

Effectivity of the Austrian Disease Management Programme for diabetes regarding metabolic control and risk profile

Submission date 06/06/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 12/07/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 23/02/2012	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
DW-7111-12570

Study information

Scientific Title

Acronym
EADMP

Study objectives

The Austrian Disease Management Programme for Diabetes aims to improve metabolic control and cardiovascular risk profile in patients with diabetes mellitus type two. It involves structured care, patient guidance, patient reminders, physician reminders, physician education.

Hypothesis:

The Austrian Disease Management Programme for Diabetes improves metabolic control and cardiovascular risk profile in patients with diabetes mellitus type two.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval received from the Ethics Commission of the Province of Salzburg, Austria on the 28th February 2007 (ref: 415-E779/2-2007).

Study design

Cluster randomised controlled trial

Primary study design

Interventional

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Diabetes mellitus type two

Interventions

The Austrian Disease Management Programme for Diabetes involves the following:

Structured care:

Physicians are encouraged to use standard documentation and a checklist of control examinations that are appropriate to current guidelines.

Patient guidance:

1. Regular doctors visits (at least every three months)
2. Patient education provided by a diabetes counsellor/nurse and/or physicians specifically trained in patient education in diabetes; four modules of 135 minutes each on the following topics:

- 2.1. General information about diabetes
- 2.2. Methods of metabolic control (glucose self-control)
- 2.3. Medication for diabetes
- 2.4. Nutrition/diet
- 2.5. Diabetic foot syndrome
- 2.6. Importance of physical activity
- 2.7. Cardiovascular risk factors
- 2.8. Micro- and macro-angiopathy

Given once at the beginning of the DMP and repeated at least once every three years.

Patient reminders:

Letter of information that patient should visit his doctor and discuss appropriate steps, administered by the Salzburg Public Health Insurance.

Physician reminders:

Letter of information that patient should be invited to visit and which steps should be taken, administered by the Salzburg Public Health Insurance.

Physician education:

10 hours of Continuous Medical Education (CME) provided by the Department of Diabetology of the Paracelsus University Hospital - Salzburger Landeskliniken and the Institute of General Practice, Family Medicine and Prevention at the beginning of DMP on current guidelines and management of diabetes mellitus type two; information about the DMP.

The DMP will be run for one year for the randomised trial, however continuation is planned.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

The following will be assessed at baseline and after one year (i.e. at the end of the trial):

1. HbA1c
2. Number of days hospitalised
3. Percentage of physical and laboratory examinations according to current guidelines

Key secondary outcome(s)

The following will be assessed at baseline and after one year (i.e. at the end of the trial):

1. Cardiovascular risk profile
2. Weight reduction
3. Smoking cessation
4. Improved knowledge about diabetes
5. Improved quality of life (measured using the EuroQoL [EQ-5D] questionnaire)
6. Improved patient satisfaction

Completion date

31/10/2008

Eligibility**Key inclusion criteria**

1. Patients with diabetes mellitus type two (American Diabetes Association [ADA]/World Health Organisation [WHO] criteria)
2. Aged greater than 18 years

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Dementia
2. Psychiatric illness
3. Malignant tumour

Date of first enrolment

01/07/2007

Date of final enrolment

31/10/2008

Locations

Countries of recruitment

Austria

Study participating centre

Strubergasse 21

Salzburg

Austria

A-5020

Sponsor information

Organisation

Salzburg Public Health Insurance (Salzburger Gebietskrankenkasse [SGKK]) (Austria)

Funder(s)

Funder type

Industry

Funder Name

Salzburg Public Health Insurance (Salzburger Gebietskrankenkasse [SGKK]) (Austria)

Funder Name

Investigator funding

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	05/11/2010		Yes	No