

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

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 14/01/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 10/08/2020	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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-hour 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 Lady's Children's 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 Children's Research Centre.

Who is the main contact?

Vincent Mc Darby

vincentmcdarby@hotmail.com

## Contact information

### Type(s)

Scientific

### Contact name

Dr Declan Cody

### 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**

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

info@nationalchildrensresearchcentre.ie

**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