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Using a novel, structured, group-based intervention and Facebook support to increase the wellbeing of adolescents with diabetes

Submission date
23/10/2012

Recruitment status
No longer recruiting

Registration date
14/01/2013

Overall study status
Completed

Last Edited
10/08/2020

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Adherence to diabetes management regimens has been found to be particularly poor during adolescence. One factor that has been found to be a good predictor of adherence at this age is self-efficacy, which is an adolescents confidence in their ability to carry out the tasks involved in good diabetes management. Interventions (treatments) aimed at increasing the adherence of adolescents have tended to focus on factors that increase self-efficacy. However, these interventions tend to be costly, requiring significant time input from members of a diabetes team. In addition, any improvements in adherence are often small and short-lived.
This study aims to use a novel, structured, group-based intervention to increase the self-efficacy of adolescents by strengthening three of the adolescents support networks: their caregivers, their healthcare providers and their diabetic peers. In addition, a social network site (i.e. Facebook) will be used to help maintain the support networks after the intervention has ended. It is believed that the increase in self-efficacy will increase adherence, resulting in fewer complications and better quality of life. The intervention will be designed so that it can be run in other diabetes centres by any member of a diabetes team.

Who can participate?
Adolescent male and females between the ages of twelve and eighteen with Type 1 Diabetes Mellitus attending the diabetes unit at Our Ladys Childrens Hospital, Crumlin.

What does the study involve?
Participants will be randomly allocated into treatment and control conditions. Those in the control condition will attend their regular three monthly diabetes clinic appointments as normal. Those in the treatment condition, as well as attending their regular three monthly diabetes clinic appointments, will attend eight structured adolescent group-based sessions lasting one-hour each. The sessions will be run over a twelve-week period, with weekly sessions for the first four weeks followed by fortnightly sessions for the subsequent eight weeks. The groups will contain six to eight adolescents of the same gender and of similar age. The sessions, as well as demonstrating how to use a specially created private secure Facebook page, will focus on strategies to help adolescents utilise the support of diabetes team members, parents and other

members of the group to better manage their diabetes.
There will also be three separate parent sessions of one-hours duration each occurring at four-week intervals. These sessions will look at how parents can best support adolescents in implementing the strategies learned in the group sessions.
Participants and their parents in both the treatment and control conditions will be asked to complete questionnaires at their routine clinic visits that look at adolescent wellbeing. We will also look at the glycated haemoglobin (HbA1C) readings that are measured at routine clinic visits. At the end of the study, we will compare the HbA1c readings and the questionnaire responses of the treatment condition with the control condition.

What are the possible benefits and risks of participating?
Participants in the treatment group will be provided with the opportunity to communicate with peers with diabetes on a closed secure page of a social network site (i.e. Facebook). This opens the possibility of participants bullying other participants by means of the social network site (i.e. cyber bullying) and of participants making inappropriate disclosures within the secure page of the social network site. In order to address these concerns ground rules for using the social network site will be discussed with all treatment group participants and public communications within the secure page of the social network site will be monitored by the researchers.
By taking part in the study there are no risks of physical injury or harm. All participants (both treatment and control) will complete a number of questionnaires exploring their psychological wellbeing. These questionnaires will be scored by a Senior Clinical Psychologist. If any participant's responses indicate a concern with regard to their psychological wellbeing this will be followed up by the psychologist to ensure that the necessary professionals and agencies are informed and all risk to the participant is minimised.

Where is the study run from?
The study is being run from the diabetes unit at Our Ladys Childrens Hospital, Crumlin.

When is the study starting and how long is it expected to run?
The study started in November 2012 and is expected to run until May 2015.

Who is funding the study?
The study is being funded by the National Childrens Research Centre.

