

Diabetes care Implementation Study

Submission date 02/05/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 02/05/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 04/01/2021	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

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Quality of life

Participant information sheet

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 measure

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.

Secondary outcome measures

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.

Overall study start date

01/03/2004

Completion date

30/05/2007

Eligibility

Key inclusion criteria

Diabetes Mellitus type two (DM2)

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

3500

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)

Sponsor details

Julius Center for Health Sciences and Primary Care

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juliuscenter@azu.nl

Sponsor type

Hospital/treatment centre

Website

<http://www.umcutrecht.nl/zorg/>

ROR

<https://ror.org/04pp8hn57>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

University Medical Centre Utrecht (UMCU) (The Netherlands)

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?
Results article	results	01/12/2008	04/01/2021	Yes	No