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Improvement of primary health care for patients with diabetes

Submission date
10/03/2011

Recruitment status
No longer recruiting

Registration date
17/06/2011

Overall study status
Completed

Last Edited
15/05/2023

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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?
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Contact information

Type(s)
Scientific

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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 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 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?
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