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Adolescent Support Systems Increasing Self-efficacy Trial - Comparing a novel, structured group-based intervention with social network website support to standard clinical care on the physiological and psychological wellbeing of adolescents with Type 1 Diabetes

Acronym
ASSIST

Study objectives
Using a novel, structured, group-based intervention to increase the perception, availability and utilisation of parent, healthcare provider and diabetic peer support will increase self-efficacy resulting in a decrease in HbA1c and an increase in Quality of Life

Ethics approval required
Old ethics approval format

Ethics approval(s)
Our Lady's Children's Hospital Ethics Committee, Ireland, 15 March 2012, ref: GEN/259/12

Study design
Randomised controlled trial with 12-month follow up

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)

Quality of life

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 1 Diabetes

Interventions
1. All eligible participants and their parents will be posted information outlining the proposed study and inviting them to take part. Participants can withdraw from the study at any point.
2. All participants will be placed into one of four demographic groups depending on their gender and whether or not they are in the junior or senior cycle of their secondary school placement. Participants have been divided into these demographic categories to make the groups more homogeneous in order to facilitate group interaction.
3. Participants in each of the four demographic groups will then be assigned to a block of 12 individuals. Once a block is filled, an envelope containing random assignments for treatment or control will be opened, and participants in that block will be assigned to the respective group. This process will be repeated until the required sample size is achieved.
4. On commencement participants and their parents will complete the baseline questionnaires and HbA1c will be recorded. HbA1c measures will be acquired during the course of routine medical work-up in the clinic.
5. Participants in the control groups will receive intervention as per normal (i.e. three monthly clinic visits and intra-clinic visits if control is poor as per routine diabetes team decision making).
6. The intervention consists of eight structured adolescent group-based sessions lasting one hour each. The experimenter will run the sessions over a twelve-week period with weekly sessions for the first four weeks followed by fortnightly sessions for the subsequent eight weeks. Adolescent sessions will use a combination of different evidence-based techniques to increase the perception availability and utilisation of the three support networks, including cognitive restructuring, persuasive communication, collaborative goal setting and the social process of encouragement. These techniques are generalisable and can be implemented by all members of a diabetes team. Adolescents will also be educated on the use of the social network site to facilitate communication with diabetic peers and members of the diabetes team.
7. There will be three hour-long parent sessions occurring once every four weeks for the duration of the intervention. Parent sessions will focus on using collaborative as opposed to critical approaches to support diabetes management.
8. There will be a single hour-long session with the diabetes team that will focus on patient centred communication and collaborative goal setting.
9. The baseline questionnaires and HbA1c will be recorded again at the end of the twelve-week intervention period. They will then continue to be recorded every three months post intervention at the adolescents regular diabetes clinic appointment for twelve months post intervention.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure

Difference between the treatment and control conditions in Glycated Hemoglobin (HbA1c) expressed in mmol/mol and quality of life as measured by the Pediatric Quality of Life questionnaire

Secondary outcome measures
Difference between the treatment and control conditions on physiological and psychological wellbeing using the following questionnaires:
1. Self-Efficacy for Diabetes Scale
2. Illness Perceptions Questionnaire
3. Self-Care Inventory
4. Hospital Anxiety and Depression Scale
5. Diabetes Family Responsibility Questionnaire
6. Healthcare Climate Questionnaire
7. Collaborative Parental Involvement Scale for Youths with Type 1 Diabetes
8. Perceived Competence for Diabetes Scale
9. Diabetes Family Conflict Scale.
10. Measure of Adolescents Attitude Towards Effectiveness of Peer Support
11. Measure of Frequency of Utilisation of Peer Support
12. Measure of Frequency of Utilisation of Clinical Team Support

Overall study start date
01/11/2012

Completion date
31/05/2015

Eligibility

Key inclusion criteria
1. Age >12 years and <19 years with a diagnosis of Type 1 Diabetes >12 months
2. Attending the diabetes unit at Our Lady's Children's Hospital, Crumlin
3. Willing to be assigned to any of the study treatment groups

Participant type(s)
Patient

Age group
Child

Lower age limit
12 Years

Upper age limit
19 Years

Sex
Both

Target number of participants
48

Key exclusion criteria
Residing a distance from Our Lady's Children's Hospital, Crumlin that makes it impractical for them to commute to the hospital on a weekly basis

Date of first enrolment
01/11/2012

Date of final enrolment
31/05/2015

Locations

Countries of recruitment
Ireland

Study participating centre
Diabetes & Endocrinology Unit
Dublin
Ireland
12

Sponsor information

Organisation
National Children's Research Centre (Ireland)

Sponsor details
Our Lady's Children's Hospital
Crumlin
Dublin
Ireland
12
+353 (01) 4096419 or 6585
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Sponsor type
Research organisation

Website
http://www.nationalchildrensresearchcentre.ie/

ROR
https://ror.org/02typaz40

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
National Children's Research Centre - Our Lady's Children's Hospital (Ireland)

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