

# Life skills for adolescents with type 1 diabetes and their parents

<b>Submission date</b> 22/01/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 08/03/2010	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Protocol
<b>Last Edited</b> 15/08/2014	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**  
1

## Study information

**Scientific Title**  
Life skills for adolescents with type 1 diabetes and their parents: an interventional study with a concurrent mixed methods design

**Study objectives**

Guided self-determination can be developed and implemented for adolescents and their parents in Paediatric Outpatient Clinics and have a positive impact on adolescents' development of diabetes self-management to specific diabetes-related problems including achieving better glycaemic control.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

The study has been considered by the Danish Ethical Committee and they concluded that as this trial does not involve any interventions further than a routine HbA1c test, formal ethics approval was not required. This project is registered at the the Danish Data Tilsyn (ref: 2008-41-2322).

**Study design**

Interventional randomised controlled trial with a concurrent mixed methods design (quantitative and qualitative)

**Primary study design**

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Type I diabetes

**Interventions**

Participants are randomised to an intervention group (n = 34) or a control group (n = 34). Adolescents and parents in the intervention group receive guided self-determination at the Paediatric Outpatient Clinic appointments using reflection sheets as a starting point for the conversations with doctors, nurses and dieticians. Participants in the control group carry out the appointments as usual, when attending the Paediatric Outpatient Clinic.

The participants are seen 8 times a year irrespective of whether they are in the intervention group or in the control group. The first four visits are planned to be every month and thereafter every second month for both groups.

The participants in the intervention group are seen an hour at every visit. Furthermore the parents are offered to be seen to times alone during the project year beside the visits they participate in together with their adolescents.

The participants in the control group are seen as normal routine visits from half an hour to 45 minutes. Parents are offered to participate as they are used to do.

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome(s)**

Measured at baseline and every third month until the end of the study:

1. HbA1c
2. Perception of Parents Scale (POPS)
3. Health Care Climate Questionnaire (HCCQ)
4. Problem Areas in Diabetes (PAID)
5. Perception of Competence (PCD)
6. World Health Organization Wellbeing Index (WHO5 - well-being)
7. Self monitoring blood glucose (SMBG) per week and cancellations or failure to show up are registered

**Key secondary outcome(s)**

Measured at baseline, 6 months and 12 months:

Regarding the qualitative part, adolescents and their parents from the intervention group are being followed through the process. Consultations at the Paediatric Outpatient Clinics are being taped. At the end of the study adolescents, parents and health professionals are interviewed. Constant comparative analysis as recommended by Grounded Theory is used.

**Completion date**

01/01/2012

**Eligibility****Key inclusion criteria**

1. Adolescents between the ages 13 - 18 years, either sex, and their parents
2. A diagnosis of type 1 diabetes for at least 1 year
3. Poorly regulated, defined by a HbA1c above or equal to 8.0%
4. Participants must speak, read, write and understand Danish

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Child

**Lower age limit**

13 years

**Upper age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. Adolescents with severe illness, mental problems, in current psychological or psychiatric treatment

2. Adolescents who do not want to participate and do not sign a consent form
3. Parents with severe illness, mental problems, in current psychological or psychiatric treatment
4. Parents who do not want to participate and do not sign a consent form
5. Unable to speak, read, write and understand Danish

**Date of first enrolment**

09/09/2009

**Date of final enrolment**

01/01/2012

## Locations

**Countries of recruitment**

Denmark

**Study participating centre**

Hillerød Hospital

Hillerød

Denmark

3400

## Sponsor information

**Organisation**

Hillerød Hospital (Denmark)

## Funder(s)

**Funder type**

Charity

**Funder Name**

Hillerød Hospital (Denmark)

**Funder Name**

Region Hovedstadens Phd. fond (Denmark)

**Funder Name**

Novo Nordisk (Denmark)

**Alternative Name(s)**

Novo Nordisk Global

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

For-profit companies (industry)

**Location**

Denmark

**Funder Name**

Lundbeck (Denmark)

**Funder Name**

Sahva (Denmark)

**Funder Name**

Trygfonden (Denmark)

**Funder Name**

Kaptajn Løjtnant and Wife (Denmark)

## 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?
<a href="#">Results article</a>	results	12/08/2014		Yes	No
<a href="#">Protocol article</a>	protocol	14/06/2011		Yes	No

