

# 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.

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruiting
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON27915

### Source

Nationaal Trial Register

### Brief title

DiaQuest

### Health condition

Diabetes Type 1

## Sponsors and support

**Primary sponsor:** Diabetes Psychology Research group, dept. Medical Psychology, EMGO institute, VU medical center

**Source(s) of monetary or material Support:** Diabetes Research Fund

## Intervention

### Outcome measures

#### Primary outcome

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

#### Secondary outcome

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

## Study description

### Background summary

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 (13 -18 years), 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.

It is hypothesized that implementing this procedure will help to improve psychosocial and clinical outcomes, and satisfaction with care.

The study is carried out in 4 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. The impact of 3 successive HRQOL assessments (3, 6, 9 months) on the primary outcome measures - psychosocial adaptation, satisfaction with care and glycaemic control - is

determined at 12 months.

To help understand what mediates changes in outcomes, a baseline assessment is performed in patients and parents, and information is obtained in both conditions, concerning duration of consultations, topics discussed and actions undertaken (e.g. changes in regimen, referrals).

### **Study objective**

3 successive 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.

### **Intervention**

3 successive HRQoL assessments, performed preceding the outpatient consultation with the paediatrician.

## **Contacts**

### **Public**

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### **Scientific**

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## **Eligibility criteria**

## Inclusion criteria

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

## Exclusion criteria

Unable to read and speak Dutch, mental retardation, or treatment for an organic psychiatric disorder.

## Study design

### Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Active

### Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-09-2004
Enrollment:	120
Type:	Anticipated

## Ethics review

Positive opinion	
Date:	25-08-2005
Application type:	First submission

## Study registrations

## Followed up by the following (possibly more current) registration

No registrations found.

## Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

Register	ID
NTR-new	NL117
NTR-old	NTR149
Other	: Diabetes Research Fund: 2003.00.020
ISRCTN	ISRCTN65138334

## Study results

### Summary results

N/A