

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

<b>Submission date</b> 02/12/2012	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 12/12/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 12/12/2012	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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**  
Dr Vibeke Zoffmann

**Contact details**  
Steno Diabetes Center  
Jellerød Have 32  
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Denmark  
2980

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
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

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

GP practice

**Study type(s)**

Quality of life

**Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet

**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 measure**

HbA1c

**Secondary outcome measures**

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.

**Overall study start date**

01/03/2010

**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

**Age group**

Adult

**Lower age limit**

18 Years

**Upper age limit**

35 Years

**Sex**

Both

**Target number of participants**

200

**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)

## Sponsor details

Niels Steensens vej 2

Gentofte

Denmark

2820

## Sponsor type

Hospital/treatment centre

## Website

[http://www.steno.dk/documents/home\\_page/document/index.asp](http://www.steno.dk/documents/home_page/document/index.asp)

## 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**

**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