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

Submission date
11/02/2025

Recruitment status
Recruiting

Registration date
17/02/2025

Overall study status
Ongoing

Last Edited
17/02/2025

Condition category
Nutritional, Metabolic, Endocrine

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

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. Since 2014, our research team and the Young Adult Panel (YAP) have worked together to develop a new intervention that can be used in clinic appointments. This intervention is called 'D1 Now'.
The aim of this study is to test if the D1 Now intervention could improve outcomes relating to diabetes and quality of life.

Who can participate?
Young adults aged 18-25 years who have had 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 for 1 year.
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. We will ask you to visit your local clinic lab and provide a blood sample for HBA1c measurement at the beginning and end of the study. We will ask you to fill in questionnaires on the physical, mental and financial aspects of having diabetes at the beginning and end of the study. After 12 months we will ask you to take part in a group or one-to-one interview about your experiences with either using the D1 Now intervention or usual diabetes care.
D1 Now has two parts.
1. Agenda Setting Tool - a shared decision-making tool used by young adults and healthcare professionals to identify topics to discuss during clinic visits.
2. Support Worker - an advocate for young adults who is available at every clinic appointment and can be contacted in between appointments.

What are the possible benefits and risks of participating?
Taking part in this study may help young adults with type 1 diabetes (T1D) feel more supported

in managing their condition. If your hospital is in the intervention group, you will have access to the D1 Now intervention, which includes an Agenda Setting Tool to help guide discussions during clinic visits and a Support Worker to offer additional support between appointments. This may improve how you engage with your diabetes care team and help tailor your clinic visits to focus on what matters most to you. Even if your hospital is in the usual care group, your participation will help improve diabetes care for young adults in the future. This study aims to make diabetes care more young-person-centred, and your input will help shape better healthcare experiences for people with T1D in the future. Risks: There are no major risks to taking part in this study. Providing a blood sample for HbA1c measurement is a routine procedure and may cause slight discomfort. Answering questionnaires or participating in interviews may take some time, and some questions about your diabetes experience might feel personal. However, you can skip any questions you are uncomfortable with. Your participation is completely voluntary, and you can withdraw at any time without affecting your diabetes care.

Where is the study run from?
The study is being run in 12 young adult diabetes clinics across the Island of Ireland. The coordinating centre is in the Clinical Research Facility Galway

When is the study starting and how long is it expected to run for?
February 2024 to May 2028

Who is funding the study?
The Health Research Board (HRB) in Ireland through its Definitive Intervention and Feasibility Award scheme (DIFA-2023-018)

Who is the main contact?
D1 Now Programme manager (D1now@universityofgalway.ie)

Study website
https://www.d1now.ie

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
DIFA-2023-018

Study information

Scientific Title
The D1 Now Intervention to improve outcomes in young adults living with type 1 diabetes: a definitive cluster randomised controlled trial

Acronym
D1 Now Study

Study objectives
The D1 Now intervention will result in a clinically significant reduction in HbA1c levels over 12 months compared to usual care.

Ethics approval required
Ethics approval required

Ethics approval(s)
Submitted 05/02/2025, HSE Dublin and Midlands Reference REC (HSE Area Office, Arden Road, Tullamore, Co., Offaly, Tullamore, R35 TY28, Ireland; N/A; REC.B.CorporateMidlands@hse.ie), ref: RRECB0125SD

Study design
Two-arm cluster randomized controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
The study website will (in time) include links to all the main study documents: https://d1now.ie/

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

Interventions
The D1 Now Study employs a cluster-randomised controlled trial design, where participating diabetes clinics (clusters) are randomly assigned to either the intervention or control arm. Randomisation (by an independent statistician) occurs at the clinic level rather than the individual participant level to prevent cross-contamination. Due to the staggered recruitment process, clinics will be randomised as they complete regulatory approvals and baseline data collection.

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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. We will ask you to visit your local clinic lab and provide a blood sample for HBA1c measurement at the beginning and end of the study. We will ask you to fill in questionnaires on the physical, mental and financial aspects of having diabetes at the beginning and end of the study. After 12 months we will ask you to take part in a group or one-to-one interview about your experiences with either using the D1 Now intervention or usual diabetes care.

