

Monitoring health-related quality of life in adolescents with type 1 diabetes prior to periodic outpatient consultation: impact on psychosocial adaptation, satisfaction with care and glycaemic control - a randomised controlled cross-over study

Submission date 20/12/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 20/12/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 31/07/2008	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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Diabetes Research Fund: 2003.00.020; NTR149

Study information

Scientific Title

Acronym

DiaQuest

Study objectives

Three successive health-related quality of life (HRQoL) assessments, performed preceding the outpatient consultation with the paediatrician, impact positively on psychosocial adaptation, satisfaction with care, and glycaemic control at 12 months follow-up.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the local medical ethics committee

Study design

Multicentre, randomised, active controlled crossover trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Diabetes Mellitus Type I (DM type I)

Interventions

In a prospective multi-centre study, the effects are studied of an office-based, computerised Health-Related Quality of Life assessment in adolescent type 1 diabetes patients, prior to their periodic outpatient consultation. The outcomes of the assessment are discussed during

consultation, as a means of tailoring care to the (changing) psychosocial needs of the adolescent with diabetes.

The study is carried out in four paediatric diabetes outpatient clinics (n=120), including the VUMC. At baseline, a comprehensive medico-psychosocial assessment is scheduled in participating patients and their parent(s). After randomisation, two centres in the control condition continue to deliver care-as-usual (3-monthly outpatient consultations). In the two centres randomised to the experimental condition, three successive HRQOL assessments are carried out prior to the 3-monthly consultation and outcomes are discussed during consultation.

After 12 months, centres cross over to the other study arm, and patients are followed up for another 12 months. The study thus has a duration of 24 months per patient.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

1. Psychosocial adaptation
2. Satisfaction with care
3. Glycaemic control

Secondary outcome measures

1. Duration of the consultation
2. The topics discussed
3. Diabetes care-related actions
4. Patient-and parent related characteristics

Overall study start date

01/09/2004

Completion date

01/09/2008

Eligibility

Key inclusion criteria

Adolescents in the age range 13 - 18 with type 1 diabetes.

Participant type(s)

Patient

Age group

Child

Lower age limit

13 Years

Upper age limit

18 Years

Sex

Not Specified

Target number of participants

120

Key exclusion criteria

1. Unable to read and speak Dutch
2. Mental retardation
3. Treatment for an organic psychiatric disorder

Date of first enrolment

01/09/2004

Date of final enrolment

01/09/2008

Locations**Countries of recruitment**

Netherlands

Study participating centre

VU University Medical Centre

Amsterdam

Netherlands

1081 BT

Sponsor information**Organisation**

Vrije University Medical Centre (VUMC) (The Netherlands)

Sponsor details

EMGO-Institute and Department of Public and Occupational Health

Van der Boechorststraat 7

Amsterdam

Netherlands

1081 BT

Sponsor type

University/education

Website

<http://www.vumc.nl>

ROR

<https://ror.org/00q6h8f30>

Funder(s)

Funder type

Charity

Funder Name

Diabetes Research Fund (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	01/08/2008		Yes	No