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A new beginning in life for young adults with poorly controlled type 1 diabetes

Submission date
02/12/2012

Recruitment status
No longer recruiting

Registration date
12/12/2012

Overall study status
Completed

Last Edited
12/12/2012

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims:
Being young and having to face a life with a chronic condition is a great challenge. In diabetes care more than half of the patients with type 1 diabetes live with poor glycaemic control which can lead to increased risk of diabetes related complications and poor quality of life. This study investigates patients own judgement of their situation and the problems connected with diabetes self-management.

Who can participate?
Young adults aged 18-35 years old, who have had type 1 diabetes for at least 1 year.

What does the study involve?
Participants are randomly distributed to having GSD immediately or 18 months delayed. They choose whether the course should have an individual or a group based form. Patients fill in reflection sheets before each appointment and talk with GSD-trained nurses about the issues they have written or drawn on the sheets. Through this process the young adults discover new aspects of their own way of living with the illness and also a new potential for managing diabetes in daily life. The nurses also discover new aspects in each patients life and thereby become able to support patients in finding their own way in managing the situation.

What are the possible benefits and risks of participating?
Participants will benefit from the course by learning to better control their diabetes. There are no known risks associated with taking part in this study.

Where is the study run from?
Steno Diabetes Center, Denmark

When is the study starting and how long is it expected to run for?
The study started n March 2010 and is due to end in September 2013.

Who is funding the study?
Steno Diabetes Center, Denmark
Danish National Board of Health, Denmark
Novo Nordisk - Department of Global Health, Denmark

Who is the main contact?
Vibeke Zoffmann
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Guided self-determination tested in a flexible program for young adults with poorly controlled type 1 diabetes: a randomised controlled trial

Study objectives
It is hypothesised that attending in a group based or individual course using Guided Self-determination (GSD) will improve the way young adults with poorly controlled type 1 diabetes live with their illness. The null hypothesis of no difference will be rejected if participants in the intervention group compared to those in a control group have decreased their HbA1c and improved their psychosocial functioning 18 months after the intervention.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The National Committee on Health Research Ethics ref: H-D-2009-Fsp-29
The Danish Data Protection Agency ref: 2010-41-5448

Study design

Randomized controlled trial a waitlist design

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Type 1 diabetes in poor control

Interventions
Participants are by chance distributed 2:1 to having GSD immediately or 18 months delayed. They choose whether the course should have an individual form (eight 1-hour sessions in day time) or a group based form (eight 2½-hour sessions late afternoon). Patients fill in reflection sheets before each appointment and talk with GSD-trained nurses about the issues they have written or drawn on the sheets. Through this process the young adults discover new aspects of their own way of living with the illness and also a new potential for managing diabetes in daily life. The nurses also discover new aspects in each patients life and thereby become able to support patients in finding their own way in managing the situation. As part of GSD, advantages and disadvantages of different levels of HbA1c are also translated to patients in a meaningful way allowing patients to take autonomous decisions about their own goals which consequently in higher degree will be self-concordant.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
HbA1c

Key secondary outcome(s))
1. Health Care Climate Questionnaire (HCCQ)
2. Treatment Self Regulation Questionnaire (TSRQ)
3. Problem Areas In Diabetes (PAID)
4. Perceived Competence with diabetes (PCD)
5. WHO-5
6. Rosenbergs self-esteem scale (RSES)
7. Self-monitored blood-glucoses (SMBG) per week
8.Cancellations or failures to show-up
9. Type and amount of insulin treatment.

Completion date
30/09/2013

Eligibility

Key inclusion criteria

1. Young adults, 18-35 years old with duration of type 1 diabetes at least 1 year
2. HbA1c at least 8.0% and mean HbA1c during the past 1-2 years at least 7.5%

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
35 years

Sex
All

Key exclusion criteria
Young adults who due to mental or physical state and language barriers are unable to read and reflect on the reflection sheets used in GSD

Date of first enrolment
01/03/2010

Date of final enrolment
30/09/2013

Locations

Countries of recruitment
Denmark

Study participating centre
Steno Diabetes Center
Kokkedal
Denmark
2980

Sponsor information

Organisation

Steno Diabetes Center (Denmark)

ROR
https://ror.org/03w7awk87

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Steno Diabetes Center [Kliniske udviklingsmidler] (Denmark)

Funder Name
Danish national Board of Health (Denmark) ref: 7-203-02-434/5

Funder Name
Novo Nordisk Department of Global Health (Denmark)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration