

Life skills for adolescents with type 1 diabetes and their parents

Submission date
22/01/2010

Recruitment status
No longer recruiting

☐ Prospectively registered

☒ Protocol

Registration date
08/03/2010

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
15/08/2014

Condition category
Nutritional, Metabolic, Endocrine

☐ 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

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 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 dietitians. 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 measure

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

Secondary outcome measures

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.

Overall study start date

09/09/2009

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

Age group

Child

Lower age limit

13 Years

Upper age limit

18 Years

Sex

Both

Target number of participants

68 adolescents and (n) parents

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)

Sponsor details

c/o Assistant Professor Vibeke Zoffmann
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Sponsor type

Hospital/treatment centre

Website

<http://www.hillerodhospital.dk/menu/>

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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	14/06/2011		Yes	No
Results article	results	12/08/2014		Yes	No