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Life skills for adolescents with type 1 diabetes and their parents

Submission date	Recruitment status	[_] Prospectively registered
22/01/2010	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
08/03/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
15/08/2014	Nutritional, Metabolic, Endocrine	

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).

Primary study design
Interventional

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

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 dietricians. Participants in the control group carry out the appointments as usual, when attending the Paediatric Outpatient Clinic.

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

The paticipants in the intervention group are seen an hour at every visit. Futhermore 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 Questionaire (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?
Results article	results	12/08/2014		Yes	No
Protocol article	protocol	14/06/2011		Yes	No