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A novel approach to improving health outcomes among young adults with type 1 diabetes

Submission date
09/08/2019

Recruitment status
No longer recruiting

Registration date
12/11/2019

Overall study status
Completed

Last Edited
14/03/2022

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
Traditional diabetes care methods may not be the most appropriate for supporting young adults' self-management of type 1 diabetes (T1D). Previous research has shown that often during this period of transition, young adults are at a high risk of disengaging from services that no longer suit their needs. With that, the 'D1 Now' intervention has been developed by a research team based in NUI Galway. It aims to improve outcomes among young adults (18-25 years) with T1D.

The aim of this study is to test if the D1 Now study is feasible and acceptable among young adults with T1D and Diabetes staff. In addition, the results of this study will inform a large scale study of D1 Now.

Who can participate?
Participants include, young adults and Diabetes centre staff. To be eligible, young adults must be aged 18-25 years and have a definite diagnosis of T1D for more than 1 year.

What does the study involve?
Intervention (or 'D1 Now') hospitals
If your hospital is one of those allocated to the intervention, you will be invited to take part in the D1 Now intervention.

What is the D1 Now intervention?
The D1 Now intervention comprises three components which will span 3 young adult clinic appointments during a 12 month period. They are as follows:
1. Interactive Messaging System-Florence
Florence or "Flo" is an SMS texting system that presents an easy-to-use, friendly interface for young adults and clinicians. The system operates by responding to health information sent and received by SMS from young adults.

2. The Agenda Setting Tool
The second intervention component is an agenda-setting tool (namely, the T1C tool) that you will use before and within consultations.

3. The Support-Worker
The support worker will act as an additional member of the existing diabetes team. They will have responsibility for coordinating Florence and use of the agenda-setting tool and improve continuity by acting as a liaison between you and the clinic.

Usual care hospitals
If your hospital is one of those allocated to usual care, you will continue with your routine diabetes service over 12 months.

Data collection
We will ask you to fill in questionnaires on the physical, mental and financial aspects of having diabetes. After 12 months we will ask you to take part in a group or one-one interview about your experiences with either using the D1 Now intervention or usual diabetes care.

What are the possible benefits and risks of participating?
Taking part in this study may give you a chance to express your opinions as a young adult with Type 1 Diabetes. By expressing your opinions, you are providing information that this research team will study to develop ideas which may improve services and resources for young adults with Type 1 Diabetes.

There are very few risks with this study. One risk that we have identified is that data may go missing when we bring it from the diabetes clinic to NUI Galway. It is very unlikely that this will happen as all our researchers will take the utmost care with any study materials. If this was to happen, your personal data would not be at risk as any data that leaves the diabetes clinic will be anonymised.

Where is the study run from?
The study is being run in 4 hospitals sites in Dublin and one in Belfast.

When is the study starting and how long is it expected to run for?
The study will begin in October 2019 and run until December 2020.

Who is funding the study?
The Health Research Board (HRB) in Ireland.

Who is the main contact?
Dr Eimear Morrissey, eimear.morrissey@nuigalway.ie
(updated 06/01/2021, previously: Dr Blathin Casey, blathin.casey@nuigalway.ie)

Study website
http://www.d1now.ie

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Improving outcomes among young adults with type 1 diabetes: The D1 Now pilot RCT

Acronym
D1 Now

Study objectives
The aim of the D1 Now pilot RCT is to gather and analyse acceptability and feasibility data that will allow for (1) the refinement of the intervention, and (2) the development of a definitive cluster RCT protocol to test the effectiveness of this intervention.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 15/07/2019, the Beaumont Hospital Ethics (Medical Research) Committee (Ethics (Medical Research) Committee, Beaumont Hospital, Beaumont Road, Dublin 9, Ireland; beaumontethics@rcsi.com; 0035318092680), ref: 15/07/2019
2. Approved 19/08/2019, the Research Ethics Committee (REC) of St. Vincent's Healthcare Group (SVHG) (Ethics Department, Education Research Centre, St. Vincent's University Hospital, Elm Park, Dublin 4; sue.canny@ucd.ie or jacinta.mcmanus@ucd.ie; 0035312214117)
3. Approved 19/09/2019, Tallaght University Hospital / St. James's Hospital Joint Research Ethics (Research Ethics Committee, Tallaght University Hospital, Tallaght, Dublin 24;

