

# A trial to ascertain if providing a structured education programme on managing type 2 diabetes and maintaining a healthier lifestyle helps people with intellectual disabilities manage their blood sugar levels

<b>Submission date</b>	<b>Recruitment status</b>	<input checked="" type="checkbox"/> Prospectively registered
26/10/2022	No longer recruiting	<input checked="" type="checkbox"/> Protocol
<b>Registration date</b>	<b>Overall study status</b>	<input type="checkbox"/> Statistical analysis plan
09/11/2022	Ongoing	<input type="checkbox"/> Results
<b>Last Edited</b>	<b>Condition category</b>	<input type="checkbox"/> Individual participant data
07/01/2026	Nutritional, Metabolic, Endocrine	<input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

We want to find the best way to help people with a learning or intellectual disability who have Type 2 diabetes. We will test whether providing some structured education around managing their diabetes and maintaining healthier lifestyles (diet, exercise) helps people with intellectual disabilities manage their blood sugar and stay healthier in the future.

People with intellectual disabilities are more likely to develop Type 2 Diabetes. They tend to develop it at a younger age and are less likely to have access to appropriate support that would help them manage the condition. This may make it more likely that they will have other health problems, such as heart or kidney disease and strokes, and die younger.

We have developed an education programme called DESMOND-ID, which is about diabetes and is suitable for adults with intellectual disabilities and their carers/partners/advocates. The programme lasts 7 weeks, two and a half hours per week, followed by two booster sessions at 3 and 5 months. The adult with intellectual disability and their carer/partner/advocate are encouraged to attend together. The programme supports people to better manage their diabetes. We have already done a small study which showed that the programme can be delivered and is acceptable to service users and carers. We now need to do a larger research study to find out if our programme brings about health benefits for adults with intellectual disabilities who have Type 2 Diabetes. For example, we want to see the effects on people's diets, physical activity and diabetes control (blood sugar). To test the programme, we will conduct a randomised trial.

### Who can participate?

Adults with intellectual disabilities who have Type 2 diabetes from Northern Ireland, Scotland and England (Leicestershire)

## What does the study involve?

Half of the participants will be randomly chosen to receive the diabetes education (DESMOND-ID) while the others continue with their usual care. We will measure everyone's blood sugar (HbA1c) when they are recruited and twice more later in the study. We will then compare the results for the people allocated to the programme and those in the control group. We also compare other things between the groups, such as blood pressure, cholesterol, weight, and health and well-being measures; and carry out an economic evaluation to see if DESMOND-ID is good value for money. Our study has two stages and will last 4 years. The first stage will be a pilot trial to check that enough people will join the study. If successful, we will move to the second stage, the main trial.

Patient and public involvement: CAN, a local intellectual disability charity in Northern Ireland, has already helped us to develop this proposal. We also did a survey with 38 adults with intellectual disabilities and Type 2 Diabetes and used their answers to design the study. We are grateful for their committed and ongoing support. We will continue to work closely with our PPI stakeholders (CAN, Diabetes UK, Mencap).

## What are the possible benefits and risks of participating?

People with intellectual disabilities are more likely to develop Type 2 diabetes. They tend to develop it at a younger age and are less likely to have access to appropriate support that would help them to manage the condition such as structured education. This may make it more likely that they will have other health problems, such as heart or kidney disease and strokes, and die younger. Between 2015-17 we adapted a national Type 2 diabetes self-management education programme called DESMOND for adults with intellectual disabilities and their carers/partners /advocates, we called this DESMOND-ID. The programme lasts 7 weeks, two and a half hours per week, followed by two booster sessions at 1 and 3 months. The adult with intellectual disability and their carer/partner/advocate are encouraged to attend together. The programme is delivered by two educators, such as health professionals and a lay educator and is delivered in a day centre or health centre. The programme supports people to better manage their diabetes. We have already completed a feasibility randomised controlled trial with 39 adults with intellectual disability and Type 2 diabetes, which showed that the programme can be delivered and is acceptable to service users and carers. We now need to do a larger research study to find out if our programme brings about health benefits for adults with intellectual disabilities who have Type 2 Diabetes. For example, we want to see the effects on people's diets, physical activity, and diabetes control (blood sugar).

