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Rapid improvement cycles for the therapeutic treatment of diabetes complications

Submission date	Recruitment status	[X] Prospectively registered
16/01/2009	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
20/04/2009	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
20/04/2009	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

Protocol serial number
N/A

Study information

Scientific Title
Can rapid improvement cycles improve the therapeutic treatment of diabetes complications? A pragmatic cluster randomised controlled trial.

Study objectives

The scope of this study is to assess whether the application of rapid improvement cycles involving specific and circumspect clinical topics of the organisation of Italian Diabetic Units (prevention of arteriosclerotic cardio-vasculopathies; prescription of anti-hypertension drugs; prescription of anti-aggregant drugs) is able to improve the processes and the outcomes of care to diabetics. The Diabetic Units in the action branch will participate in the training course on rapid improvement cycles, then will produce quality improvement projects and will receive support and coaching from an expert.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Interventional pragmatic cluster randomised, controlled clinical trial

Primary study design
Interventional

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Diabetes complications

Interventions
The selected Diabetes Units will attend the 'basic course' that discusses the topic of the correct method for inputting data for the indicators that will be assessed in this study, and the method by which aptitude to input data will be verified.

The Diabetic Units in the control branch will not receive any further education or support in addition to that obtained from participating in the basic course.

The Diabetic Units that will belong to the action branch will participate in the training course on rapid improvement cycles. The topic of the theoretical-practical course will be improvement of the quality of medical care; participants will learn skills in using the improvement methods of the Intermountain Healthcare's Mini-advanced Training Program In Health Care Delivery Improvement designed to facilitate the development of the necessary skills for participating dynamically in quality improvement activities. In the three following months, participants will produce a quality improvement project on the first topic discussed in the study and, at the same time, will receive support and coaching from an expert in quality improvement methodologies, through planned tele-conferences and remote assistance (e-mails). At the end of this three-month period, the action branch participants will present their projects in a session during which they will be reviewed and assessed by a group of experts in improving the quality of medical care.

During the following period, the participants will carry out improvement projects on the other topics discussed in the study, and a year after the study started, the improvement ventures will be presented in an interim meeting lasting one day, to which the Diabetic Units enrolled in the action group will be invited.

During the whole experiment and once a month, the participants in the action group will receive remote help from an expert in quality improvement methodologies, through teleconferences and e-mails; an electronic forum will be set up in which participants will be able to share their experiences, exchange solutions and documentation (benchmark), ask questions concerning the improvement projects they are carrying out. At the end of the second year of the experiment, all the participating Diabetic Units will present their quality improvement ventures, and the outcomes obtained by the two groups will be compared.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Control of cardiovascular risk factors:
1. Patients taking cholesterol-lowering drugs with low density lipoprotein cholesterol (C-LDL) greater than 100 mg/dl/total number of patients with C-LDL greater than 100 mg/dl
2. Patients undergoing anti-hypertension treatment with pulmonary arterial (PA) pressure greater than 140/90 mmHg/total number of patients with PA pressure greater than 140/90 mmHg

Prescription of anti-aggregant drugs:
3. Patients undergoing anti-aggregant platelet treatment/total number of patients

Primary outcomes will be assessed after 1 year and after 2 years from the start of the study.

Key secondary outcome(s))
No secondary outcome measures

Completion date
31/12/2011

Eligibility

Key inclusion criteria
1. Diabetes Units that use an electronic clinical record
2. Diabetes Units included in the list of centres taking part in production of the AMD Annals (AMD Annals. Diabetes care: quality indicators of diabetes care in Italy - http://www.infodiabetes.it/annali/index.asp), that offer the first representation of the practical efficacy level of the care provided by diabetology centres

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Other

Sex
All

Key exclusion criteria
1. Has already taken part in quality improvement studies of the type and intensity of this one
2. Located in an area adjacent to that of enrolled Diabetes Units, excluding the worst classified Diabetes Unit

Date of first enrolment
01/06/2009

Date of final enrolment
31/12/2011

Locations

Countries of recruitment
Italy

Study participating centre
Via Amendola 2
Reggio Emilia
Italy
42100

Sponsor information

Organisation
Italian Association of Clinical Diabetologists (Associazione Medici Diabetologi [AMD]) (Italy)

ROR
https://ror.org/0451etm15

Funder(s)

Funder type
Research organisation

Funder Name
Italian Association of Clinical Diabetologists (Associazione Medici Diabetologi [AMD]) (Italy)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration