STEADFAST: EDUCATION OUTCOMES IN YOUNG PEOPLE WITH DIABETES: INNOVATIVE INVOLVEMENT AND GOVERNANCE TO SUPPORT PUBLIC TRUST

THE STEADFAST PROJECT

V3.0 04/05/2022

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SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the relevant study regulations, GCP guidelines, and CTR's SOPs.

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

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Position: Director of Population Health, Centre for Trials Research
Signature:
Date:
Chief Investigator
Name: Dr Rob French
Position: Senior Research Fellow, I&I, School of Medicine
Signature:
Date:

General Information This protocol describes the STEADFAST project and provides information about the procedures for entering participants into the project. The protocol should not be used as a guide, or as an aide-memoire for the treatment of other participants. Every care has been taken in drafting this protocol; however, corrections or amendments may be necessary. These will be circulated to the

known Investigators in the project. Problems relating to the project should be referred, in the first instance, to CTR (steadfast@cardiff.ac.uk) and the CI (frenchr3@cardiff.ac.uk).

Contact details – Chief Investigator/s & Co-Investigator/s

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Study Co-ordination:

The STEADFAST project is being coordinated by the Centre for Trials Research (CTR), Cardiff University, a Clinical Research Collaboration (UKCRC) registered studies unit. This protocol has been developed by the STEADFAST Study Management Group (SMG). For **all queries** please contact the STEADFAST study team through the main study email address. Any other queries will be directed through the Study Manager to either the Chief Investigator or a Co-Investigators

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Glossary of abbreviations

AE	Adverse Event
AR	Adverse Reaction
CF	Consent Form
BAME	Black, Asian and minority ethnic
CI	Chief Investigator
CRF	Case Report Form
CTR	Centre for Trials Research
CTU	Clinical Trials Unit
CU	Cardiff University
COPI	Control of Patient Information
DARE	Data and Analytics Research Environments
GAfREC	Governance Arrangements for NHS Research Ethics Committees
GCP	Good Clinical Practice
HDRUK	Health Data Research UK
IC	Informed consent
IEC	Independent Ethics Committee
IG	Information Governance
ISF	Investigator Site File
ISRCTN	International Standard Randomised Controlled Study Number
MRC	Medical Research Council
NHS	National Health Service
NICE	National Institute for Clinical Excellence
PI	Principal Investigator
PIS	Participant Information Sheet
PPIE	Patient and public involvement and engagement
QA	Quality Assurance
QC	Quality control
R&D	Research and Development
REC	Research Ethics Committee
RGF	Research Governance Framework for Health and Social Care
SAE	Serious Adverse Event
SOP	Standard Operating Procedure
SSA	Site Specific Assessment
SMF	Study Master File
SMG	Study Management Group
SSC	Study Steering Committee
T1D	Type 1 Diabetes
UKRI	UK Research and Innovation

1 Amendment History

The following amendments and/or administrative changes have been made to this protocol since the implementation of the first approved version.

Amendment No.	Protocol version no.	Date issued	Summary of changes made since previous version
1	2.0	28/02/2022	Updated footer. Altered inclusion / exclusion criteria. Updated Socio-economic status recording methods in "Aim 2" to include Welsh Index of Multiple Deprivation Map 2019, and Scottish Index of Multiple Deprivation Map 2019. Amended upper age category in study design and setting from 25 to 24. Deletion of repetition in 7.2 Changed £25 per session to per hour. Changed duration of focus groups from approximately one hour to between one and two hours.
2	3.0	04/05/2022	Removed information regarding sponsor as Cardiff University's research governance team confirmed no sponsor was required. Updated details on focus groups, they are now age specific not subject specific. Participants are only expected to attend one which will cover all subjects. Updated information on consent including electronic. Updated contents.