This is a low-risk study. There is the potential burden for the person with ID with regard to gathering the blood and the baseline data and at each follow-up point. This has been explored with our ID partners and we have reduced the data being collected and developed user-friendly versions of the questionnaires. Our clinical research nurses and research associates will be experienced in communicating with participants with ID. As all the potential participants will have Type 2 diabetes and would routinely 1-2 times per year, have blood taken by their GP /Practice Nurse/Diabetes Specialist Nurse, we do not see the taking of blood samples causing any distress. Our clinical research nurses will be experienced in taking blood samples from adults with ID. We are asking, where possible, the person with ID to attend the education programme together with a family member, carer, partner, or friend. However, we have been informed by our ID partners that some participants may not want to bring anyone with them or have anyone to accompany them. Therefore, this will not be an exclusion criterion and prevent any potential distress.

## Where is the study run from?

Queen's University Belfast (QUB) (UK)

When is the study starting and how long is it expected to run for?

September 2020 to June 2026

Who is funding the study?

National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?

Pauline McElhill, DESMOND-ID@NICTU.hscni.net

## Contact information

**Type(s)**

Public

**Contact name**

Ms Pauline McElhill

**Contact details**

Northern Ireland Clinical Trials Unit

7 Lennoxvale

Belfast

United Kingdom

BT9 5BY

+44 (0)28 961 51447

DESMOND-ID@NICTU.hscni.net

## Additional identifiers

**Clinical Trials Information System (CTIS)**

Nil known

**Integrated Research Application System (IRAS)**

318439

**ClinicalTrials.gov (NCT)**

Nil known

**Protocol serial number**

22/0055, 19/160, NIHR131692

## Study information

**Scientific Title**

The clinical and cost-effectiveness of the Diabetes Education and Self-Management for Ongoing and Newly Diagnosed (DESMOND) programme for adults with Intellectual Disability (ID) and Type 2 Diabetes

**Acronym**

My Diabetes and Me Study

## **Study objectives**

In adults with intellectual disability and Type 2 diabetes, a diabetes education programme structured specifically for individuals with ID and T2D will improve Hb1Ac levels.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Approved 25/10/2022, Office for Research Ethics Committee Northern Ireland (ORECNI) (Business Services Organisation, Lissie Industrial Estate West, 5 Rathdown Walk, Moira Road, Lisburn, BT28 2RF, UK; +44 (0)28 9536 1400; info.orecni@hscni.net), ref: 22/NI/0156

## **Study design**

Two-stage parallel group randomized trial with an internal pilot, economic evaluation and process evaluation

## **Primary study design**

Interventional

## **Study type(s)**

Quality of life

## **Health condition(s) or problem(s) studied**

Type 2 diabetes

## **Interventions**

Design:

This is a two-stage parallel group randomised trial with an internal pilot, economic evaluation, and process evaluation.

In PICO terms:

Population: 450 adults aged  $\geq 18$  years; mild/moderate ID and T2D

Intervention: DESMOND-ID education programme in addition to Treatment As Usual (TAU)

Comparator: TAU

Primary outcome: Change in HbA1c from baseline to 6 months post-randomisation

## **Study timeline and key tasks:**

The total trial duration of the trial will be 45 months, including follow-up at 6 and 12 months after randomisation for all participants and at 18 months after randomisation for those participants recruited to the internal pilot. We will open the first site within 5 months. The internal pilot will run between months 5-14. Following successful confirmation of recruitment rates, the internal pilot will move into the main trial. The total recruitment period will last for 25 months, with a follow-up period of 6 and 12 months for all participants and 18 months for participants recruited into the internal pilot. There will be 3 months at the end for final data analysis, reporting and close down.

