 diabetes

Submission date
22/02/2013

Recruitment status
No longer recruiting

Registration date
12/04/2013

Overall study status
Completed

Last Edited
16/11/2015

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Cardiovascular disease is the predominant life threatening complication related to type 2 diabetes. An array of behavioural directives is imposed on persons with type 2 diabetes, such as quitting smoking, increasing exercise, normalizing weight, and adhering to monitoring, dietary and medication prescriptions. Evidence on effectiveness of these interventions is varying and some may even do more harm than good. Patients frequently feel demotivated and overloaded by the pure number of medical prescriptions. This might contribute to poor long-term adherence even to the most effective preventative interventions. The overall objective is to improve the quality of decision-making by enhancing patients' understanding and their ability to deliberate between the available preventative options, and by supporting them to participate in decision-making more actively. An informed shared decision making program was developed. The program consists of a decision aid booklet and a corresponding counselling module provided by diabetes educators. It comprises current easy to understand evidence-based information media. The specific aim of this study is to investigate the efficacy of this informed shared decision making program. We will evaluate, if patients who attend the program estimate their heart attack risk realistically, understand benefits and harms of the preventative options, and are more adherent to their decisions.

Who can participate?
A total of 154 men and women with type 2 diabetes will be recruited, aged between 40 and 69 years, with no previous heart attack or other cardiovascular disease.

What does the study involve?
Two study groups will be compared: The intervention group will receive the informed shared decision making program; the control group will receive placebo counselling, i.e. a program which is similar in structure and differs in the provided content. Both counselling programs take 90 minutes. Two weeks before the counselling the patients will be asked to read and work through information material.

What are the possible benefits and risks of participating?
Participants will receive information and a new kind of counselling, which may result in a higher motivation to deliberate pros and cons of the available preventative options and make informed decisions. This might also influence the communication between patients and care providers. There are no known risks associated with participating in the study. The information provided within the counselling intervention is consistent with current scientific evidence and has been developed by a team of researchers and diabetes experts. Trained diabetes educators provide the counselling. The counselling strategy reflects current educational practice.

Where is the study run from?
The study is a joined venture of the Unit of Health Science and Education at the University of Hamburg and the Jena University Medical Centre, in Germany. Study site is the Clinic for Endocrinology and Metabolic Diseases of the University Medical Centre Jena.

When is the study starting and how long is it expected to run for?
The study will start in March 2013 and will have a follow-up of six months. Recruitment of participants will need about three months.

Who is funding the study?
European Foundation for the Study of Diabetes

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title

Efficacy of an evidence-based Informed Shared Decision Making program for prevention of myocardial infarction in type 2 diabetes: a randomised controlled trial

Acronym
ISDM

Study objectives
We hypothesize that patients who attend the Informed Shared Decision Making (ISDM) program estimate their heart attack risk realistically, understand benefits and harms of the preventative options, and are more adherent to their decisions.

The registration was initiated on 22/02/2013 and finalised on 12/04/2013. Following the prospective submission on 22/02/2013, there were no subsequent changes to the protocol. The recruitment started on 12/03/2013, after initiation of public registration.

On 29/05/2015 the overall trial end date was changed from 12/12/2013 to 01/03/2015.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics committee of the Friedrich-Schiller-University, Jena, 27/09/2011

Primary study design
Interventional

Study design
Parallel group two-arm single-blinded randomized controlled superiority trial with 6 months of follow-up

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Evidence-based patient information on the prevention of heart attack in type 2 diabetes

Interventions
Two study groups will be compared:

Intervention group: ISDM program consisting of a decision aid booklet and a curriculum for group counseling.

Control group: Placebo counseling, i.e. a program similar in structure and different in the provided content.

Each counselling program consists of one session taking 90 minutes. Two weeks before the counselling the patients will be asked to read and work through information material.

Follow up: 6 months

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
The patients' comprehension of heart attack prevention that includes the understanding of the concept of risk, the notion of heart attack risk, and the benefits and harms of preventative measures.

Key secondary outcome(s)
1. Adherence to the individual treatment goals regarding statin treatment, blood-pressure treatment, glucose control, and smoking cessation
2. Adherence to the preventative option prioritized by the individual patient

Completion date
01/03/2015

Eligibility

Key inclusion criteria
1. Patients (men and women) are eligible with type 2 diabetes
2. Aged between 45 and 69 years
3. With no previous diagnosis of ischemic heart disease (ICD I20-I25)
4. With former participation in Decision Making (DMP) education programs for type 2 diabetes
5. HbA1c-values between 6 and 9%

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Patients will be excluded if they have:
1. Cognitive disorders
2. Proliferative retinopathy
3. Chronic kidney disease stage three or higher [Kidney Disease Outcomes Quality Initiative (KDOQI)]
4. Addiction to alcohol
5. Metastatic cancer

Date of first enrolment

12/03/2013

Date of final enrolment
01/06/2014

Locations

Countries of recruitment
Germany

Study participating centre
Universität Hamburg
Hamburg
Germany
20146

Sponsor information

Organisation
European Foundation for the Study of Diabetes (EFSD) (Germany)

ROR
https://ror.org/05tgz4m05

Funder(s)

Funder type
Charity

Funder Name
European Foundation for the Study of Diabetes (EFSD) (Germany)

Alternative Name(s)
The European Association for the Study of Diabetes, European Association for the Study of Diabetes (EASD), EFSD

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Germany

Results and Publications

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?
Results article	results	13/11/2015		Yes	No
Protocol article	protocol	19/10/2013		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes