My Diabetes and Me Study

The clinical and cost-effectiveness of the DESMOND-ID education programme for adults with Intellectual disability and Type 2 Diabetes

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Chief Investigator:	Professor Laurence Taggart Room 05.308, School of Nursing & Midwifery MBC Building 97 Lisburn Road Belfast BT9 7BL

PROTOCOL AUTHORISATION

Protocol Title	The clinical and cost-effectiveness of the DESMOND-ID education programme for adults with Intellectual Disability and Type 2 Diabetes
Protocol Short Title (if applicable)	My Diabetes and Me Study
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A review of the protocol has been completed and is understood and approved by the following:

Laurence Taggart		____ / ____ / ____
Chief Investigator Name	Signature	Date DD/MM/YYY

Cliona McDowell		____ / ____ / ____
Statistician	Signature	Date DD/MM/YYY

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LIST OF ABBREVIATIONS

Abbreviation / Acronym	Full Wording
AE	Adverse Event
AR	Adverse Reaction
BHSCT	Belfast Health & Social Care Trust
BMI	Body Mass Index
CAN	Compass Advocacy Network
CI	Chief Investigator
CONSORT	Consolidated Standards of Reporting Trials
CRF	Case Report Form
CRN	Clinical Research Nurse
CTA	Clinical Trial Authorisations
CTU	Clinical Trials Unit
DMEC	Data Monitoring and Ethics Committee
DESMOND	Diabetes Education and Self-Management for Ongoing and Newly Diagnosed
DMP	Data Management Plan
EQ-5D-Y	EuroQol-5 Dimension-Youth
GCP	Good Clinical Practice
GLMM	Generalised Linear Mixed Model
GP	General Practitioner
HRA	Health Research Authority
HRQoL	Health Related Quality of Life
HTA	Health Technology Assessment
ICH	International Conference of Harmonisation
ICJME	International Committee of Medical Journal Editors
ID	Intellectual Disability
IPQ	Illness Perception Questionnaire
IRAS	Integrated Research Application System
IRB	Institutional Review Board
ISF	Investigator Site File
ISRCTN	International Standard Randomised Controlled Trial Number Register
ModRUM	Modular Research Use Measure
MRC	Medical Research Council
NICE	National Institute for Health and Care Excellence
NICRN	Northern Ireland Clinical Research Network
NICTU	Northern Ireland Clinical Trials Unit
NIHR	National Institute for Health and Care Research
PCRN	Primary Care Research Nurse
PI	Principal Investigator
PIS	Participant Information Sheet
PPI	Personal Public Involvement
QALY	Quality Adjusted Life Year
QRI	QuinTet Recruitment Intervention
QUB	Queen's University Belfast
R&D	Research & Development
RA	Research Associate
REC	Research Ethics Committee
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan

SAR	Serious Adverse Reaction
SDV	Source Data Verification
SOPs	Standard Operating Procedures
SPCRN	Scottish Primary Clinical Research Network
SUSAR	Suspected Unexpected Serious Adverse Reaction
T2D	Type 2 Diabetes
TAU	Treatment As Usual
TMF	Trial Master File
TMG	Trial Management Group
TSC	Trial Steering Committee
WHO	World Health Organisation

1 STUDY SUMMARY

Scientific title	**Full 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 **Short Title:** My Diabetes and Me Study
Public title	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.
Health condition(s) or problem(s) studied	Type 2 Diabetes (T2D) in adults with Intellectual Disability.
Study Design	2-stage parallel group randomised trial with an internal pilot, economic evaluation and process evaluation.
Study Aim and Objectives	**Aim** To determine whether DESMOND-ID improves outcomes and is cost-effective compared to treatment as usual in adults with ID and T2D. **Primary objective** To conduct a UK based, multicentre, randomised control trial to determine the effectiveness of the DESMOND-ID programme on HbA1c levels (primary outcome) and a range of secondary outcomes compared to treatment as usual (TAU). **Secondary objectives** 1. To determine the cost-effectiveness of the DESMOND-ID programme compared to TAU via a within-trial economic evaluation and a long-term model. 2. To determine the facilitators, barriers and mechanisms of actions involved in the DESMOND-ID process via a process evaluation.
Study Intervention	DESMOND-ID Education Programme
Primary Outcome	Change in HbA1c from baseline to 6 months post-randomisation

Key Secondary Outcomes	12 months (all participants) and 18 months (Internal Pilot participants only) • Change in HbA1c from baseline At 6 and 12 months (all participants), and at 18 months (Internal Pilot participants only) • Metabolic and cardiovascular measures • Illness perception • Glasgow Depression Scale • Health related quality of life • Health and social care service use and associated costs • Intervention costs
Key Inclusion and Exclusion Criteria	**Inclusion Criteria:** • Diagnosed with T2D. • Aged ≥18yrs. • Mild/moderate ID as confirmed by health professional/medical records. • Sufficient communication skills to engage in a group education programme * • Able to give informed consent* • Living in the community *Participants should have sufficient English language skills in order to fully consider/give consent and can speak and understand English in order to undertake the programme if allocated to the intervention. **Exclusion Criteria:** • Type 1 Diabetes • Severe/profound ID. • Displaying severe challenging behaviour. • Acute psychotic illness. • Lack mental capacity to give consent.
Countries of Recruitment	England, Scotland and Northern Ireland
Study Setting	Health and Social Care Settings in the Community
Target Sample Size	450
Study Duration	45 Months

2 STUDY TEAM

Chief Investigator	**Professor Laurence Taggart** Queen's University, Belfast
Co-Investigators	**Dr Alison Dunkley** University of Leicester
	Dr Maria Truesdale The University Court of the University of Glasgow
	Professor Kamlesh Khunti University of Leicester
	Professor Mike Clarke Northern Ireland Clinical Trials Unit
	Mr Dan Pollard The University of Sheffield
	Professor Alan Brennan The University of Sheffield
	Dr Michelle Hadjiconstantinou University of Leicester
	Professor Viv Coates Ulster University
	Mrs Janet Schoffield COMPASS Charity
	Cliona McDowell Northern Ireland Clinical Trials Unit
	Dr Ashley Agus Northern Ireland Clinical Trials Unit
Statistician	**Sorcha Toase** Northern Ireland Clinical Trials Unit
Health Economists	**Dr Ashley Agus** Northern Ireland Clinical Trials Unit **Mr Daniel Pollard** University of Sheffield
Clinical Trials Unit	Northern Ireland Clinical Trials Unit (NICTU) 7 Lennoxvale, Belfast, N. Ireland, BT9 5BY
Primary Sponsor	Queen's University Belfast 97 Lisburn Road Belfast, BT9 7BL Northern Ireland
Primary Sponsor's Reference	22/0055
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3 ROLES AND RESPONSIBILITIES

3.1 Funder

The National Institute for Health and Care Research (NIHR) Health Technology Assessment (HTA) Programme will be providing the research costs to the DESMOND-ID study (Reference 19/160).

The funder has no role in the study design, data acquisition, analysis, interpretation or manuscript preparation.

3.2 Sponsor

Queen's University, Belfast (QUB) will act as Sponsor for the study and the Chief Investigator (CI) will take overall responsibility for the conduct of the trial. Separate agreements will be put in place between the Sponsor, CI and each organisation who will undertake Sponsor delegated duties in relation to the management of the study.

The Sponsor has no role in the collection, analysis, interpretation of the data, writing of the report and the decision to submit the report for publication.

3.3 Trial Oversight Committees

The CI will have overall responsibility for the conduct of the study. The Clinical Trials Unit (CTU) will undertake trial management including preparing clinical trial applications (REC and research governance), safety reporting, site initiation/training, monitoring, statistical analysis and reporting. The health economic analysis will be undertaken by the CTU and the University of Sheffield.

The Trial Manager/Co-ordinator will be responsible on a day-to-day basis for overseeing and co-ordinating the work of the multi-disciplinary trial team. Additional trial specific oversight committees will be convened for the DESMOND-ID trial; these will include a Trial Management Group (TMG), Data Monitoring and Ethics Committee (DMEC) and Trial Steering Committee (TSC). The CTU will facilitate in the setting-up and the co-ordination of these trial committees.

3.4 Trial Management Group (TMG)

A TMG will be established and chaired by the CI or the Trial Manager/Co-ordinator in their absence. It will have representatives from the Clinical Trials Unit (CTU) and co-investigators, and will meet face to face or by teleconference on a monthly basis and will communicate between times via telephone and email as needed. The roles and responsibilities of the TMG will be detailed in the TMG Charter. Meetings will be formally minuted and a list of actions recorded and stored in the Trial Master File (TMF). All the day-to-day activity will be managed by the Trial Manager/Co-ordinator.

3.5 Trial Steering Committee (TSC)

The TSC will provide oversight with respect to the conduct of the study on behalf of the Funder and Sponsor.

A group of experienced clinicians and trialists will act as a TSC with an independent Chair and at least 75% independent membership. Janet Schofield (Director of CAN in Northern Ireland) will also sit on the TSC and will be the PPI Representative. Membership and roles of the TSC will be listed in the TSC Charter.

The TSC will meet up to twice per year and be in regular contact via phone and email. Additional meetings may be held at their request.
Observers may be invited to be in attendance at TSC meetings, such as the Sponsor, Funder representatives or the Trial Manager/Trial Co-ordinator to provide input on behalf of the CTU. Meetings will be formally minuted and stored in the TMF.

