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Diabetes care Implementation Study

Submission date	Recruitment status	[_] Prospectively registered
02/05/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
02/05/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
04/01/2021	Nutritional, Metabolic, Endocrine	

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
Diabetes care Implementation Study

Acronym

DIS

Study objectives
Diabetes care can be improved by task delegation to a practice nurse supported by computerised decision support and benchmarking.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from the local ethics committee (Medical Ethics Committee, UMC-Utrecht) on the 24th February 2004 (ref: 03/233-E).

Study design
Randomised, active controlled, parallel group, multicentre trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Diabetes Mellitus type two (DM2)

Interventions
Implementing the Diabetes Care Protocol (DCP) developed by Diagnosis 4 Health.

Characteristics: consultation hour exclusively scheduled for DM2 patients and delegation of routine diabetes care tasks to a trained practice nurse who uses the DCP software that supports management and medical decisions.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
1. Change in:
a. HbA1c %
b. Blood pressure
c. Total cholesterol

The primary and secondary outcomes will all be measured at baseline and after one year follow-up.

Key secondary outcome(s))
1. Change in cardiovascular risk
2. Effects on quality of life and patient treatment satisfaction
3. Effects on process of care

The primary and secondary outcomes will all be measured at baseline and after one year follow-up.

Completion date
30/05/2007

Eligibility

Key inclusion criteria
Diabetes Mellitus type two (DM2)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Total final enrolment
3391

Key exclusion criteria
1. Under treatment of medical specialist
2. Terminally ill patients
3. Patients with complex multi-morbidity
4. Patients not able to visit the general practice

Date of first enrolment
01/03/2004

Date of final enrolment
30/05/2007

Locations

Countries of recruitment
Netherlands

Study participating centre

University Medical Centre Utrecht
Utrecht
Netherlands
3500 GA

Sponsor information

Organisation
University Medical Centre Utrecht (UMCU) (The Netherlands)

ROR
https://ror.org/04pp8hn57

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Medical Centre Utrecht (UMCU) (The Netherlands)

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	01/12/2008	04/01/2021	Yes	No