ISRCTN16144112 https://doi.org/10.1186/ISRCTN16144112

Diversity in diabetes feasibility study

Submission date	Recruitment status	[X] Prospectively registered
31/05/2024	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
28/08/2024	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
28/08/2024	Nutritional, Metabolic, Endocrine	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
This study aims to find out if giving children and young people from socio-economic backgrounds typically underserved by healthcare services, dedicated support guided by their social needs can help them better manage their diabetes. Working directly with children and young people with type 1 diabetes and their families from typically underserved populations, researchers have developed an intervention that they believe will encourage children and young people from this background to better engage with their healthcare. They want to look at the feasibility of setting up this service within two centres in the NHS.

Who can participate?
Children and young people with type 1 diabetes being treated by the two centres taking part in this study

What does the study involve?
Those taking part in the study will talk with a dedicated youth worker at the hospital to develop a package of additional social support relevant to them which will be provided over 6 months. The researchers will record the child’s or young person's blood sugar level before the support package begins then again 6 months later after the support package ends to see how they are managing their diabetes.
The child or young person will fill in some questionnaires about how they feel about their life before and after the support.
Once the additional guidance stops after 6 months those who agree might be asked to speak with the study team to discuss what they felt about the support that they got and what the researchers could do to improve it.
Those who delivered the intervention will also be invited to speak with the trial team about what they felt about the interventions (additional social support), and if they were able to deliver it.

What are the possible benefits and risks of participating?
Those taking part in this study may benefit by being able to better manage their diabetes and control of their blood sugar. This might lead to less complications in the future
Those taking part in this study will need to spend more time at the hospital to talk with the support worker who will work with them to produce a package of care that makes sure that they are receiving all the support available to them.

There will also be some time needed to fill in the questionnaires, but this will only be a few minutes.

Where is the study run from?
University of Birmingham (UK)

When is the study starting and how long is it expected to run for?
January 2024 to June 2027

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?
Prof. Tim Barrett, t.g.barrett@bham.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Prof Tim Barrett

Contact details
University of Birmingham
Birmingham
United Kingdom
B15 2TT
-
t.g.barrett@bham.ac.uk

Additional identifiers

Integrated Research Application System (IRAS)
344404

Central Portfolio Management System (CPMS)
63043

National Institute for Health and Care Research (NIHR)
202358

Study information

Scientific Title
Feasibility study of a complex intervention to improve glycaemic outcomes in children and young people from socio-economically deprived and/or ethnic minority groups

Acronym
DIDs Feasibility

Study objectives
To determine whether a complex intervention designed to improve outcomes in children and young people with type 1 diabetes from socio-economically deprived groups and/or ethnic minorities, is feasible in relation to:
1. Recruitment (staff and participants)
2. Intervention delivery, acceptability and engagement

Ethics approval required
Ethics approval required

Ethics approval(s)
Not yet submitted

Primary study design
Interventional

Study design
Pragmatic prospective single-arm non-randomized feasibility study

Study type(s)
Quality of life, Efficacy

Health condition(s) or problem(s) studied
Type 1 diabetes (children and young people)

Interventions
A bespoke package of interventions including:
1. Peer support
2. Life-coaching
3. Family support worker or Youth Worker input
4. Enhanced supportive ethos from the children's diabetes clinic

Those taking part in the study will talk with a dedicated youth worker at the hospital to develop a package of additional social support relevant to them which will be provided over 6 months. The researchers will record the child's or young person's overall blood sugar level (glycated hemoglobin [HbA1c]) before the support package begins, then again 6 months later after the support package ends to see how they are managing their diabetes.

The child or young person will fill in some questionnaires about how they feel about their life before and after the support.

Once the additional guidance stops after 6 months those who agree might be asked to speak with the study team to discuss what they felt about the support that they got, and what the researchers could do to improve it.

Those who delivered the intervention will also be invited to speak with the trial team to discuss what they felt about the interventions (additional social support), and if they were able to deliver it.