The TSC will be responsible for monitoring and supervising the progress of the study and will also advise on the trial protocol, assess the pilot against the progression criteria, consider DMEC recommendations and provide recommendations to the Sponsor and Funder.

3.6 Data Monitoring and Ethics Committee (DMEC)

An independent DMEC will be convened and will comprise of at least 2 independent clinicians with relevant experience in clinical trials, and an independent statistician. One of the independent clinicians will have experience in the regulatory aspects of clinical trials. It will have an independent Chair and will meet at least twice a year and additional meetings can be convened if necessary. Meetings will be formally minuted and the DMEC chair will approve any minutes prior to circulation to the rest of the members. The DMEC chair will also provide DMEC recommendations to the TSC who will decide what actions, if any, are required. Copies of all documentation will be stored in the TMF.

The role of the independent DMEC will be detailed in the DMEC charter but will include, monitoring the data and making recommendations to the TSC on whether there are any ethical reasons why the trial should not continue. The DMEC will consider the need for any interim analysis; advising the TSC regarding the release of data and/or information; and will consider data emerging from other related studies.

3.7 User Involvement or any other relevant committees

The specific needs of individuals with intellectual disability will be taken into consideration when preparing information leaflets and consent forms. Janet Schofield will represent the individual's perspective on the TSC ensuring that the trial remains considerate of the needs of the persons living with diabetes and their families.

4 BACKGROUND AND RATIONALE

4.1 Background Information

According to the WHO (2016), Type 2 diabetes (T2D) is increasing in the general population, bringing significant health risks, and rising costs for healthcare providers globally (1). Management of T2D aims to optimize glucose levels/HbA1c to avoid long-term complications. Individuals living with T2D require considerable skill to self-manage their condition effectively, but some find this difficult.

Structured diabetes education can help improve self-care behaviours, lower HbA1c and impact disease progression (2). Diabetes education has been shown to be cost effective by reducing hospital admissions and lowering lifetime healthcare costs through a reduced risk of complications (3). The Diabetes National Framework Standard 3 (4), the recent NICE Guidelines on Diabetes (NG28) (5) and Department of Health (6) guidance all recommend that everyone with T2D should attend a diabetes self-management programme. Yet if people with ID and T2D are not offered diabetes education programmes, they cannot benefit from the potential health improvements.

Williams et al. (2020) (7) estimated the 'global direct health expenditure on diabetes in 2019 is USD 760 billion and is expected to grow to a projected USD 825 billion by 2030 and USD 845 billion by 2045'. Similar growth figures have also been estimated for Europe and the UK. Diabetes care is estimated to account for up to 10% of NHS expenditure in the UK (8). Set against this, diabetes self-management education programmes have been shown to be cost effective by lowering lifetime healthcare costs by reducing complications and hospital admissions and readmissions (9). Money spent on T2D self-management education interventions to optimize glycaemic control will result in fewer long-term complications and, hence, cost savings in the longer term.

4.2 Rationale for the Study

DESMOND (Diabetes Education and Self-Management for Ongoing and Newly Diagnosed) is a 6-hour group education programme, delivered by health professionals and lay educators over two half days or one full day. DESMOND improves individuals' understanding of T2D, improves diet, increases physical activity, reduces weight, helps effective smoking cessation; reduces depression and promotes positive behaviour change thereby improving health (blood pressure, blood lipids, cholesterol) and decreasing HbA1c with sustained improvements maintained at three-years (10, 11). It is a cost-effective intervention in the management of T2D (12, 13).

Since the original DESMOND initiative for people diagnosed with T2D, it has been successfully adapted to meet the needs of some vulnerable and hard-to-reach groups including ethnic minority communities (14, 15), people with T2D and co-morbidities (16) and those at risk of diabetes (17). A fundamental goal of DESMOND is a more engaged and informed individual, whereby the person living with diabetes becomes the expert. The robust evidence of the clinical and cost effectiveness of the DESMOND education programmes, have strongly highlighted the importance of structured group education to teach T2D self-management systematically. The roll-out of DESMOND training across the UK has enabled many healthcare providers to meet many of the demands of people T2D, but it is not offered to individuals with ID (18, 19, 20).

During our recent Diabetes UK grant, we successfully adapted the DESMOND programme for use with and by adults with ID (creating the DESMOND-ID programme). The DESMOND-ID programme is delivered over 7 weeks (2hours per week) and the adult with ID is

accompanied by a family/paid carer or spouse/partner or supporter, where appropriate. Our feasibility trial has also shown that the DESMOND-ID programme can be delivered to adults with ID and T2D in the context of a randomised trial (14). The trial found that we can successfully identify and recruit adults with ID into such a study, obtain their consent, obtain blood samples, administer questionnaires, and randomise the adults to either the DESMOND-ID programme or usual care. The study confirmed that DESMOND-ID may be able to decrease HbA1c. DESMOND-ID was valued and accepted by adults with ID, carers and educators. Results were promising but need confirming in a definitive randomised trial. This study will test if DESMOND-ID can bring about the same benefits for adults with ID as the DESMOND studies have shown for non-disabled adults, improving the health of this population and reducing inequalities in health.

4.3 Rational for the Intervention

More than 1.5 million people in the UK are living with a learning or intellectual disability (ID), experiencing a disproportionate burden of health inequalities compared with the general population (22). People with ID are now living longer and, so, morbidity due to chronic conditions such as diabetes is becoming ever more important. T2D is 2-3 times more common in people with ID than the general population (18,19) and people with ID and T2D have poorer outcomes including delayed diagnosis, poor management of symptoms, more severe complications and unnecessary hospitalisations (7-9). Furthermore, they are not offered the diabetes education programmes recommended for, and routinely available to the general adult population (18, 19, 20).

The Equality Act (22) sets out the legal requirement for public health services to provide reasonable adjustments for people with a disability, which should include provision of accessible therapeutic support. Addressing this gap is an NHS priority in order to avoid premature deaths and serious diabetic complications, to improve health care among people with ID and reduce costs for healthcare providers.

Current national UK diabetes education programmes are not tailored to address the needs of people with ID, which include their cognitive and communication needs, low literacy skills and learning styles (18, 19, 20). This is despite NICE (5) recommending that diabetes education should meet the specific needs of different populations. Evidence of the impact of diabetes education programmes on HbA1c for adults with ID is sparse. We aim to fill this gap by evaluating a T2D education programme and to determine if it is clinically and cost effective compared to treatment as usual (TAU).

4.4 Rationale for Comparator

Adults with ID and T2D who are randomly allocated to the control group will receive TAU only and will not be offered any form of diabetes group education. However, each person will be offered a service user friendly book already developed on how to manage T2D. TAU for this population normally includes health centre visits every 3-6 months in which the person meets with their primary healthcare team. We will monitor TAU for this population across the different countries.

5 STUDY AIM AND OBJECTIVES

5.1 Research Hypothesis

In adults with intellectual disability and Type 2 diabetes, a diabetes education programme structured specifically for individuals with ID and T2D will improve HbA1c levels.

5.2 Study Aim

To determine whether DESMOND-ID improves outcomes and is cost-effective compared to TAU in adults with ID and T2D.

5.3 Study Objectives

5.3.1 Primary objective

To conduct a UK based, multicentre, randomised control trial to determine the effectiveness of the DESMOND-ID programme on HbA1c levels (primary outcome) and a range of secondary outcomes compared to TAU.

5.3.2 Secondary objectives

1. To determine the cost-effectiveness of the DESMOND-ID programme compared to TAU via a within-trial economic evaluation and a long-term model.

2. To determine the facilitators, barriers and mechanisms of actions involved in the DESMOND-ID process via a process evaluation.

6 STUDY DESIGN

6.1 Study Design

This is a 2-stage parallel group randomised trial with an internal pilot, economic evaluation and process evaluation.

In PICO terms:
Population: 450 adults aged ≥18yrs; mild/moderate ID and T2D
Intervention: DESMOND-ID education programme in addition to TAU
Comparator: TAU
Primary outcome: Change in HbA1c from baseline to 6 months post-randomisation

6.2 Internal Pilot Study

The pilot (Stage 1) will run for 10 months to assess recruitment rates and retention for the primary outcome at 6 months. The internal pilot will also allow us to identify any key difficulties and address them in preparation for the main trial. The initial 3 clinical sites will recruit a total of 108 adults with ID during this period. If recruitment of 108 individuals occurs more quickly than anticipated, progression to full trial may occur earlier than 6 months at the discretion of the Funder.

Participants enrolled in the pilot will be included in the analysis of the main study.

