ISRCTN65138334 https://doi.org/10.1186/ISRCTN65138334

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

Registration date
20/12/2005

Overall study status
Completed

Last Edited
31/07/2008

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr M. de Wit

Contact details
VU University Medical Centre
Medical Psychology
Van der Boechorststraat 7
Amsterdam
Netherlands
1081 BT
+31 (0)20 444 8420
m.dewit@vumc.nl

Additional identifiers

Protocol serial number

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

Study type(s)
Treatment

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(s)
1. Psychosocial adaptation
2. Satisfaction with care
3. Glycaemic control

Key secondary outcome(s))
1. Duration of the consultation
2. The topics discussed
3. Diabetes care-related actions
4. Patient-and parent related characteristics

Completion date
01/09/2008

Eligibility

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

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
13 years

Upper age limit
18 years

Sex
Not Specified

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)

ROR
https://ror.org/00q6h8f30

Funder(s)

Funder type
Charity

Funder Name
Diabetes Research Fund (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	01/08/2008		Yes	No