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ELSID - Evaluation of a Large Scale Implementation of Disease Management Programmes for patients with type 2 diabetes

Submission date	Recruitment status	[X] Prospectively registered
22/06/2005	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
20/07/2005	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
02/10/2017	Nutritional, Metabolic, Endocrine	[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
ELSID - Evaluation of a Large Scale Implementation of Disease Management Programmes for patients with type 2 diabete: a randomised controlled trial

Acronym
ELSID

Study objectives
1. The German-Diabetes-Disease Management Program (DMP 1) is more effective than routine diabetes care (CG)
2. An optimally implemented form of the Diabetes-Disease Management Program (DMP 2) is more effective than the German-Diabetes-DMP(DMP 1).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Type 2 diabetes

Interventions
Randomisation between DMP 1 and DMP 2.

GPs in the DMP 1 group will offer regular consultations at 3- or 6-month intervals including detailed diabetes-specific anamnesis, physical examination including taking blood pressure and analysis of HbA1c. Agreements are made concerning further treatment, eg target values for HbA1c and blood pressure and participation in patient education programmes for diabetes or

hypertension. All medical findings and the current medication have to be documented within structured, standardized documentation sheets at each consultation. If required a referral to a specialist (eg ophthalmologist) will be arranged.

In addition, in the DMP 2 group the following interventions are planned: interactive quality circle meetings for the GPs, educational meetings for medical assistants in the practices, outreach visits including the practice team, homepage with 'best practice' examples.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
HbA1c and blood pressure.

Secondary outcome measures
Prescriptions, hospitalizations, referrals, severe complications, SCORE risk chart.

Overall study start date
01/08/2005

Completion date
31/07/2008

Eligibility

Key inclusion criteria
Control group: Practices and patients with type 2 diabetes not participating in a Diabetes-Disease Management Programme
DMP 1 and DMP 2 group: Practices and patients with type 2 diabetes participating in a Diabetes-Disease Management Programme

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
4000 patients

Key exclusion criteria
Control group: Practices or Patients participating in any Disease Management Programmes

Date of first enrolment

01/08/2005

Date of final enrolment
31/07/2008

Locations

Countries of recruitment
Germany

Study participating centre
Vossstrasse 2
Heidelberg
Germany
69115

Sponsor information

Organisation
AOK-Bundesverband (Germany)

Sponsor details
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Sponsor type
Industry

Website
http://www.aok-bv.de

ROR
https://ror.org/004cmqw89

Funder(s)

Funder type
Industry

Funder Name
AOK-Bundesverband

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Protocol article	protocol	04/10/2005		Yes	No