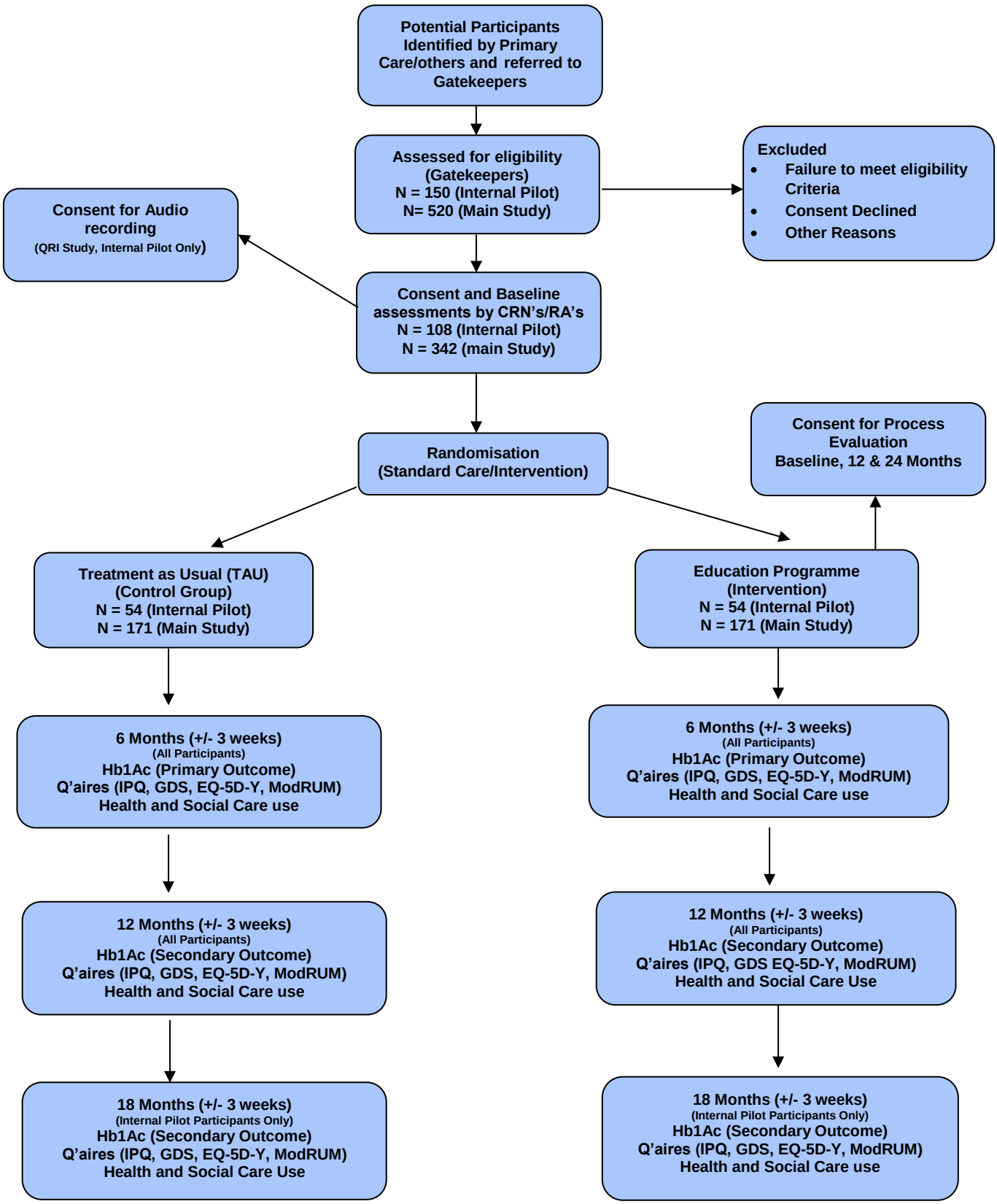
We will use the traffic light system to guide progression as recommended in recent best practice and will use the worst performing of the 3 elements in Table 1 to select which of the following actions to take:

- **Green:** progress to main trial with ongoing set-up of all sites, and a review of screening logs and protocol to address any barriers to recruitment or follow-up at 6 months.
- **Amber:** progress to main trial after discussion with TSC and HTA panel, with ongoing site setup and a full review of screening logs and protocol deviations to implement solutions to barriers leading to poor recruitment or follow-up at 6 months
- **Red:** decision to progress to main trial made by the TSC and the HTA.

Table 1: Progression criteria.

	Red	**Amber**	**Green**
Recruitment			
Number of sites opened	2	3	3
% of target recruitment per site (target: 36 per site)	<84%	85-99%	100%
Retention			
% of recruited individuals with follow up data at 6 months	<84%	85-99%	100%

6.3 Study Schematic Diagram (Internal Pilot/Main Study)



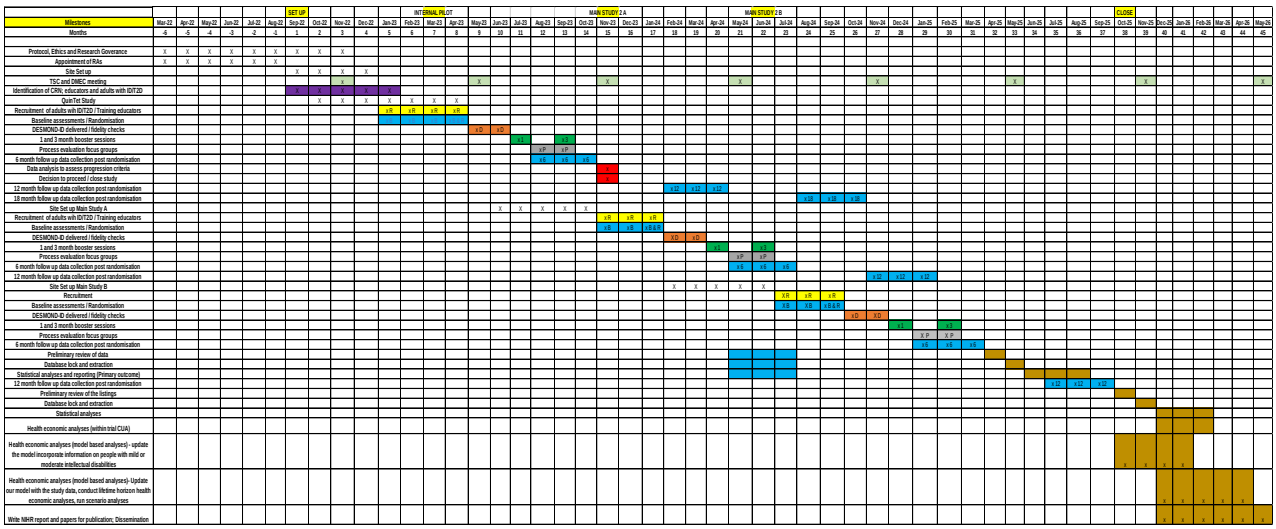
6.4 **Study timeline and key tasks**

The total 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. Details of specific trial tasks and timelines are presented in Table 2.

We will open the first site within 5 months and aim to have 8 sites open within 22 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 take place to month 25, with a follow up period of 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.

Table 2. Study timeline Gantt chart



6.5 **End of Study**

The end of trial will be when database lock occurs for the final study analysis after 450 participants have been randomised and followed up.

The study will be stopped early if:

- Mandated by The Research Ethics Committee,
- Mandated by the Sponsor e.g. following recommendation from the DMEC/TSC.
- Funding ceases.

The RECs that originally gave a favorable opinion of the trial will be notified in writing if the trial has been concluded or stopped early.

7 Participants

7.1 Study Setting

The internal pilot and main trial will take place in Health and Social Care settings in the community across 3 countries in the UK.

We have chosen a range of clinical sites across three UK countries (Northern Ireland, Scotland, and England to maximise recruitment across a large population and improve the applicability of our results.
The clinical sites cover a range of urban and semi-rural areas and include areas with high levels of deprivation and a variety ofethnically and culturally diverse. We will use a range of health and social care settings to deliver the DESMOND-ID education programme in the community at places that people with ID and T2D would be familiar with (i.e. selected to minimise potential for anxiety/stress).

To be involved in the study, community ID or other appropriate healthcare professionals at the clinical sites must be prepared to participate in the DESMOND-ID training package and be prepared to deliver the intervention. They must also demonstrate and document a willingness to comply with the protocol, standard operating procedures (SOPs), the principles of GCP (Good Clinical Practice) and regulatory requirements.

A list of study sites will be maintained in the TMF.

7.2 Study Population

Adults with T2D and ID living in the community.

7.3 Eligibility Criteria

Participants will need to be assessed using the inclusion and exclusion criteria as set out below. Eligibility to participate in the trial will be confirmed by a person who is named and delegated the role on the site Delegation Log.

7.4 Inclusion criteria

Participants will be eligible to participate in the study in accordance with the following criteria:

- Diagnosed with T2D
- Aged ≥18yrs
- Mild/moderate ID as confirmed by health professional/medical records
- Sufficient communication skills to engage in a group education programme*
- Able to give informed consent*
- Living in the community

*Participants should have sufficient English language skills in order to fully consider/give consent and can speak and understand English in order to undertake the programme if allocated to the intervention.

The eligibility criteria require that participants must be 18 years of age or older, living in the community, with mild/moderate ID and T2D identified in their clinical notes and by the ID team or GP clinical records.

There are several definitions of learning disability or ID used in the UK. A commonly used one is from Valuing People: A new strategy for learning disability for the 21st century, the government White Paper for England about health and social care support for people with an

ID (23). It explains that an ID includes the presence of: a significantly reduced ability to understand new or complex information or to learn new skills; a reduced ability to cope independently; an impairment that started before adulthood, with a lasting effect on development. To explain the wide range of different abilities the idea of a continuum of learning has been used for some time:

Mild ID – A person who is said to have a mild ID is usually able to hold a conversation and communicate most of their needs and wishes. They may need some support to understand abstract or complex ideas. People are often independent in caring for themselves and doing many everyday tasks. They usually have some basic reading and writing skills. People with a mild ID quite often go undiagnosed.

Moderate ID – People with a moderate ID are likely to have some language skills that mean they can communicate about their day to day needs and wishes. People may need some support with caring for themselves, but many will be able to carry out day to day tasks with support.