## **Study Intervention and Comparator:**

DESMOND-ID is based on a series of psychological theories of learning and education: Leventhal's Common-Sense Theory (i.e. illness representation, illness beliefs), Dual Process Theory (process of learning), and Social Learning Theory (i.e. self-efficacy). The philosophy of the programme was founded on the empowerment of individuals living with diabetes, as evidenced in published

work, and its development followed a systematic approach, guided by the MRC framework for developing and evaluating complex interventions. The DESMOND-ID programme will be delivered face-to-face in a range of community settings over a period of 7 weeks to 6-8 adults with ID and T2D and their carer/partner/advocate in a group setting, with two booster sessions in subsequent months (1 and 3 months). Week 1 of the programme focuses on carers/partners /advocates only with the aim of improving their understanding of T2D and how DESMOND-ID works along with their supporting role.

In weeks 2-6, we encourage the adult with ID and T2D and their carer/partner/advocate to attend together if possible. These weeks focus on introductions to 'My story with T2D', 'My body and T2D', 'What is T2D' and what it does to your body, food and blood sugar. Knowing what your blood sugar levels mean, being active, heart and circulation problems, other T2D health problems, what can I do to keep healthy, food and fats, making healthier food choices and a diabetes health action plan. We adapted the original DESMOND programme by lengthening the programme, simplifying the core concepts, and making greater use of pictorial representations (photos, pictures, symbols). We also made more use of repetitious learning/interactive sessions, placing a stronger focus on developing skills and promoting "self-efficacy" in food choices and increasing physical activity, and the involvement of carers to support the person with ID and T2D, using health action plans and goal setting which are reviewed each week, and emphasising celebration and fun.

The booster sessions will be delivered at 1 and 3 months after the start of the DESMOND-ID programme. Each booster session will also last 2½ hours and will be delivered by the educators. These sessions will explore how each adult with ID and T2D and their carer/partner/advocate are implementing their health action plan and any potential barriers.

Those in the DESMOND-ID group will also receive TAU, ensuring that they do not lose any treatments or care that are standard. Those in the control arm will receive TAU and a service user-friendly book already developed on how to manage T2D. TAU will be established at the start of the study and again at the end of the study. The participants in both the intervention and control groups will complete data gathering instruments at baseline, 6, 12 and 18 months (internal pilot patients only).

#### Assignment of interventions:

**Allocation Concealment Mechanism:** The randomisation sequence will be concealed by using a central or automated randomisation system and a participant's allocation will not be revealed until they have consented to join the trial.

#### Randomisation Procedure:

Once informed consent has been obtained, participants will be randomised via a central or automated randomisation system. Sites will be provided with trial-specific randomisation guidelines. Randomisation will be completed by an appropriately trained and delegated member of the research team. Participants will be allocated to the intervention or standard care. The participants will be randomised using a central or automated web-based or telephone system with a 1:1 allocation ratio.

#### Blinding:

Due to the nature of the intervention, it is not possible to blind the participants to their allocated treatment.

#### Intervention Type

Other

**Primary outcome(s)**

Change in HbA1c from baseline to 6 months post-randomisation measured using blood test

**Key secondary outcome(s)**

1. Change in HbA1c from baseline at 12 months (all participants) and 18 months (Internal Pilot participants only) measured using blood test

At 6 and 12 months (all participants), and at 18 months (Internal Pilot participants only):

2. Metabolic and cardiovascular measures: Lipids (Total cholesterol, Low-density lipoprotein (LDL) cholesterol, High-density lipoprotein (HDL) cholesterol), estimated Glomerular Filtration Rate (eGFR), Diastolic and systolic blood pressure (mmHg); Weight (kg); Body Mass Index (kg/m<sup>2</sup>)

