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Constructive parental support and clarified responsibility to youth with type 1 diabetes starting continuous subcutaneous insulin infusion

Submission date
19/10/2012

Recruitment status
No longer recruiting

Registration date
25/01/2013

Overall study status
Completed

Last Edited
19/02/2021

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
In children, type 1 diabetes is the most predominant form of diabetes and it is increasing in Sweden. The most common treatment is insulin injections (multiple daily injections, MDI), but treatment with insulin pump (continuous subcutaneous insulin infusion, CSII) is an alternative. In 2011, 42 % of the children with type 1 diabetes in Sweden were treated with insulin pump. When looking on glycemic (blood glucose level) control in children using insulin pump, studies are showing different results. One reason for poor glycemic control among adolescents treated with insulin pump is omitted insulin injections before meals. The reason for missed doses is mainly explained by lost focus, the children forget the doses. The distribution of the responsibility for diabetes self-management between children and parents is often unclear and needs to be clarified.
In general, children with chronic diseases and their parents report significant lower perceived health and quality of life (QOL) compared with healthy children. Adolescence is the transitional phase of development from childhood towards adulthood. It imposes challenges on the individuals with diabetes, their families and the diabetes care team.
There is great support for continued parental involvement and shared diabetes management during adolescence. There are five categories important for decision making competence; cognitive maturity, personal qualities, experience, social network and parent involvement. Teenagers describe that parental involvement can be constructive or destructive. The challenge is to find a level that is comfortable for all involved.
Person-centred care highlights the importance of knowing the person behind the patient in order to engage the person as an active partner in his/her cares and treatment. Guided self-determination (GSD) is a person-centred reflection model that intends to guide the patient to become self-determined and develop life skills to manage difficulties in the diabetes self-management by using structured worksheet. It has been effective both in individual and group training in adults with type 1 diabetes and there is an on-going study in Denmark on youth with type 1 diabetes using a version adapted to adolescents and parents (Guided self-determination-Young, GSD-Y). The goal with our study is to evaluate if an intervention (treatment) with GSD-Y

leads to less diabetes related family conflicts, increased perceived health and quality of life and improved glycemic control.

Who can participate?
The study intends to involve 80 youths between 12 and 17 years who are planned to start insulin pump.

What does the study involve?
The participants will be randomly allocated to either intervention or control group.
All youth will receive standard insulin pump start training, including technical skills and how to use carbohydrate counting with insulin pump. The parents will simulate diabetes by wearing pump and test blood glucose before the child will start insulin pump treatment. The intervention group will be divided in groups of four adolescents and their parents. The education intervention will be performed by diabetes nurses during four opportunities the first four month after starting on insulin pump. The GSD-Y method will be used.

What are the possible benefits and risks of participating?
All youth will receive standard insulin pump start training, including technical skills and how to use carbohydrate counting with insulin pump. The GSD-Y (Guided self-determination-Young, GSD-Y) education will hopefully lead to increased parental support and clarified responsibility distribution, may decrease negative impact of diabetes, improve perceived health, quality of life and glycemic control.
By taking part in this study there are no risks of physical injury or harm.

Where is the study run from?
The study will take place at Astrid Lindgren Childrens Hospital, Karolinska University hospital and Sachs children and youth hospital, Södersjukhuset, Stockholm, Sweden.

When is the study starting and how long is it expected to run for?
The plan is to include the first patient in January 2013 and will run until the required number of 80 participants has been recruited.

Who is funding the study?
Funding has been provided by the Swedish Diabetes association, The Swedish childrens diabetes association, Uppsala University, medical faculty, Jerring foundation and Groschinskys foundation.

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Constructive parental support and clarified responsibility to youth with type 1 diabetes starting continuous subcutaneous insulin infusion: a randomized controlled study

Study objectives
Increased parental support and clarified responsibility distribution may decrease negative impact of diabetes, improve perceived health, quality of life and glycemic control among young treated with continuous subcutaneous insulin infusion.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Review Board in Stockholm, 8 June 2011, ref: 2011/762-31/4

Study design
Open randomized intervention study

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 to request a patient information sheet.