It will be easily identifiable to recognise adults with ID and T2D who are already known to statutory ID services. For adults with ID and T2D not known to ID services, we will ask GPs/Practice Nurses/Diabetes Nurses to identify potential participants using the Read Codes that are held within the GP Practice. Read Codes are a clinical terminology system that are used across Northern Ireland, Scotland and England in GP Practices to identify individuals for clinical encoding of multiple patient phenomena such as those with ID and T2D.

7.5 Exclusion criteria

- Type 1 Diabetes
- Severe/profound ID.
- Displaying severe challenging behaviour.
- Acute psychotic illness.
- Lack mental capacity to give consent.

8 Interventions

8.1 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 (24) and its development followed a systematic approach, guided by the MRC framework for developing and evaluating complex interventions (25).

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). The education sessions will be delivered together by a healthcare professional, and DESMOND lay educators in each site, who will receive 3 days of training in DESMOND-ID, 3-days for preparation and supervision of the delivery of the intervention.

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 2-7, 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.

Week 1 Carers, Partners & Advocates ONLY	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7
	Welcome and introduction (25 mins)	Welcome back (20 mins)	Welcome back (20 mins)	Welcome back (20 mins)	Welcome back (20 mins)	Welcome back (20 mins)
	My story with diabetes (part 1) (15 mins)	My story with diabetes (part 2) (15 mins)	Knowing what your blood sugar levels mean (35 mins)	Heart and circulation problems: what can I do to keep healthy? (part 1) (40 mins)	Food and fats (35 mins)	Diabetes health action plan: what will I work on? (35 mins)
	My body and diabetes (20 mins)	What diabetes does to your body? (25 mins)	Break (15 mins)	Break (15 mins)	Break (15 mins)	Break (15 mins)
	Break (15 mins)	Break (15 mins)	Being active (40 mins)	Other diabetes health problems: what can I do to keep healthy? (part 2) (35 mins)	Making healthier food choices (40 mins)	Keeping my plan going (35 mins)
	What is diabetes? (35mins)	Food and blood sugar (35 mins)	What did I learn today? (10 mins)	What did I learn today? (10 mins)	What did I learn today? (10 mins)	Important questions and celebration of achievement (15 mins)
	What did I learn today and preparing for next week? (10 mins)	What did I learn today and preparing for next week? (10 mins)	What did I learn today and preparing for next week? (10 mins)	What did I learn today and preparing for next week? (10 mins)	What did I learn today and preparing for next week? (10 mins)	
	2 hours	2 hours	2 hours	2 hours	2 hours	2 hours

The booster sessions will be delivered at 1 and 3 months after the completion of the DESMOND-ID programme. Each booster session will also last 2 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. The costs of taxi travel, bus fares and/or parking will be reimbursed to participants who need this.

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 participants only).

8.2 **Assignment of interventions**

8.2.1 Sequence Generation

The randomisation sequence will be saved in a restricted section of the TMF which will only be accessible to the statisticians and not to individuals who enrol or assign interventions. It will be generated using random permuted blocks of mixed size.

8.2.2 Allocation Concealment Mechanism

The randomisation sequence will be concealed by using a centralised randomisation system and a participant's allocation will not be revealed until they have consented to join the trial.

8.2.3 Randomisation Procedure

Once informed consent has been obtained participants will be randomised via a centralised/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 centralised/automated web-based or telephone system with a 1:1 allocation ratio. Randomisation will be stratified by site.
At the time of randomisation, each participant will be allocated a unique Participant Study Number, which will be used throughout the study for participant identification. The research team will then ensure that the participant's GP is informed of their participation in the study.

8.2.4 Blinding

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

8.3 **Outcome Measures**

8.3.1 Primary Outcome Measure

The primary outcome is to see a change in HbA1c from baseline to 6 months post-randomisation.

8.3.2 Secondary Outcome Measures

1) HbA1c at 12mths (all participants) and 18 months (internal pilot participants).
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; Weight; Body Mass Index (BMI). At 6 and 12mths (all participants) and 18 months (internal pilot participants).
3) Illness perception measured using the Illness Perception Questionnaire-Revised (IPQ) at 6 and 12mths (all participants) and 18 months (internal pilot participants).
4) Depression measured using the Glasgow Depression Scale at 6 and 12mths (all participants), and 18 months (internal pilot participants).
5) Health related quality of life measured using the EQ-5D-Y at 6 and 12mths (all participants), and 18 months (internal pilot participants).
6) Health and social care service use and costs measured using the Modular Resource use Measure (ModRUM) at 6 and 12mths (all participants), and 18 months (internal pilot participants).
7) Intervention costs recorded prospectively by study team.

9 Screening, Consent and Recruitment

9.1 Screening & Recruitment strategy

Recruitment will take a multi-pronged approach via community ID teams including associated services, and the Primary Care Networks of the Northern Ireland Clinical Research Network (NICRN), the Scottish Primary Clinical Research Networks (SPCRN) and the NIHR Clinical Research Network East Midlands for all the clinical sites across the three countries.

Some eligible participants will be identified via their usual community ID teams and associated services (including ID residential homes and ID day centres/opportunities). While additional potential participants with a mild ID and T2D not known to statutory ID services will be identified by primary care/general practices in each site using the Read Code system described above (Section 7.4). Each ID clinical team will work with us to compile a list of who has already been contacted in order to avoid duplication. Each community ID team and GP practice will contact potential participants and those who agree will be referred to the study by the clinicians in the participating clinical sites who will undertake the initial screenings.

We will run a social media campaign to advertise the study and help identify potential participants. We will also advertise this study in settings where adults with ID attend (i.e. day centres, care providers, etc.). If a potential participant indicates their willingness to be part of the study, their contact details will be forwarded to the team. The Research Associate (RA) or the Clinical Research Nurse (CRN) will forward the participant an initial invitation letter with a reply slip. When this reply slip is returned to the research team, the RA or CRN will then telephone the participant to arrange to visit and discuss the study with interested participants in the presence of a family or paid carer or spouse/partner/advocate as appropriate. All participants will be posted out easy-read information sheets with pictures or symbols to explain the purpose of the study and what is involved. These will be produced in collaboration with people with ID and T2D and our PPI partners (led by Janet Schofield). In

collaboration with the adults with ID and their nominated carers/partners/advocates the participants consent will be sought to participate in this study.

From our PPI survey, we know that some adults with a mild ID and T2D will be living alone in their own home and may not have a carer/partner to accompany them during the education programme, and we will not exclude those individuals from taking part in the trial.

All potential participants will be screened against the inclusion and exclusion criteria. All screening data must be recorded by the Principal Investigator (PI) or designee onto the My Diabetes and Me Study screening log. The outcome of the screening process and reasons for the non-recruitment of potentially eligible participants will also be recorded on the My Diabetes and Me screening log.

The PI or designee will be required to submit screening data to the CTU each month. Monthly screening log data will be used to monitor trial recruitment and provide feedback to sites.

9.2 **Informed consent procedure**

The study will be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki. It is the responsibility of the Principal Investigator (PI) (designee CRN or RA in each clinical site) to obtain written informed consent from each participant prior to entry into the trial. The designee taking informed consent must be GCP trained, suitably qualified and experienced and have been delegated this duty by the Principal Investigator on the delegation log. Appropriate signatures and dates must be obtained on the consent documentation prior to collection of trial data and the provision of the intervention.

According to the Mental Capacity Act (26) it is often wrongly assumed that all people with ID do not have the mental capacity to make decisions of their own. It must be assumed that an adult with an ID has the capacity until proven otherwise. Therefore, it is important that the person is given the information required in a user-friendly format to make an informed decision using reasonable adjustments. We plan to manage on-going consent including assessment of capacity to consent using the following steps.

1. In addition to the usual requirements for consent training, the CRNs and RAs will receive study specific training at each site in how to assess capacity to consent and ensure informed consent is maintained throughout the project on a case-by-case basis. This training will involve how to enhance their communication skills, supplemented with user-friendly information (PIS, consent form and questionnaires) supported by visual aids, to assess the person's decision-making capacity and understanding of trial participation to fulfil the tenets of capacity legislation in the three jurisdictions.

2. All participants will receive an easy read PIS and consent form with pictures / symbols to explain the purpose of the study and what is involved. The PIS and consent form have been prepared in collaboration with our PPI representatives.

3. The CRNs and RA's will clearly explain the decisions to be made about joining the My Diabetes and Me Study, having bloods taken and completing some questionnaires at several time points, being randomised to either the intervention or control arm, and taking part in the QRI and process evaluation interview (qualitative study) using the user-friendly PIS or additional media or communication aids if required. The CRNs / RAs will explain what is involved in participating in the

DESMOND-ID education programme (time commitments) and being randomised to the control group.

4. The CRNs / RAs will assess if the person can retain the information and weigh up the pros and cons of making the decision to participate in study. The CRNs / RAs will allow plenty of time to communicate with the person with ID and check they can retain this information.

5. The CRN / RA will ask for a family member, carer, partner or advocate who is familiar with the communication needs of the person with ID to be present during the interview, where appropriate.

6. The CRNs and RAs will undertake the GCP course prior to going onto the delegation log. Assurance of on-going consent will be sought on a continual basis through the routine interactions with the CRNs / RAs and individuals with ID.

