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A randomized controlled trial of an empowerment intervention for female adolescents with diabetes.

Submission date
14/12/2014

Recruitment status
No longer recruiting

Registration date
18/02/2015

Overall study status
Completed

Last Edited
23/11/2023

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims

In children and adolescents type 1 diabetes is the most predominant form of diabetes in Sweden. Diabetes is a condition that causes a person's blood sugar (glucose) level to become too high. Insulin is a hormone (produced by an organ called the pancreas) that controls the amount of glucose in the blood. Type 1 diabetes occurs when the pancreas does not make any insulin. People with type 1 diabetes have to give themselves insulin every day. The most common way to do this is by injections, but insulin pump is an alternative. Regardless of treatment, less than half of Swedish diabetic paediatric patients (patients under 18) are able to bring down the amount of glucose in their blood back down to normal levels. There are clear, age-related differences in blood glucose control. After the diabetic child starts school at 7 years of age, the blood glucose levels tend to increase, and continues to increase more as the child gets older. Teenage girls tend to have the worse glucose control of all age groups. Adolescent patients with diabetes should be able to take more responsibility for management of their own diabetes and not rely on their parents to manage their condition for them. However, how this responsibility is shared in this transition period is often unclear. There is much published support for continued parental involvement and shared responsibility for managing the child's diabetes during adolescence. The relationship between parent and child appears to be important in managing the child's glucose levels. Adolescents who have many diabetes-related conflicts with their parents have higher glucose levels compared with those who have fewer conflicts. Teenagers describe how parental involvement can be helpful or damaging. Person-centred care focuses on seeing a person as an individual rather than simply concentrating on their illness and helps to engage the person as an active partner in his/her own care and treatment. When a child or an adolescent has diabetes the whole family needs to be involved and the parents are often the primary caregivers. Guided self-determination-Young (GSD-Y) is a person-centred reflection model that intends to guide the teenager, while working with their parents and health care professionals to develop the skills necessary to manage difficulties in diabetes self-management by using a structured worksheet. It has proved successful in improving the life skills in teenagers in a Danish study. We want to test whether an intervention (treatment) with Guided Self Determination Young (GSD-Y), in female adolescents and their parents, leads to improved blood glucose control, self-management, treatment satisfaction, perceived health and quality of life, fewer diabetes-

related family conflicts and improved psychosocial self-efficacy (their own belief in managing the effects of living with diabetes). The reason we have chosen female adolescents is that they have more difficulty in controlling their blood glucose levels than males.

Who can participate?
Female diabetics aged between 15-20 and their parents. All participants must not have any problems understanding Swedish.

What does the study involve?
Participants are randomly allocated into one of two groups. Those in group 1 (control) are given their standard care and visit a diabetes nurse or physician every two to three months. Those in group 2 (treatment) are given standard care and also receive seven individual GSD-Y education visits of between an hour and 90 minutes in length. These visits are with a diabetes nurse, dietician or a physician and occur over six to eight month period.

What are the possible benefits and risks of participating?
Participants in the treatment group will receive an education that hopefully leads to improved glucose control, self-management, treatment satisfaction and quality of life, fewer diabetes-related family conflicts and improved psychosocial self-efficacy. The study is not associated with any known increased risks. However, it is possible that patients participating in the study feel that they are more reminded of their illness.

Where is the study run from?
Sachs´Children and Youths Hospital, Söderjukhuset, Stockholm (Sweden)

When is study starting and how long is it expected to run for?
January 2015 to December 2022

Who is funding the study?
1. Södersjukhuset and Karolinska Institute (Sweden)
2. Diabetes foundation (Sweden)
3. Child Diabetes foundation (Sweden)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A randomized controlled trial and a qualitative interview study of an empowerment intervention (Guided Self-Determination - Young) for female adolescents with diabetes, evaluating glycemic control and perceived health and quality of life, compared with usual care