Health condition(s) or problem(s) studied
Type 1 diabetes

Interventions
Participants will be randomized to either intervention (n=40) or control group (n=40) when they have decided to start on CSII. All youth will receive standard start training, including technical skills and how to use carbohydrate counting with CSII. The parents will simulate diabetes by wearing pump and test blood glucose before the child will start insulin pump treatment. The intervention group will be divided in groups of four adolescents and their parents.

The intervention will be performed by diabetes nurses during start of CSII and four opportunities the first four month after starting on CSII. Person-centred care highlights the importance of knowing the person behind the patient in order to engage the person as an active partner in his/her cares and treatment. Guided self-determination (GSD) is a person-centred reflection model that intends to guide the patient to become self-determined and develop life skills to manage difficulties in the diabetes self-management by using structured worksheet. It has been effective both in individual and group training in adults with type 1 diabetes. In an on-going Danish study GSD has been adopted to adolescents and parents (Guided self-determination-Young, GSD-Y). The GSD-Y method will be used in the intervention group.

The participants in the control group are followed according to normal routine.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Measured before start of CSII:
1. HbA1c
2. Length and weight
3. Mean frequency of self-monitoring of blood glucose (SMBG)
4. Check your health measure perceived physical and emotional health, social relations, general quality of life and impact of diabetes
5. Disabkids is measuring generic health in children with chronic illness and have a specific diabetes module
6. DFCS (Diabetes family conflict scale) is the most widely used measure of diabetes-specific family conflict
7. Swe-DES 23 measures the psychosocial self-efficacy of people with diabetes
8. Treatment satisfaction

Measure 6 and 12 month after start CSII:
1. Same measures as before start CSII
2. Frequency of missed bolus doses
3. Usage of carbohydrate counting

Secondary outcome measures
Two weeks after completing the program 20 adolescents will be interviewed. This qualitative interview study will evaluate how adolescents perceive their parent support after taking part in the education program. The questions will be designed especially for this study. The interviews will be taped and transcribed and the analysis method will be qualitative content analysis.

Overall study start date
01/03/2011

Completion date
31/12/2017

Eligibility

Key inclusion criteria
1. Children between the ages 12 and 17 years who are planned to start on Continuous Subcutaneous Insulin Infusion (CSII)
2. A diagnosis of type 1 diabetes for at least 1 year

Participant type(s)
Patient

Age group
Child

Lower age limit
12 Years

Upper age limit
17 Years

Sex
Both

Target number of participants
80 youth and their parents

Key exclusion criteria
1. If the teenager or the parent has difficulties to understand Swedish
2. Usage of continuous glucose monitoring (CGM) during study period

Date of first enrolment
01/01/2013

Date of final enrolment
31/12/2015

Locations

Countries of recruitment

Sweden

Study participating centre
Sachs Children and Youth Hospital
Stockholm
Sweden
11883

Sponsor information

Organisation
Uppsala University (Sweden)

Sponsor details
c/o Anna Lindholm Olinder, PhD
Karolinska Institute Södersjukhuset
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11883

Sponsor type
University/education

Website
http://www.uu.se/en

ROR
https://ror.org/048a87296

Funder(s)

Funder type
University/education

Funder Name
Uppsala University (Sweden)

Funder Name

Swedish Diabetes Foundation (Sweden)

Funder Name
The Swedish Child Diabetes Foundation (Sweden)

Funder Name
The Jerring Foundation (Sweden)

Funder Name
The Clas Groschinsky Foundation (Sweden)

Results and Publications

Publication and dissemination plan
All data will be used as a part of Anna-Lena Brorsson's thesis. A manuscript including the qualitative interview-study is planned to be submitted for publication in a peer reviewed journal in January 2017. A manuscript including the quantitative data is planned to be submitted Spring 2018.

Intention to publish date
31/12/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study is not expected to be made available due to ethical reasons.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	20/12/2013		Yes	No
Results article	qualitative study results	26/11/2017	19/02/2021	Yes	No