9.3 Withdrawal of consent

Participants may withdraw or be withdrawn from the study at any time without prejudice.

In the event of a request to withdraw from the study, the researcher will determine which elements of the study are to be withdrawn from the following possibilities and this will be documented:

- Education Programme
- Process Evaluation
- QRI Interview Recordings
- Collection of bloods
- On-going data collection
- Contact for follow-up questionnaires

In the event that the request is to withdraw from all elements of the study, only anonymised data recorded up to the point of withdrawal will be included in the study analysis.

10 SCHEDULE OF ASSESSMENT

10.1 **Participant Assessments**

All participants recruited to the trial must be evaluated according to the schedule of assessments described. Data will be collected as detailed at each time point below.

Study Visits and Procedures

Baseline

- HbA1c
- Demographics (Date of birth, Gender, Ethnicity)
- Living Status (Where do you live, who do you live with?)
- Carer Information
- Medications
- Medical History (Health conditions related to Diabetes)
- 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; Weight; Body Mass Index (BMI).
- Questionnaires (IPQ, Glasgow Depression Scale, EQ-5D-Y, ModRUM).

6 Months (+/- 3 weeks) from randomisation

- HbA1c
- Living Status (Where do you live, who do you live with?)
- Carer Information
- Medications
- Medical History (Health conditions related to Diabetes)
- 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; Weight; Body Mass Index (BMI).
- Questionnaires (IPQ, Glasgow Depression Scale, EQ-5D-Y, ModRUM).

12 Months (+/- 3 weeks) from randomisation

- HbA1c
- Living Status (Where do you live, who do you live with?)
- Carer Information
- Medications
- Medical History (Health conditions related to Diabetes)
- 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; Weight; Body Mass Index (BMI).
- Questionnaires (IPQ, Glasgow Depression Scale, EQ-5D-Y, ModRUM).

18 Months (+/- 3 weeks) from randomisation – (Internal Pilot recruits only)

- HbA1c
- Living Status (Where do you live, who do you live with?)
- Carer Information
- Medications

- Medical History (Health conditions related to Diabetes)
- 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; Weight; Body Mass Index (BMI).
- Questionnaires (IPQ, Glasgow Depression Scale, EQ-5D-Y, ModRUM).

As the study is collecting HbA1C, Questionnaires, Metabolic and Cardiovascular Measures at each time point, if in the event that the research team becomes aware of an abnormal result or an issue of concern they will contact the GP to make them aware. This process is documented in the study PIS and Consent form.

10.2 **Study Instruments**

10.2.1 Illness Perception Questionnaire Revised (IPQ)

The Illness Perception Questionnaire (IPQ) (27) is a new method for assessing cognitive representations of illness. The IPQ is a theoretically derived measure comprising five scales that provides information about the five components that have been found to underlie the cognitive representation of illness. The IPQ will be used to examine a participants' understanding of diabetes (illness coherence score), perception of the duration of their illness (timeline score) and perception of their ability to affect the course of their diabetes (personal responsibility score).

10.2.2 Glasgow Depression Scale

The Glasgow Depression Scale for people with a Learning Disability (GDS-LD) (28) is a self-report questionnaire containing 20 items which ask a participant about their experiences in the previous week.
Participants must select one from three possible answers: (1) never/no, (2) sometimes and (3) always/a lot, each being scored 0, 1 or 2. Total scores are calculated, ranging from 0 to 40.

10.2.3 EuroQol-5 Dimension-Youth (EQ-5D-Y)

This EQ-5D-Y (29) is aimed at young people aged 8 years and older and is adapted directly from the EQ-5D-3L (43) with simplified wording making it more appropriate for this population. It is a generic preference-based measure of health, which provides a description of health using five dimensions (mobility, self-care, usual activities, pain/discomfort and anxiety/depression each with 3 levels of severity. Responses can be converted to an overall utility score for the calculation of quality adjusted life years (QALYS).

10.2.4 ModRUM (Modular Resource Use Measure)

ModRUM (30) is a validated, concise, generic, measure designed to collect self-report data on the healthcare services people use in UK-based studies. The measure contains a set of core modules that can be expanded to ask participants for additional details by substituting 'core' questions for 'depth' questions.

10.3 **Process Evaluation**

Process evaluation will be carried out to identify facilitators, barriers and mechanisms involved in the DESMOND-ID process. In addition to the anthropometrics, self-reported outcomes and blood tests, we will also collect process evaluation data using qualitative and quantitative methods. More specifically, we will collect data using interviews with the intervention arm

participants and educators, and from the trial management logs and observations of intervention delivery (see Table 3).

Trial Management Logs

How many consented to take part in the trial, how many in the pilot and main study, how many in the intervention and control group.

Observations of sessions for behaviours

Intervention fidelity (IF) will explore the effect of the training on the educators' ability to deliver sessions. The fidelity of the intervention will be assessed through: i) observing Educators delivering a proportion of intervention sessions; and ii) interviews with educators at 12 and 24 months. We will observe all educators at least once across the 3 different sites and observe all sessions up to 3 times (e.g. carer session at start, weeks 1-6 participant sessions, 2 x booster sessions at 1 month post last weekly session (approx. week 10), and 3 months post last weekly session (approx. week 18).

The DESMOND-ID educators will have received training to understand the philosophy of the self-management programme and to learn the content of the sessions (how to deliver in an interactive way), applying facilitation skills based on Motivational Interviewing (techniques including open-ended questions, affirmations, reflections, and summaries). To ensure these skills were practiced consistently across the sites, these will be assessed using an assessment tool, an IF checklist that is used in similar self-management programmes. Each skill in the assessment tool will be rated as 'Present' (the behaviour was observed regularly), 'Absent' (the behaviour was not observed) or 'Attempted' (the behaviour was observed occasionally). Duration of the group sessions and talk time (the proportion of time the educator and participant talk) will also be recorded.

Training

To assess Educator's skill acquisition of delivering DESMOND_ID, a sample of training (equivalent of 1 course) will be recorded and coded by an independent rater according to a priori criteria based on the DESMOND-ID training plan and behaviours. In line with this, process variables such as facilitator attendance and duration of training will also be captured. Educators will also be given an opportunity at the end of each training session to complete a training evaluation form. Fidelity of training will be assessed quantitatively by calculating the proportion of the presence of pre-specified content (i.e. % planned components as per the training plan).

Interviews

An evaluation qualitative study (consisting of one-to-one or a focus group interview) will be conducted at each site with adults with ID and T2D who participate in the trial, their family member, carer, partner or friend, and educators delivering the DESMOND-ID programme. The aim is to explore individual experiences with intervention participants, as well as barriers and facilitators to intervention delivery with educators.

The semi-structured interviews will address dimensions of the RE-AIM framework for the process evaluation, including intervention fidelity, dose delivered, exposure and satisfaction. Educators and participants (from the intervention group) will be invited to separate interviews.

Topic Guide

Interviews will be guided by flexible topic guides to cover questions around reasons for taking part, views on intervention, experience in attending and experience in making healthy lifestyle changes. The topic guides will have further input by PPI members with ID, to ensure the questions are appropriate for the target population.

Participant eligibility and recruitment:

Study Participants
Approximately 10-15 adults with ID and their family member, carer, partner or friend per 3 sites will be recruited for the interviews (based on information power) in the main study. An easy-read invitation letter, an easy-read information sheet and an easy-read reply slip about the interviews will be sent to adults with ID and family member, carer, partner or friend who participate in the intervention. They will be asked to return the reply slip by post, or telephone the research team to express their interest in taking part or if they would like to ask further information about the qualitative study. The research team will telephone those who are interested to take part, they will confirm they are still willing to take part, if they are, they will then arrange a data and time for the interview to take place.

Educators
All educators involved in the delivery of the intervention will be invited to take part in a 1:1 or a focus group interview. Educators will be sent a PIS and consent will be obtained prior to their interview.

Data collection
To ensure that we purposefully include a wide range of adults with ID, we will use maximum variation sampling by gender and age. Data collection for this qualitative study will occur shortly after the adults with ID/T2D have attended their second booster session. We have developed a semi-structured interview schedule for each group with input from our PPI partners to guide the discussions and to ensure we capture feedback accordingly. Each interview may take up to 60 minute and will be facilitated by an experienced qualitative researcher and if possible, a co-moderator in each site. We aim to minimise participant burden by taking regular breaks where needed. To aid memory, visuals of the sessions/resources will be shown during the interview to accompany the questions.

Interviews with study participants will be conducted in person. For educators/staff, they will have the option of telephone interviews.

The sessions will be audio-recorded and transcribed verbatim by an independent transcriber. The qualitative researcher will store the audio files in a password-protected University of Leicester drive.Audio recordings will be shared with the transcription services via a secure online University of Leicester portal ‘File Drop’, which encrypts files and requests a passcode for the receiver to access the files. Participant confidentiality will be protected. Personal details of participants will be kept confidential and anonymised and will be securely stored in a locked filing cabinet or on secure password protected networks at our research facility at Leicester University, adhering to relevant data protection and GDPR policies Audio recordings will be labelled with an anonymous study identifier and destroyed at the end of the study. Transcripts will be anonymised and securely stored for 10 years post-study.

Data coding and analysis: Interview data from both months 12 and 24 time points will be managed, coded, and analysed using the NVivo 12 qualitative data indexing software. Data analysis will begin after the first few interviews to allow time to refine the interview guides accordingly. The data from each participant group will be analysed separately and then compared and reported. Data will be analysed using inductive thematic analysis by the qualitative research team. Interpretation of the findings will be conducted by both the qualitative research team and a selected PPI group.