ResearchEthics@tuh.ie/ Sadhbh.ONeill@tuh.ie; 0035314142199)
4. Approved 10/10/2019, East Midlands - Leicester Central Research Ethics Committee (East Midlands - Leicester Central Research Ethics Committee, Devonshire Place, 78 London Road, Leicester, LE2 0RA; NRESCommittee.EastMidlands-LeicesterCentral@nhs.net; 0207 104 8107, 0207 104 8108)

Study design
Cluster randomised pilot study

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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

Interventions
The D1 Now intervention comprises three components:
1. Interactive Messaging System-Florence
Florence or “Flo” is a SMS texting system that presents an easy-to-use, friendly interface for patients and clinicians. The system operates by responding to health information sent and received by SMS from the patient. The T1D Florence messaging system in this study sends reminders and asks questions about 4 topics: 1) alcohol intake, 2) motivation/support, 3) blood glucose monitoring and 4) ketone/sick days.

2. The Agenda Setting Tool
The second intervention component is an agenda setting tool (namely, the T1C tool) that is used by the young adult before and within consultations and aims to improve the patient-clinician relationship and enhance shared decision-making. The T1C tool provides a holistic approach to care planning, bringing together a measure for psychological wellbeing (diabetes distress) as well as clinical results (HbA1c and a hypo awareness score). It enables the clinician to plot the results on a circular chart which prompts consideration of the relationship between the three measures. The tool has 2 parts, the first is completed by the young adult in the waiting room and the second is completed with the clinician(s).

3. The Support-Worker
The support worker will act as an additional member of the existing diabetes team. They will have responsibility for coordinating Florence and use of the agenda setting tool and improve continuity by acting as a liaison between the young adult and the clinic.

The incorporation of the Support-Worker into the team will be assessed in two ways – 1) external and 2) internal. The external Support-Worker will be hired for the purpose of the trial and will be embedded in one intervention site to join the existing diabetes team. The internal Support-Worker will be a member of the existing team. This person, a nurse/doctor/dietician /psychologist, will be upskilled on the role of the Support-Worker by the research team and provided support by the external Support-Worker.

Together, the 3 intervention components (i.e. the D1 Now Intervention) will be delivered and assessed over a 12 month period by participating patients and Diabetes Centre staff. At a minimum, patients will have 3 clinic appointments spread over this 12 month period in which they will use the D1 Now intervention.

In this study, we have 2 intervention 'arms' and one control arm. The 2 intervention arms are 1) The D1 Now intervention with an external Support Worker and 2) the D1 Now intervention with an internal Support Worker. The control arm is a 'usual care' control.

The internal Support Worker arm will be a member of the existing Diabetes team. This person, a nurse/doctor/dietitian/psychologist, will be up-skilled on the role of the Support-Worker by the research team and provided support by the Support-Worker in the 'External' intervention arm. The external Support Worker will be hired for the purposes of this study and join an already existing Diabetes team.

Duration of treatment in each intervention arm is 12 months with outcomes measured at baseline (month 0) and month (12). The randomisation process was completed by an independent statistician prior to recruitment to the trial.

Intervention Type
Behavioural

Primary outcome measure
1. Recruitment of diabetes centres is measured using documentation of the number of invitations sent, the number of refusals and number of acceptances at beginning of the trial.
2. Recruitment of patients is measured using documentation of the number of invitations sent, the number of initial responses, the number of follow-up phone-calls required, the number of refusals and the number of acceptances at the beginning of the trial.
3. Attrition is measured using the number of participants who consent to participate and who remain in the study until the end of follow up at 12 months.
4. Missing data in returned questionnaires is measured at month 0 and month 12.
5. The comprehensibility and acceptability of all questionnaires is measured by asking participants; how the questionnaires might be improved, and how long they took to complete at month 0 and month 12.