The D1 Now intervention comprises two components:
1. The Agenda Setting Tool
The first intervention component is an agenda-setting tool (namely, the AST 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 AST tool provides a holistic approach to care planning, bringing together a measure for psychological wellbeing (diabetes distress) as well as clinical results (HbA1c). The tool has two parts, the first is completed by the young adult in the waiting room and the second is completed with the clinician(s) during the consultation.
2. The Support-Worker
The support worker will act as an additional member of the existing diabetes team. They will have responsibility for the use of the agenda-setting tool and improve continuity by acting as a liaison between the young adult and the clinic. The support worker will be hired for the purpose of the trial and will be embedded in the intervention sites to join the existing diabetes team. Together, the two 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 three clinic appointments spread over this 12-month period in which they will use the D1 Now intervention.

Intervention Type
Behavioural

Primary outcome measure
Change in blood glucose control measured via a central laboratory HbA1c assay at baseline and at a 12-month follow-up visit

Secondary outcome measures
The effectiveness of the D1 Now intervention on clinical outcomes:
1. Diabetes-related distress is measured using the Problem Areas in Diabetes-11 (PAID-11) at month 0 and month 12
2. Diabetes-related quality of life is measured using the Audit of Diabetes Dependent Quality of life (ADDQOL) at month 0 and month 12
3. Self-management is measured using the Diabetes Self-Management Questionnaire (DSMQ) at month 0 and month 12
4. Level of clinic engagement is measured using clinic attendance and obtained from the clinic administration system at month 0 and month 12
5. Perceived level of control is measured using the Diabetes Empowerment Scale – Short Form (DES-SF) at month 0 and month 12
6. The number of instances of diabetic ketoacidosis (DKA) over the previous 12 months is measured using the definition ‘an episode of hyperglycaemia, ketoacidosis and ketonuria requiring hospital admission and care’ and obtained from both the medical notes and through self-report at month 0 and 12
7. The number of instances of severe hypoglycaemia over the previous 12 months is measured using the definition ‘an episode of hypoglycaemia that requires assistance from another person to treat’ and obtained through self-report at months 0 and 12
8. The frequency of stigmatising experiences among young adults with Type 1 diabetes measured using the Diabetes Stigma Assessment Scale (DSAS-1) at months 0 and 12
9. A process evaluation to examine the implementation and delivery of the D1 Now intervention and the overall trial processes at 12 months
10. The mechanisms of impact are assessed using a bespoke questionnaire developed by the D1 Now study team at month 0 and month 12
11. Participants' perceptions and experiences with the D1 Now intervention and usual care explored through semi-structured interviews with participants and staff at 12 months
12. The cost-effectiveness of the D1 Now intervention through a detailed health economic analysis, comparing it to usual care in terms of resource utilisation and quality-adjusted life years (QALYs). 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
14/02/2024

Completion date
30/05/2028

Eligibility

Key inclusion criteria
1. Willing and able to provide written informed consent
2. Currently registered to the outpatient diabetes clinic at a participating centre
3. Individuals with a confirmed diagnosis of type 1 diabetes for more than 12 months
4. Individuals aged 18 through 25 years at the time of recruitment

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
25 Years

Sex
Both

Target number of participants
348

Key exclusion criteria
1. Individuals who participated in the D1 Now pilot RCT
2. Individuals who are pregnant/planning to become pregnant during the intervention period
3. Individuals who are unable to communicate in English
4. Individuals who were or are currently members of the D1 Now Young Adult Panel

Date of first enrolment
01/05/2025

Date of final enrolment
01/07/2026

Locations

Countries of recruitment
Ireland

Northern Ireland

Study participating centre
Galway University Hospitals
Newcastle Road
Galway
Ireland
H91 TK33

Sponsor information

Organisation
Ollscoil na Gaillimhe – University of Galway

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Sponsor type
University/education

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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 process evaluation, 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
01/08/2028

Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date