Data protection: All audio recorders used will be in the possession of the qualitative researcher at all times and will be labelled with a study identifier and stored securely in a locked drawer based at the Leicester General Hospital, Leicester Diabetes Centre. Encrypted audio files will be sent to an independent transcriber for transcription. The independent transcriber has previous experience working on University of Leicester research projects and a service agreement is in place. Audio recordings will be destroyed once transcription is complete. Transcripts will be anonymised and refer to participants only by their assigned ID number. Transcripts will be stored securely on the University of Leicester R Drive and destroyed ten years after study completion. Any additional electronic study documents will also be anonymised and stored safely on the R Drive of a password protected University of Leicester computer and/or laptop. This R Drive is backed up regularly by University of Leicester IT Services and used specifically for research purposes.

Table 3: Summary of Process evaluation dimensions and data collected

Process evaluation				
	Element assessed	**Data source**	**Team responsible**	**Time-point collected**
Implementation				
Reach	The number of intended audience that participate in the intervention	-Study records	CTU	Baseline 12months 24months
Fidelity	The extent to which the intervention was delivered as planned	-Observations -Interviews with educators	IMPACT/ Psychology teams CTU	During the intervention delivery period (0-6 months - at approximately weeks 1, 2, 3, 4, 5, 6, 10, 18) At the end of the second booster 12 months At the end of the second booster 24 months
Dose delivered	The quantity of each intervention component delivered (i.e. educators trained, sessions delivered, participants attended each session)	-Study records (attendance lists)	CTU	Baseline 12 months 24 months
Mechanisms of impact				

Recruitment	Success of methods used to approach and recruit participants	-Study Records	CTU	12 months 24 months
Exposure	Proportion of participants in the intervention group who participated in the study	-Study records	CTU	12 months 24 months
Context	Factors external to the intervention, which may influence intervention implementation	-Interviews with educators and participants	Psychology qualitative team	At the end of the second booster 12 months At the end of the second booster 24 months
Satisfaction	Satisfaction of participants with the overall intervention	-Interviews with participants	Psychology qualitative team	At the end of the second booster 12 months At the end of the second booster 24 months

10.4 Participant Follow-up & Procedures

In recognition of the time spent by each adult with ID and T2D in this study, a £10 shopping voucher will be given to each participant, in both the intervention and control group, at each time point (baseline, 6, 12 and 18 month follow-up) as a token of our appreciation.

Participants will be asked to let the trial team know if their contact details change or they move house at any time following recruitment to the study.

11 Data Collection and Data Management

11.1 Data Collection

To ensure accurate, complete, and reliable data are collected, the CTU will provide training to site staff.

All data for a participant will be collected and recorded in source documents and transferred onto a bespoke, web based, electronic CRF for the study. A data dictionary, record of automatic and manual data queries, and a full audit trail, will ensure data captured are consistent, reliable and fully compliant with GCP. Identification will be through their unique participant study number, allocated at the time of randomisation. Data will be collected and recorded on the electronic or paper CRF by the CRN/RA as agreed for each jurisdiction and as per the CRF submission guidelines.

11.2 Data Quality

The Chief Investigator and NICTU will provide training to site staff on trial processes and procedures including CRF completion and data collection. Within the NICTU the clinical data management process is governed by Standard Operating Procedures (SOPs), which help ensure standardisation and adherence to International Conference on Harmonisation Good

Clinical Practice (ICH GCP) guidelines and regulatory requirements. Data is to be entered onto the electronic database as per the CRF entry timelines.

On-site/Remote monitoring visits during the trial will check; the accuracy of the data entered into the CRF, entries against source documents alongside adherence to the protocol, trial specific procedures and Good Clinical Practice (GCP). This monitoring will be carried out as per the trial specific Monitoring Plan.

Changes to data will be recorded and fully auditable. Data errors will be documented, and corrective actions implemented.

Data validation will be implemented, and discrepancy reports will be generated following data entry to identify data that may be out of range or inconsistent, or protocol deviations, based on data validation checks programmed into the clinical trial database.

An independent Data Monitoring & Ethics Committee (DMEC) will be convened for the study to carry out reviews of the study data at intervals during the study.

11.3 Data Management

The PI (or designee) will collect all data and record this in the CRF. Each participant will be allocated a unique Participant Study Number at randomisation and this will be used to identify the participant on the CRF for the duration of the trial.

Data will be collected from the time of trial entry. Trial data will be entered onto a CRF and processed electronically as per CTU Standard Operating Procedures (SOPs) and the study specific Data Management Plan (DMP). Data queries will be raised electronically. Where clarification from site staff is required for missing data, site staff will respond to data queries ensuring that amendments are made as required. Site staff/CTU staff will enter trial questionnaire data onto MACRO as agreed for each jurisdiction.

12 STATISTICAL METHODS

12.1 Sample Size

191 participants in each group will have 90% power to detect a difference in means of 0.5% in HbA1c at 6 months. This cut-off point is accepted in the diabetes community as being a minimal clinically important difference, ensuring that an effect of this size or greater will be seen as a meaningful indication of the effectiveness of the intervention (15, 34). We assumed a common standard deviation of 1.5% (OK-Diabetes: www.journalslibrary.nihr.ac.uk/hta/hta22260 (31) and used a two-group t-test with a 0.05 two-sided significance level. Assuming a dropout rate of 15%, the sample size required is 225 per group: 450 in total. This dropout rate is likely to be an overestimate because our feasibility study showed that <10% of recruited adults with ID dropped out (4) and other NIHR ID intervention studies have reported similar results (21).

The current intention is to seek an excess of 30%-40% individuals within the population willing to take part in the study. Therefore, 585-630 adults with ID will be identified to provide some flexibility for those not meeting the criterion, refusals and dropouts. This 30%-40% is a generous estimate and is based on our feasibility study's recruitment rates (21) and other diabetes and ID studies (32, 34).

12.2 **Data Analysis**

12.2.1 Analysis population

The primary analysis will be conducted on outcome data from all randomised individuals according to the group in which they were allocated.

12.2.2 Statistical Methods

A detailed statistical analysis plan (SAP) will be written prior to analysis. Baseline characteristics and follow-up measurements will be summarized as means and standard deviations, medians and inter-quartile ranges, or numbers and percentages, as appropriate. The difference between randomised groups in change from baseline at 6-months for HbA1c levels will be analysed using a t-test. Analysis will use a significance threshold of 0.05. Secondary analysis for the primary outcome using ANCOVA will adjust for baseline and site. The comparison of other continuous outcomes between the two groups will be investigated using analysis of covariance, adjusting for baseline/other covariates where appropriate or t-test. Dichotomous outcomes will be analysed using chi-square and logistic regression if adjustment for covariates is required. Any adjustment for covariates will be based on clinical input and pre-specified in the SAP.

We will statistically control for any clustering effects in sensitivity analyses by undertaking generalized linear mixed models including therapist as a random effect to estimate the mean difference for continuous outcomes and the Relative Risk for dichotomous outcomes. We will also monitor the proportion of participants who come from the same residential home and if necessary, address this cluster affect in the GLMMs.

12.3 **Health Economics Evaluation**

We will assess the within trial and long-term cost-effectiveness of DESMOND-ID compared with usual care via cost-utility analyses to estimate the cost per quality adjusted life year (QALY). The economic evaluations will be in keeping with the NICE guide to methods of technology appraisal. A National Health Service (NHS) and personal social services (PSS) perspective will be adopted and costs and QALYs will be discounted at 3.5% per annum.

Trial based health economic inputs*:* Participants' use of health and social care services will be collected directly from the adults with ID and T2D (with assistance from their carer/partner/advocate) over the study period using diaries and questionnaires (ModRUM) (30). We will include the minimum set of core resource use items recently recommended for UK economic evaluations. These data collection methods will be piloted before the trial to ensure the language is appropriate for the population and completed with carers' assistance if necessary. Standard unit costs will be used to cost resources. The resource use to deliver DESMOND-ID will also be measured prospectively by the study team so the cost per participants can be estimated. Participants' health-related quality of life will be measured using the EQ-5D-Y over the study period.. The UK adult tariff will be used to obtain utilities for the calculation of QALYs. This approach has been used previously in a NIHR HTA-funded study with adults with ID (32).

Long-term modelling*:* We will conduct a model based economic analysis to calculated long-term costs and QALYs of DESMOND-ID versus TAU. To do this we will adapt our existing model of interventions for adults with type 2 diabetes, the School for Public Health Research Type 2 Diabetes Treatment (SPHR-T2D) model so that it is applicable to a population with Type 2 Diabetes and mild or moderate ID. The SPHR-T2D treatment model is an individual level microsimulation model, which simulates the life course of people with T2D, modelling trajectories of four metabolic risk factors, namely HbA1c, body mass index

(BMI), systolic blood pressure, low-density lipoprotein (LDL) and high-density lipoprotein (HDL) cholesterol. The occurrence of micro vascular (neuropathy, nephropathy, retinopathy), macro vascular (myocardial infarction, stroke, ischaemic heart disease, heart failure), peripheral vascular disease, breast cancer, colorectal cancer, depression and death are estimated in each year for each individual based upon published risk functions, metabolic trajectories (primarily related to the four risk factors), history of prior events, and other characteristics (e.g. diabetes duration). Costs and utility losses are associated with each event included in the model. To adapt the model, firstly, we will conduct literature reviews of existing economic models for people with diabetes or ID, utility parameters and costing studies. Based on these reviews, the data from the trial and discussions with clinical experts in the research team, we will update our model to reflect a population with mild or moderate ID and T2D.