Intervention Type

Behavioural

Primary outcome(s)

The feasibility of sites appointing staff and training them to implement the study outcomes:
1. Sites are able to appoint Family Support Worker /Youth Worker (FSW/YW) and complete required training for them to deliver the intervention within a 12-month period
2. Number of Children and Young People with Type 1 diabetes (CYPD) recruited in relation to target recruitment. The aim is for 36 CYPD to be recruited over 8 weeks (approximately 18 from each site)
3. Number of CYPD engaging with the intervention after 6 months. The aim is that at least 80% of participants are still engaged with the intervention at 6 months after commencement. This will be assessed by the FSW/YW who, using an engagement template and activity log (provided by the study team), will class participant engagement as either 'good', 'moderate', or 'poor' (see below), with engagement being considered acceptable if ≥80% of participants are in the 'good' and 'moderate' categories.
Poor Engagement: Engaged in ≤20% of activities offered
Moderate Engagement: Engaged in 21 to 59% of activities offered
Good Engagement: Engaged in ≥60% of activities offered
4. Number of CYPD and families receiving each component of the intervention package. The aim is that at least 70% of CYPDs and their families received each relevant component of the intervention package (as identified at the outset by the FSW/YW together with CYPD and/or their families) and that at least 70% of CYPDs and their families receive the intervention as intended (measured by intervention delivery by the provider, and intervention engagement by participants, such as through attendance at intervention related activities such as support meetings). These will be recorded on an ongoing log and checked with the CYPD by the FSW/YW at the 3- and 6-month routine visits
5. Potential barriers for completion in the main study, identified by asking participating CYPD to complete the age-appropriate version of the Standard Version of the PedsQL™ - Pediatric Quality of Life Inventory™ Diabetes Module (v3.2). As underpowered, no formal statistical analysis will be undertaken on these data, which will not be carried across to the main trial
6. A selection of CYPD (including those who have withdrawn or declined their invitation to participate in the study), their parents/guardians, those recruiting and the healthcare professionals delivering the intervention and who have given consent to be contacted will be invited to be interviewed by a member of the research team either after they decline their invitation to join the study, or after their 6 months of additional support finishes, so that potential barriers can be identified and addressed prior to rolling out to the main study.

In addition, at the end of the intervention all participating CYPD and families will be given a postcard, displaying that CYPD's trial number. This postcard will display a short open question prompt, inviting free hand-written/drawn responses to the intervention (including drawings, thoughts or comments, and single words). Once completed the postcard will be placed into a provided prepaid envelope and returned directly to the research team.

A 'digital postcard' alternative will be offered to all participants who are in mobile phone contact with the Family Support Worker/Youth Worker or direct care team. Should the CYPD prefer this option then they will be invited to respond by text to the Family Support Worker/Youth Worker using a similar short open prompt, inviting short thoughts on/ responses to the intervention. Upon receipt the Family Support Worker/Youth Worker will transcribe the response, annotate it with the CYPD's trial number and send it to the research team in Bristol via a secure method

Key secondary outcome(s)

Feedback from staff delivering the intervention, participants and carers to refine the intervention, collected using mixed methodology. For participants this will be after they exit the study when their 6 months of additional support finishes and will be undertaken by interview and written feedback via postcards and/or text messages. Staff who delivered the intervention will be interviewed at the end of a 12-month period to determine if they felt they had received sufficient training to deliver the intervention, what they felt about it, and what the barriers were to its delivery and how might these be overcome.

Completion date
14/06/2027

Eligibility

Key inclusion criteria
Carer willing to consent and participant to assent (if the participant is aged under 16 completed years or lacks the capacity to consent themselves) or participant willing and able to consent (aged 16 years and over)

AND
If white UK ethnicity:
1. Clinical diagnosis of type 1 diabetes of more than 12 months
2. Age 5-19 completed years at the time of commencement of the enrollment
3. Resident in index of multiple deprivation area deciles 1 and 2
4. Recipient of free school meals

OR
If UK minority ethnicity, other than white:
1, Clinical diagnosis of type 1 diabetes of more than 12 months
2. Age 5-19 completed years at the time of commencement of the intervention

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
5 Years

Upper age limit
19 Years

Sex
All

Key exclusion criteria

1. Diagnosis of other forms of diabetes (type 2, monogenic, secondary diabetes)
2. Psychiatric disorder that in the opinion of the local investigator might affect compliance with study procedures
3. Significant other chronic illness in addition to diabetes that may confound the results of the intervention
4. Participated in diabetes treatment trials in the 12 months prior to collection of baseline data

Date of first enrolment
01/09/2024

Date of final enrolment
01/03/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Nottingham University Hospitals NHS Trust - Queen's Medical Centre Campus
Nottingham University Hospital
Derby Road
Nottingham
United Kingdom
NG7 2UH

Study participating centre
University Hospitals of Leicester NHS Trust
Leicester Royal Infirmary
Infirmary Square
Leicester
United Kingdom
LE1 5WW

Sponsor information

Organisation
University of Birmingham

ROR

https://ror.org/03angcq70

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
As a feasibility study there are no plans to share participant data at the individual level

IPD sharing plan summary
Not expected to be made available