Acronym
GSD-Y females

Study objectives
An intervention with guided self-determination-Young may decrease negative impact of diabetes, improve glycemic control and perceived health and quality of life among young females with diabetes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical review board in Stockholm, 03/12/2014, ref: 2014/1942-31-2

Study design
A mixed methods study including an open randomized controlled intervention study and a qualitative interview study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in English

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

Interventions
In addition to standard care the intervention group will receive seven individual Guided Self-Determination-Young (GSD-Y) education visits (1-1.5 h) with a diabetes nurse, dietician or a physician over six to eight months. The facilitator has got specific education during 40 hours regarding the current method. The GSD-Y method implies that the participant works with structured reflection sheets. Prior to each visit the participant is supposed to have filled in a reflection sheet. By filling in the reflection sheet using their own words and drawings, adolescents and their parents systematically explore and express their own experiences and difficulties with diabetes in daily life. In the dialogue, between the participant and the facilitator, the facilitator uses different communication models, including mirroring, active listening and value-clarifying responses. The control group will receive standard care, and are called for visits to the diabetes nurse or the physician on the unit, every second to third month.

Intervention Type
Behavioural

Primary outcome measure
Current primary outcome measure as of 04/01/2022:
Glycemic control assessed using HbA1c measured at baseline and after 6 and 12 months

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Previous primary outcome measure:
Glycemic control, measured with HbA1c

Outcome will be measured at baseline and after 6, 12 and 24 months

Secondary outcome measures

Current secondary outcome measures as of 04/01/2022:
1. Self-management assessed using mean frequency of self-monitoring of blood glucose (SMBG)
2. Treatment satisfaction assessed using DTSQ Teen and Parent
3. Perceived health and quality of life assessed using Check your health
4. Diabetes-related family conflicts assessed using Diabetes Family Conflict Scale (DFCS)
5. Psychosocial self-efficacy assessed using Swedish Diabetes Empowerment Scale (Swe-DES 23)

All outcomes will be measured at baseline and after 6 and 12 months

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Previous secondary outcome measures:
1. Self-management: mean frequency of self-monitoring of blood glucose (SMBG)
2. Treatment satisfaction: DTSQ Teen and Parent
3. Perceived health and quality of life: Check your health,
4. Diabetes-related family conflicts: Diabetes Family Conflict Scale (DFCS)
5. Psychosocial self-efficacy: Swedish Diabetes Empowerment Scale (Swe-DES 23)

All outcomes will be measured at baseline and after 6, 12 and 24 months

Overall study start date
01/09/2014

Completion date
31/12/2022

Eligibility

Key inclusion criteria
Female adolescents with diabetes

Participant type(s)
Patient

Age group
Mixed

Lower age limit
15 Years

Upper age limit
20 Years

Sex
Female

Target number of participants
100

Key exclusion criteria
Difficulties understanding Swedish

Date of first enrolment
01/05/2017

Date of final enrolment
31/12/2021

Locations

Countries of recruitment
Sweden

Study participating centre
Sachs' children and youths hospital
Södersjukhuset
Stockholm
Sweden
118 83

Sponsor information

Organisation
Karolinska Institute / Södersjukhuset

Sponsor details
Sachs' children and youths hospital
Södersjukhuset
Stockholm
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Sponsor type
Not defined

ROR
https://ror.org/056d84691

Funder(s)

Funder type
Charity

Funder Name

Children Diabetes Foundation (Sweden)

Funder Name
Diabetes foundation (Sweden)

Results and Publications

Publication and dissemination plan
Currrent publication and dissemination plan as of 16/12/2020:
We have published a study protocol in Trials in 2017. The results will be published in scientific journals
and presented at different conferences.

Previous publication and dissemination plan:
We intend to publish a study protocol in BMC pediatrics during spring 2015. The results will be published in scientific journals and presented at different conferences.

Intention to publish date
31/05/2024

Individual participant data (IPD) sharing plan
Due to ethical reasons we can't share participant-level data.

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	24/11/2017		Yes	No