The adapted model will also incorporate data from the trial to estimate the differences in costs and QALYs for people receiving DESMOND-ID and TAU. We will obtain any treatment related costs from the economic data collected in the trial. We will include any effects of DESMOND-ID compared to TAU on HbA1c, BMI, SBP, LDL or HDL cholesterol from the main 12-month trial analysis. How long these effects will be maintained will be informed by the 18-month follow-up for the participants in the internal pilot only (N= 108) and clinical expert opinion. Finally, we will use the baseline data from the trial as far as possible to inform the characteristics of the individuals in the model.

A detailed health economic analysis plan will be written, including a health economic evaluation and long-term economic modelling.

12.4 **Missing data**

Every effort will be made to minimise missing baseline and outcome data in this trial. The level and pattern of the missing data in the baseline variables and outcomes will be established by forming appropriate tables and the likely causes of any missing data will be investigated.
This information will be used to determine whether the level and type of missing data has the potential to introduce bias into the analysis results for the proposed statistical methods, or substantially reduce the precision of estimates related to treatment effects.

13 SAFETY REPORTING

13.1 Adverse Event (AE) / Serious Adverse Event (SAE) Reporting

As the study involves a low-risk intervention, we would not expect any adverse events (AE) as a result of implementing the My Diabetes and Me Study intervention. As such, AE reporting will follow the Health Research Authority (HRA) guidelines on safety reporting for non-clinical trials of investigational medicinal products as outlined below.
Participants will be encouraged to report AEs at each visit to the study team. AEs will not be considered to be reportable events.
Only AEs and SAEs that are related to the study will be reported. All ARs will be reported on the AE Report Form within the case report form (CRF). However, if an AE is deemed to be serious (based on the definition below), then the Serious Adverse Event (SAE) should be reported to the CTU. A SAE Form should be completed by the PI or designee and submitted to the NICTU at clinicaltrials@nictu.hscni.net within 24 hours of becoming aware of the event. The AE reporting period begins upon enrolment of the participant into the trial and ends 14 days after the last day of the delivery of the intervention.

Please also refer to the My Diabetes and Me Study 'Safety Reporting Guideline' for further information.

13.2 Assessment of Seriousness

The PI or designee should make an assessment of seriousness. A serious adverse event is an adverse event on the basis that it:

- Resulted in death
- Is life-threatening
- Requires hospitalisation or prolongation of existing hospitalisation
- Results in persistent or significant disability or incapacity
- Is otherwise considered medically significant by the investigator

*Hospitalisation is defined as an inpatient admission regardless of length of stay, even if the hospitalisation is a precautionary measure for continued observation. Hospitalisations for a pre-existing condition, including elective procedures that have not worsened, do not constitute a SAE.

13.3 Assessment of Causality and Expectedness

The CTU will co-ordinate the assessment of the SAE for causality and expectedness, by a delegated member of the study team. The assessment of causality in relation to the My Diabetes and Me Study intervention will be undertaken using the definitions in Table 4

Table 4: Serious Adverse Event (SAE) causality definitions

Causality assessment	Description
Unrelated	There is no evidence of or rationale for any causal relationship.
Likely to be related	There is evidence, and a rationale, to suggest a causal relationship and other possible contributing factors can be ruled out.

As there are no expected events for this study, all serious adverse events will be considered unexpected. Therefore, the event will be classified as a Suspected Unexpected Serious Adverse Reaction (SUSAR), if the SAE occurring to a research participant is deemed to be:

- *Related*: that is, it resulted from delivery of the intervention (see Table 4), **and**
- *Unexpected*: that is, the type of event not listed in the protocol as an expected occurrence

The CTU will be responsible for reporting the SUSAR to the Sponsor and to the REC which issued the favourable ethical opinion. The CTU will submit the SAE (using the SAE report for non-CTIMPs published on the Health Research Authority website) within 15 days of becoming aware of the event.

13.4 Urgent Safety Measures

If the PI becomes aware of information that necessitates an immediate change in study procedure to protect research participants from any immediate hazard, they can implement this immediately and prior to approval by the REC.

If an urgent safety measure is taken, the PI should notify the CTU within 24 hours (via email to clinicaltrials@nictu.hscni.net), setting out the reasons for the urgent safety measure.

The CTU will notify the CI and Sponsor. The CI will notify the REC providing full details of the information they have received and the decision-making process leading to the implementation of the urgent safety measure within 3 days.

14 DATA MONITORING

14.1 Data access

The agreement with each PI will include permission for trial related monitoring, audits, ethics committee review and regulatory inspections, by providing direct access to source data and trial related documentation. Agreement / consent from participants for this will also be obtained.

The participant's confidentiality will be maintained and will not be made publicly available to the extent permitted by the applicable laws and regulations.

All essential documentation i.e. the Investigator Site file (ISF) and source data will be stored by sites. The TMF and associated trial data will be stored by the NICTU in conformance with the applicable regulatory requirements and access to stored information will be restricted to authorised personnel. Following the publication of the primary and secondary study outcomes, there may be scope for the CI in the study to conduct additional analyses on the data collected. In the event of publications arising from such analyses, those responsible will need to provide the CI with a copy of any intended manuscript for approval prior to submission

14.2 Monitoring arrangements

The CTU will be responsible for trial monitoring. On-site/Remote monitoring visits will be conducted in accordance with the trial monitoring plan. Monitoring will be an on-going activity from the time of initiation until trial close-out and will comply with the principles of Good

Clinical Practice (GCP). The frequency and type of monitoring will be detailed in the monitoring plan and agreed by the trial Sponsor.

Before the trial starts at a participating site, an initiation meeting will take place to ensure that site staff are fully aware of the trial protocol and procedures. Checks will take place to ensure all relevant essential documents and trial supplies are in place. On-site/Remote monitoring visits during the trial will check the accuracy of data entered into the CRF against the source documents, adherence to the protocol, procedures and GCP, and the progress of recruitment and follow up.

The PI or designee should ensure that access to all trial related documents including source documents are available during monitoring visits. The extent of source data verification (SDV) will be documented in the monitoring plan.

15 REGULATIONS, ETHICS AND GOVERNANCE

15.1 Sponsorship

Queen's University, Belfast will act as sponsor for the study. Sub-contracts delegating responsibilities to research sites will be established using our standard contracting processes with NHS organisations.

15.2 Regulatory and Ethical Approvals

The My Diabetes and Me study is not a Clinical Study of an Investigational Medicinal Product, and thus is not governed by the Medicines for Human Use (Clinical Trials) Regulations 2004.

The trial will require research and ethical (REC) approval and NHS permission. We will apply separately for ethical approval to a multi-centre research ethics committee (MREC) in Scotland and England. The ethics application made by the Chief Investigator will cover all collaborating sites. The application to the REC and the relevant NHS R&D offices will be made through the Integrated Research Application System (IRAS).

The trial protocol was prepared in compliance with the SPIRIT 2013 statement. The trial will be registered.

15.3 Protocol Compliance

The investigators will conduct the study in compliance with the protocol given approval/favourable opinion by the Ethics Committee. Protocol compliance will be monitored by the Trial Monitor at site visits. Any deviations from the protocol will be fully documented in in the CRF.
All protocol amendments will be undertaken in accordance with the regulatory requirements. Substantial changes to the protocol will require ethics committee approval/favourable opinion, and industrial partner agreement prior to implementation, except when modification is needed to eliminate an immediate hazard(s) to individuals.

15.4 Protocol Amendments

All protocol amendments will be undertaken in accordance with the regulatory requirements. Substantial changes to the protocol will require ethics committee approval/favourable opinion prior to implementation, except when modification is needed to eliminate an immediate hazard(s) to individuals.

15.5 Good Clinical Practice

The study will be conducted in accordance with the ethical principles originating in the Declaration of Helsinki, those in the Medical Research Council's Good Clinical Practice and the Department of Health's Research Governance Framework

15.6 Indemnity

Queen's University, Belfast will provide indemnity for any negligent harm caused to participants by the design of the research protocol.

15.7 Recruits Confidentiality

In order to maintain confidentiality, all CRFs, questionnaires, study reports and communication regarding the study will identify the individuals by the assigned unique trial identifier and initials only. Confidentiality will be maintained at every stage and will not be made publicly available to the extent permitted by the applicable laws and regulations.

15.8 Record Retention

Archiving of essential documents will take place as outlined in the Sponsor Delegation Framework.

The site PI will be provided with an ISF by the CTU and will maintain all trial records according to GCP and the applicable regulatory requirements. The PI is responsible for archiving of essential documents at local sites in accordance with the requirements of the applicable regulatory requirements, Sponsor, and local policies. The PI has a responsibility to allow Sponsor access to archived data and can be audited by the Sponsor on request. Following confirmation from the Sponsor the CTU will notify the PI when they are no longer required to maintain the files. If the PI withdraws from the responsibility of keeping the trial records, custody must be transferred to a person willing to accept responsibility and this must be documented in writing to the CTU and Sponsor.

The TMF will be held by the CTU within the BHSCT and the essential documents that make up the TMF will be listed in an SOP. On completion of the trial, the TMF and study data will be archived by the CTU according to the applicable regulatory requirements and as required by the BHSCT Sponsor.

