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A team approach in diabetes care - Does the chronic care model work in routine care for diabetes patients in primary care?

Submission date
22/02/2010

Recruitment status
No longer recruiting

Registration date
03/03/2010

Overall study status
Completed

Last Edited
15/10/2012

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.hausarztmedizin.uzh.ch

Contact information

Type(s)
Scientific

Contact name
Dr Anja Frei

Contact details
Institut für Hausarztmedizin der Universität Zürich
Universitätsspital Zürich
Sonneggstrasse 6
Zürich
Switzerland
8091
+41 (0)44 255 87 11
anja.frei@usz.ch

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The chronic care for diabetes study (CARAT): A cluster randomised controlled trial

Acronym
CARAT

Study objectives
The implementation of several elements of the Chronic Care Model (CCM) via a specially trained practice nurse improves the HbA1c level of diabetes type II patients in small, single handed practices in Switzerland significantly after one year (estimated change: 0.5% in HbA1c) and increases the proportion of patients who achieve the recommended targets regarding blood pressure (<130/80), HbA1c (=<6.5) and LDL-cholesterol (<1.8 mmol/l) significantly. Furthermore, this implementation improves patients quality of life, and several evidence based quality indicators for diabetes care. Finally, these improvements in care, aiming at a better accordance with the CCM, will be experienced by the patients as well as by the practice team.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The ethics board of the Kanton Zurich (Kantonale Ethik-Kommission Zürich) approved on the 25th of January 2010 (KEK-ZH-NR: 2009-0094/1)

Study design
Single centre cluster-randomised open label two-armed interventional study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Diabetes type II; primary care

Interventions
1. Practices in the control group:
Treatment as usual (patients will be treated by the GP as usual)

2. Practices in the intervention group:
2.1. Intervention on the practice nurse:
Participation in a 6-day educational course Treatment of long term patients - module diabetes (Betreuung von Langzeitpatienten - Modul Diabetes) organised by the Schweizerischer Verband medizinischer Praxisassistentinnen (18 - 24/04/2010): Content: treatment of diabetes patients (medical basics, diet, practical tips, communication etc.), role of the practice nurse in a team providing structured care for chronically ills, how to perform a follow-up with the CARAT-monitoring-tool
2.2. Intervention on the GPs:
Two interactive workshops of 4 hours (second 2 hours together with the practice nurses):
2.2.1. Evidenced based treatment of diabetes in a primary care setting, implementing structured and proactive care according to the Chronic Care model in practice (29/04/2010)
2.2.2. Exchange of experience and cardiovascular risk management (autumn 2010)
3. Intervention on the team:
One outreach visit will be performed by a study nurse of the study centre after completing the courses for GPs and practice nurses. The aims are to assess if the structures in the practices are appropriate to perform care according to this study protocol, to reveal possible problems which might have occurred, to discuss and implement appropriate solutions, and to check that the CARAT-tool is used as intended.
4. Intervention on the patient:
Patients will be treated by the special trained practice nurse in conjunction with the GP, treatment will be structured according to the Chronic Care Model.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Glycated Haemoglobin (HbA1c) level, measured at baseline (T0) and 1 year (T1)

Secondary outcome measures
All measures will be assessed at baseline (T0) and 1 year (T1):

1. Guideline adherence (recommended treatment goals): Proportion of patients who achieve the recommended targets regarding:
1.1. HbA1c (=<6.5)
1.2. Blood pressure (<130/80)
1.3. Low-density lipoprotein-cholesterol (LDL-cholesterol) (<1.8 mmol/l)
2. Quality of Life, assessed by SF-36 questionnaire
3. Process quality:
3.1. Proportion of patients receiving at least one eye examination per year
3.2. Proportion of patients receiving at least one food examination per year
3.3. Proportion of patients receiving at least one nephropathy screening per year

3.4. Proportion of patients receiving at least one neurological testing per year
4. Accordance to the Chronic Care Model:
4.1. Patient Assessment of Chronic Illness Care questionnaire (PACIC-5A)
4.2. Assessment of Chronic Illness Care questionnaire (ACIC)

Overall study start date
01/01/2010

Completion date
01/05/2011

Eligibility

Key inclusion criteria
1. Diabetes type II patients (Glucose in blood plasma > 7,0 mmol /l)
2. At least one measure of HbA1c > 7.0% within the last year
3. Aged older than 18 years
4. Male and female

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
12 patients and 14 practices are recruited in each arm (target total recruitment number 336). Randomisation at GP level.

Key exclusion criteria
1. Insufficient German language skills
2. Patients who contacted the practice for emergencies only or as a substitute practice
3. Patients with oncological diseases and/or an estimated life expectancy of less than six months due to severe diseases

Date of first enrolment
01/01/2010

Date of final enrolment
01/05/2011

Locations

Countries of recruitment

Switzerland

Study participating centre
Institut für Hausarztmedizin der Universität Zürich
Zürich
Switzerland
8091

Sponsor information

Organisation
Institute of General Practice Medicine - University of Zurich (Institut für Hausarztmedizin der Universität Zürich) (Switerland)

Sponsor details
University Hospital of Zurich
Sonneggstrasse 6
Zürich
Switzerland
8091
+41 (0)44 255 98 55
thomas.rosemann@usz.ch

Sponsor type
University/education

Website
http://www.hausarztmedizin.uzh.ch

ROR
https://ror.org/02crff812

Funder(s)

Funder type
University/education

Funder Name
Institute of General Practice Medicine - University of Zurich (Institut für Hausarztmedizin der Universität Zürich) (Switerland)

Funder Name
Swiss Academy for Medical Sciences (SAMW) (Switzerland) (grant number RRMA 8-09)

Funder Name
Menarini AG (Switzerland)

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	15/06/2010		Yes	No
Results article	results	15/06/2012		Yes	No