

Emotional problems in adolescents with type 1 diabetes and their parents/caregivers: The true scope of the problem

Published: 27-03-2014

Last updated: 20-04-2024

To establish (a) the prevalence and course of depression and anxiety in adolescents with type 1 diabetes and their parents/caregivers, (b) the risk factors predicting the presence of these emotional problems, (c) the care that is currently in place...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Observational non invasive

Summary

ID

NL-OMON50368

Source

ToetsingOnline

Brief title

Diabetes LEAP study

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym

type 1 diabetes; insulin-dependent diabetes

Research involving

Human

Sponsors and support

Primary sponsor: Diabeter

Source(s) of monetary or material Support: Diabetes Fonds

Intervention

Keyword: adolescents, anxiety, depression, type 1 diabetes

Outcome measures

Primary outcome

Mood and anxiety disorders in adolescents with type 1 diabetes (Diagnostic Interview Schedule for Children; DISC-IV)

Secondary outcome

For adolescents: depressive symptoms (Children's Depression Inventory-2); symptoms of anxiety (Generalized Anxiety Disorder-7).

For parents: depressive symptoms (Patient Health Questionnaire 9-item scale); symptoms of anxiety (Generalized Anxiety Disorder-7).

Description of treatment and follow-up, once the diabetologist has been informed of the presence of a mood or anxiety disorder.

Diabetes outcomes (e.g. glycemic control, adherence).

Study description

Background summary

Previous research has suggested that up to 30% of all young people with type 1 diabetes will be confronted with a mood or anxiety disorder at least once while growing up. However, the true scope of the problem is still unknown, as earlier studies have important limitations.

Study objective

To establish (a) the prevalence and course of depression and anxiety in adolescents with type 1 diabetes and their parents/caregivers, (b) the risk factors predicting the presence of these emotional problems, (c) the care that

is currently in place for these problems, and (d) the longitudinal relation between these emotional problems and diabetes outcomes.

Study design

Two-year prospective observational cohort study (baseline assessment, follow-up assessments after one and two years)

Study burden and risks

The proposed prospective observational study will provide a much needed indication of the prevalence, course and clinical impact of emotional problems among adolescents with type 1 diabetes, thereby opening avenues for proper recognition, prevention and timely treatment. The burden of participation can be considered minimal, with an estimated maximum time investment of 3 x 90 minutes (one year in between assessments). The risks associated with participation can be considered negligible. If needed, emergency consultations and immediate referral to psychological/psychiatric consultants are possible.

Contacts

Public

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (12-15 years)

Adolescents (16-17 years)

Inclusion criteria

Adolescent with type 1 diabetes aged 12-18 years

Exclusion criteria

Language difficulties or moderate to severe intellectual disabilities interfering with participation (based on medical record and diabetologists* judgement)

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Health services research

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 12-02-2015

Enrollment: 220

Type: Actual

Ethics review

Approved WMO

Date:	27-03-2014
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO	
Date:	03-04-2015
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO	
Date:	11-02-2020
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO	
Date:	14-12-2020
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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
CCMO	NL48232.015.14