15.9 Competing Interests

The NIHR HTA funds the research costs. The CI and members of the TMG have no financial or non-financial competing interests and the members of the DMEC/TSC will be asked to confirm that they have no conflicts of interest. In the event that a DMEC/TSC member reports a conflict of interest, advice will be sought from the Sponsor and the Funder.

16 DISSEMINATION/PUBLICATIONS

16.1 Publication Policy

We plan to publish our trial protocol and statistical analysis plan to ensure transparency in our methodology. Long term data will also be reported although may form the basis of separate publications.

The study findings will be submitted for publication in peer reviewed journals and for presentation at appropriate national and international conferences with abstracts on-line. Presentation at these meetings will ensure that results and any implications quickly reach all of the ID/Diabetes community.

A lay person's summary of the principal findings of the results will be sent to all individuals involved in the study at their request. An on-going update of the trial will also be provided on the CTU website.

16.2 Authorship Policy

Authorship will be determined according to the internationally agreed criteria for authorship recommended by the International Committee of Medical Journal Editors (ICMJE). Authorship of parallel studies initiated outside of the Trial Management Group will be according to individuals involved in the project but must acknowledge the contribution of the Trial Management Group and the Study Co-ordinator Centre.

16.3 Data Sharing Statement

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.

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18 APPENDICES

Table of Appendices

18.1 Appendix I: 2nd Stage QRI study

Aim: The aim of this 2nd stage of the QRI study is to investigate issues around the recruitment and consenting of adults with diabetes and ID into the **'My Diabetes and Me**

Study' RCT by the research staff. This will include views about the study design and protocol, intervention options, existing evidence, and current practice. If relevant to their role, interviews with the research staff will also elucidate the study pathway in their site from patient identification, recruitment to consent, along with views on eligibility criteria and how they are applied in practice and more broadly their thoughts on the study interventions to get a sense of their individual level of equipoise (35). A sample of potential patient participants will also be interviewed.

This 2nd Stage QRI study involves three parts:

a) During the recruitment and consenting interview with the Clinical Research Nurse or Research Associate, we would like to audio-record a sample of the dialogue between the research staff and potential adult participants with ID and T2D regarding how the individual is recruited and consented, or not, into the **'My Diabetes and Me Study'.**

b) After the recruitment and consenting interview, we would then like to interview the research staff who engaged in the recruitment and consenting of the adults with ID into the Internal Pilot of the 'My Diabetes and Me Study' and

c) After the recruitment and consenting interview, we would like to further interview a sample of the adults with ID with T2D after they have engaged with the research staff regarding the 'My Diabetes and Me Study'.

The 1st Stage QRI was undertaken with the gatekeepers (i.e. the clinical staff) in Autumn 2022 and a separate ethics application was submitted. This 2nd Stage QRI study will be conducted with the research staff and adults with ID and T2D.

Participants and recruitment of research staff: Interviews will take place across the team of research staff (e.g. Clinical Research Nurses, Research Associates, etc) in each of the three sites (approx. 6-8 research staff per site). The Co-Applicants in each site will be asked to identify the research staff who will be recruiting and consenting the adults with ID and T2D who meet the inclusion criterion. Each member of research staff will be given a PIS and asked to sign a consent form to engage in a 1-1 interview with the Post-Doctoral Researcher (PDR) during the course of the internal pilot recruitment and consenting stage, this will be audio recorded only and last approx. 45-60mins. These interviews can take place face to face or virtually via Zoom / Teams.

Interviews with adults with ID and T2D: Interviews with 6-12 adults with ID per site will explore their views on the presentation of the study information, understanding and acceptance of trial processes (including randomisation) and reasons underlying decisions to accept or decline trial participation (36).

After these potential participants with ID and T2D have met with the local site gatekeeper and verbally agreed to meet with a member of the research staff to hear more about the 'My Diabetes and Me Study', they will be asked first to participate and consent to this 2nd Stage QRI study. We will add a question to the consent form, asking if they consent to being contacted by the QRI PDR for a short research interview to help the researchers understand their thoughts on the study and why they decided to participate or not. If they consent then the QRI PDR can contact them and explain more about the interview.

If we have more than 12 adults with ID per site who agree to engage in these 1-1 interviews, we will focus on key informants to help us understand particular issues relating to study recruitment until we reach twelve. For those individuals with ID who agreed to participate in these 1-1 interviews and did not get selected, we will contact them letting them know they were not selected and thanking them for consenting to be part of the QRI study. Nonetheless, they will still be part of the Internal Pilot if they have agreed to it.

Recording of the recruitment and consenting discussions with the researcher and adults with ID: Recruitment decisions will be influenced by the interaction between the research staff and the potential participant with ID, so appointments in which the 'My Diabetes and Me Study' RCT is discussed will be audio recorded, with participant permission, until a decision on study participation has been reached. This will involve a two-stage consenting process. Stage 1, both the research staff and the adult with ID will need to consent to participate in the QRI study. Stage 2, the adult with ID consents to participate in the Internal Pilot study. Note, one consent form will be used but it will seek consent for each of the two different studies (the QRI study and the Internal Pilot). It is important to note that adults with ID may not wish to consent for the QRI study but still consent to be in the 'My Diabetes and Me Study'. The discussions will be analysed noting, in particular, how the study is introduced and explained, whether equipoise is being conveyed, how/if patient intervention preferences are engaged with, and how randomisation is explained to identify recruitment difficulties and improve information provision for informed decision-making.

We will audio record between 6-12 interviews with the research staff and the adults with ID and T2D in each of the three sites. The local co-Applicant in each site will be asked to identify the research staff who will be consenting the adults with ID and T2D who meet the inclusion criterion. The information about the recruitment discussion will be embedded into the participant information sheet (PIS) relating to the Internal Pilot study. Where possible the PIS will be sent in advance via the Gatekeeper. It will include an explanation of why we want to record the discussion pointing out that the purpose is to understand the process of recruitment. The main research study will also be explained in this PIS. Written consent to have the recruitment discussion recorded will be sought at the start of the meeting, explaining that this is part of a study that they will hear more about during the discussion. We will then seek written consent along with the other consents once they have heard and had time to absorb all the information covered during the discussion. This will be audio recorded and last approx. 20-30mins. These interviews will be face to face.

Topic Guide: The interview schedule will be guided by emerging findings from the Stage 1 QRI study with the Gatekeepers, the recruitment log and team meetings. A topic guide relevant to the role of the interviewee will be used to ensure key areas stated above are covered but with flexibility to let participants raise issues of importance to them. It is anticipated that some of the interviews will be conducted in person but some by video-platform or telephone, and recorded through the platform or on an encrypted audio-recording device. The interviews will continue throughout the four-month recruitment period in the Internal Pilot stage, targeting areas where recruitment is slower than anticipated.

Data analysis: Recordings from the semi-structured interviews, recruitment and consenting discussions will be uploaded to the study database or transferred to Ulster University through approved secure data transfer facilities as soon as possible after collection. In the case of recordings through video platforms, only audio-recorded data will be retained and analysed. Data will be subjected to full or targeted transcription and edited to ensure anonymity of informants. Interviews and recruitment consultations, along with screening logs and study documentation, will be subject to counts, content, thematic and/or targeted conversation analyses. Preliminary analysis will be used to identify 'clear obstacles' and 'hidden challenges' (35) to inform strategies for the main RCT.

Development and implementation of recruitment intervention strategies: Results of this 2nd Stage QRI study highlighting barriers and facilitators to recruitment and consent will be discussed with the CI and TMG. The timing and frequency of discussions will be flexible, depending upon the type of issues identified and the timeframe available to address issues. The QRI team, in conjunction with the CI and TMG, will devise strategies grounded in evidence from Stages 1 and 2 of the QRI study, and drawing on those known to be effective in previous QRI studies to improve recruitment and information provision. These might include confidential individual or anonymised group feedback, additional recruitment training

for the gatekeepers and the recruiters (for example offering advice on patient identification, determining eligibility or how to explain aspects of the study), recruitment tips documents, or proposing changes to the study documentation or study pathway.

In practice this 2nd Stage of the QRI study will be conducted flexibly and iteratively within the Internal Pilot stage of the study. The QRI team will be mindful of the progression criterion (see table 1 above) and every effort will be made to ensure the specified targets are achieved whilst safe-guarding informed consent.

Consent process for QRI: Three clinical sites will be involved in the Internal Pilot study spanning three countries: Northern Ireland (Northern HSC Trust), Scotland (Greater Glasgow and Clyde Trust) and England (Leicester City Trust). Research staff participating in the Internal Pilot and involved with trial design/conduct or with patient identification, eligibility and consent will be approached by the QRI researcher, who will explain the QRI study, share an information leaflet and take consent. Consent for recordings/interviews will be obtained.

Data protection details are included in the main RCT protocol as part of the process evaluation of main study. This information in the PIS has been agreed by the PPI team to ensure the important concepts are explained in a format that is readily assimilated by those with an ID.

Review of study documentation: The QRI team will also work closely with the central study team to ensure that all study documents are clear and balanced at outset. As recruitment progresses, study documents will be reviewed in light of data gathered through the QRI to consider if improvements can be made to them.

Attendance at investigator group meetings: The QRI researcher will attend TMG to gain an overview of the study and any arising challenges, building on the evidence gained from other sources.