Secondary outcome measures
1. Glycated Haemoglobin (HbA1c) is measured using laboratory HbA1C at month 0 and month 12.
2. Diabetes Related Distress is measured using the Problem Areas in Diabetes-11 (PAID-11) at month 0 and month 12.
3. Diabetes Related Quality of Life is measured using the Audit of Diabetes Dependent Quality of life (ADDQOL) at month 0 and month 12.
4. Self-Management is measured using Diabetes Self-Management Questionnaire (DSMQ) at month 0 and month 12.
5. Level of Clinic Engagement is measured using clinic attendance and will be obtained from the

clinic administration system at month 0 and month 12.
6. Perceived Level of Control is measured using the Diabetes Empowerment Scale – Short Form (DES-SF) at month 0 and month 12.
7. Number of Instances of Diabetes Ketoacidosis is measured using the definition ‘an episode of hyperglycaemia, ketoacidosis and ketonuria requiring hospital admission and care’ and this will be obtained from both the medical notes and through self-report at month 0 and 12.
8. Number of Instances of Severe Hypoglycaemia is measured using the definition ‘an episode of hypoglycaemia that requires assistance from another person to treat’ and this will be obtained through self-report at month 0 and 12.
9. Cost-effectiveness is measured using a bespoke questionnaire developed by the D1 Now study team and the EQ-5D-5L at month 0 and month 12.

Overall study start date
01/04/2017

Completion date
31/01/2021

Eligibility

Key inclusion criteria
1. Physician confirmed diagnosis of T1D for more than 12 months.
2. Age between 18-25 years on the date of recruitment.
3. Access to a mobile phone device.

Participant type(s)
Patient

Age group
Other

Lower age limit
18 Years

Upper age limit
25 Years

Sex
Both

Target number of participants
100

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
19/08/2019

Date of final enrolment

31/12/2019

Locations

Countries of recruitment
Ireland

Northern Ireland

United Kingdom

Study participating centre
Diabetes Centre, Beaumont Hospital
Beaumont Road, Dublin 9.
Dublin
Ireland
N/A

Study participating centre
Diabetes Day Centre, St Vincent's University Hospital.
196 Merrion Road, Elm Park, Dublin 4.
Dublin
Ireland
N/A

Study participating centre
Diabetes Centre, St Columcille's Hospital
Loughlinstown, Dublin 18.
Dublin
Ireland
N/A

Study participating centre
Diabetes Centre, Tallaght University Hospital
The Simms Building, Tallaght Cross West, Dublin 24
Dublin
Ireland
N/A

Study participating centre

Diabetes Centre Royal Victoria Hospital
274 Grosvenor Rd, Belfast BT12 6BA, UK.
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Sponsor information

Organisation
NUI Galway

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Sponsor type
University/education

ROR
https://ror.org/03bea9k73

Funder(s)

Funder type
Government

Funder Name
Health Research Board

Alternative Name(s)
Health Research Board, Ireland, An Bord Taighde Sláinte, HRB

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Ireland

Results and Publications

Publication and dissemination plan
The trial protocol and the results of the trial (including qualitative and health economic sub-studies) will be published in a peer-reviewed journal. Open access publications will be favoured to ensure timely dissemination of findings.

Intention to publish date
01/06/2021

Individual participant data (IPD) sharing plan
Current IPD sharing statement as of 23/07/2020:
Data will be managed and stored at the School of Medicine at NUI Galway led by programme manager Dr Eimear Morrissey (eimear.morrissey@nuigalway.ie). Data will be a combination of patient self-report data and data from medical records (e.g HbA1c). Data will be available from first patient recruitment and stored indefinitely on password protected data management software. The data management software is password protected and any attempt to break into the data will be alerted to the data controllers. In addition, the software will provide updates and store information when someone has either consulted, altered, disclosed or erased data to make it known to the research team. All data will be pseudo-anonymised and all participants will have provided consent. Data will be analysed only for the aims of this study and completed by the D1 Now research team at NUI Galway with the programme manager acting as gate-keeper to the data from the protected software package.

Previous IPD sharing statement
Data will be managed and stored by the Clinical Research Facility (CRF) at NUI Galway led by senior data manager Mary Byrne (mary.m.byrne@nuigalway.ie). Data will be a combination of patient self-report data and data from medical records (e.g HbA1c). Data will be available from first patient recruitment and stored indefinitely in the CRF data management software. The data management software is password protected and any attempt to break into the data will be alerted to the data controllers. In addition, the software will provide updates and store information when someone has either consulted, altered, disclosed or erased data to make it known to the research team. All data will be pseudo-anonymised and all participants will have provided consent. Data will be analysed only for the aims of this study and completed by the D1 Now research team at NUI Galway with the CRF acting as gate-keepers to the data from their protected software package.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/09/2020	06/01/2021	Yes	No
Results article		08/03/2022	14/03/2022	Yes	No