3. Illness perception measured using the Illness Perception Questionnaire Revised (IPQ)

4. Depression measured using the Glasgow Depression Scale

5. Health-related quality of life measured using EQ-5D

6. Health and social care service use and associated costs measured using ModRUM (Modular Resource Use Measure)

7. Intervention costs measured using ModRUM

**Completion date**

01/06/2026

## Eligibility

**Key inclusion criteria**

1. Diagnosed with T2D

2. Aged ≥18 years

3. Mild/moderate ID as confirmed by health professional/medical records

4. Sufficient communication skills to engage in a group education programme

5. Able to give informed consent

6. Living in the community

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Mixed

**Lower age limit**

18 years

**Upper age limit**

100 years

**Sex**

All

**Total final enrolment**

0

**Key exclusion criteria**

1. Type 1 diabetes
2. Severe/profound ID
3. Displaying severe challenging behaviour
4. Acute psychotic illness
5. Lack mental capacity to give consent

**Date of first enrolment**

01/01/2023

**Date of final enrolment**

30/06/2024

## Locations

**Countries of recruitment**

United Kingdom

England

Northern Ireland

Scotland

**Study participating centre**

**NHS Greater Glasgow and Clyde Trust**

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Glasgow  
Scotland  
G12 0XH

**Study participating centre**

**Northern Health & Social Care Trust**

Trust Headquarters  
Bretten Hall  
Bush Road  
Antrim  
Northern Ireland  
BT41 2RL

**Study participating centre**

**Northern Health & Social Care Trust**

Holywell Hospital  
60 Steeple Road  
Antrim  
Northern Ireland  
BT40 2UA

**Study participating centre**

**Western Health & Social Care Trust**

Brooke Lodge  
Lakeview Hospital  
Clooney Road  
Derry  
Northern Ireland  
BT47 6WJ

**Study participating centre**

**Belfast Health & Social Care Trust**

Muckamore Abbey Hospital / Everton Complex  
1 Abbey Rd  
Muckamore  
Antrim  
Northern Ireland  
BT41 4SH

**Study participating centre**

**Southern Health & Social Care Trust**

The Acorns  
Longstone Hospital Site  
73 Loughgall Road  
Armagh  
Northern Ireland  
BT61 7PR

**Study participating centre**

**South Eastern Health and Social Care Trust**

Disability Resource Centre  
Downpatrick  
Northern Ireland  
BT30 9AD

**Study participating centre**  
**University Hospital Leicester**  
Bloom Wing  
Leicester Diabetes Centre  
Leicester General Hospital  
Leicester  
England  
LE5 4PW

**Study participating centre**  
**Hertfordshire Partnership University NHS Foundation Trust**  
Essex and Norfolk  
Little Plumstead Hospital  
Norwich  
England  
NR13 5EW

**Study participating centre**  
**NHS Lanarkshire**  
Netherton House  
University Hospital of Wishaw  
94-104 Netherton Street  
Wishaw  
Scotland  
ML2 0DZ

**Study participating centre**  
**NHS Lothian**  
Clinical Research Facility  
Royal Infirmary of Edinburgh  
51 Little France Crescent  
Edinburgh  
Scotland  
EH16 4SA

**Study participating centre**  
**Greater Glasgow and Clyde**  
College of Medical Veterinary and Life Sciences  
University of Glasgow  
Room 253, level 2  
Clarice Pears Building  
Byres Road  
Glasgow

Scotland  
G12 8TB

## Sponsor information

**Organisation**  
Queen's University Belfast

**ROR**  
<https://ror.org/00hswnk62>

## Funder(s)

**Funder type**  
Government

**Funder Name**  
Health Technology Assessment Programme

**Alternative Name(s)**  
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

**Funding Body Type**  
Government organisation

**Funding Body Subtype**  
National government

**Location**  
United Kingdom

## Results and Publications

### Individual participant data (IPD) sharing plan

The study will comply with the good practice principles for sharing individual participant data from publicly funded clinical trials and data sharing will be undertaken in accordance with the required regulatory requirements. Requests for data sharing will be reviewed on an individual basis by the CI.

Laurence.taggart@qub.ac.uk

### IPD sharing plan summary

Available on request, Published as a supplement to the results publication, Stored in non-publicly available repository

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#"><u>Protocol article</u></a>		06/10/2025	07/01/2026	Yes	No