

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

Submission date 22/06/2005	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input checked="" type="checkbox"/> Protocol
Registration date 20/07/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 02/10/2017	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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 diabetes: 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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Bonn

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info@bv.aok.de

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