2 Synopsis

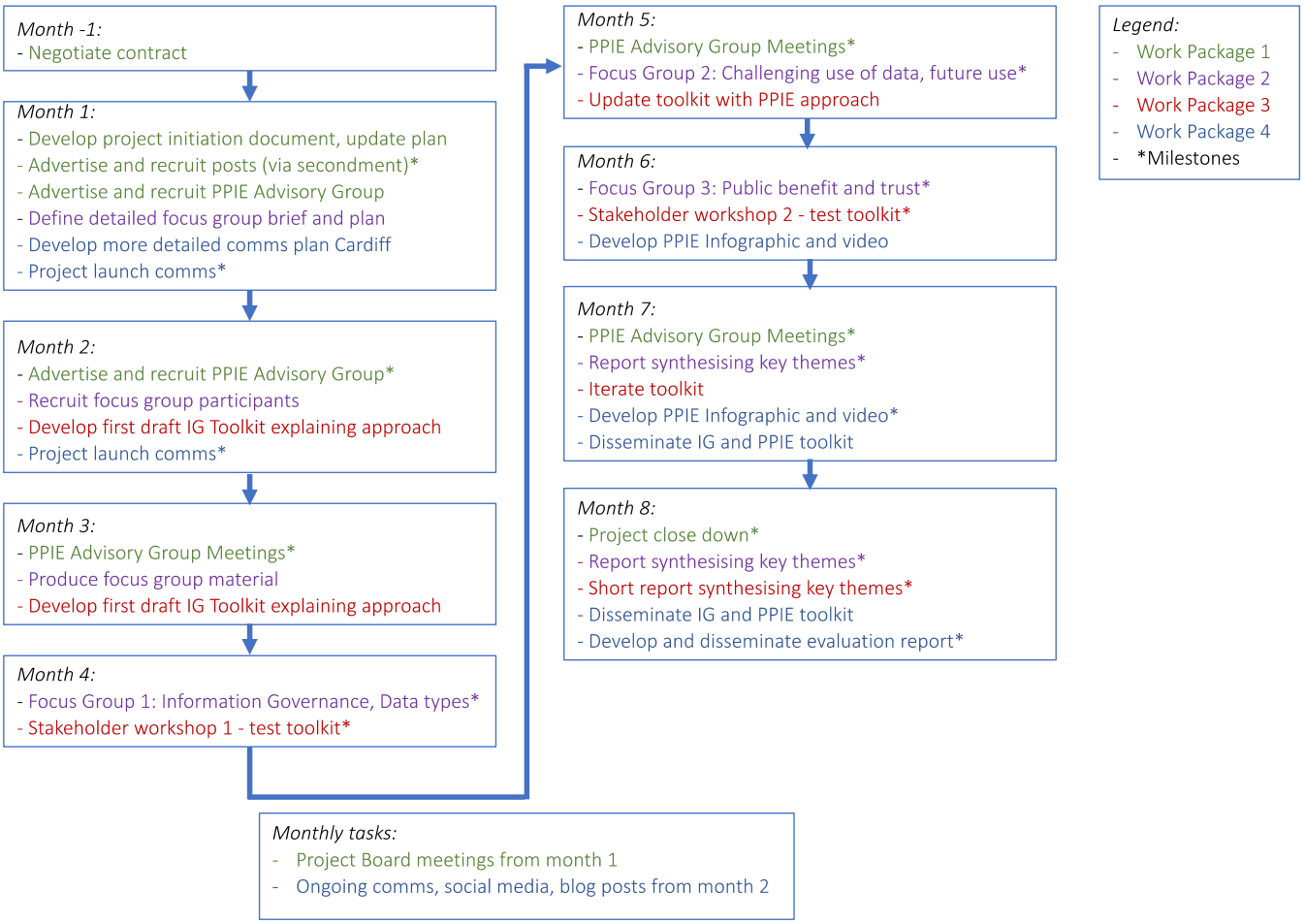
Short title	STEADFAST: Education outcomes in young people with diabetes: innovative involvement and governance to support public trust
Acronym	STEADFAST
Internal ref. no.	
Development phase	
Funder and ref.	UK Research and Innovation (UKRI) – Health Data Research UK (HDRUK) Data and Analytics Research Environments (DARE) sprint competition
Study design	Intervention Development
Study participants	Children and young people with a diagnosis of type 1 diabetes (T1D).
Planned sample size	60 for focus groups
Planned number of sites	N/A
Inclusion criteria Focus Groups	• Between the ages of 13 and 24 years old • T1D diagnosis • Access to / enable access to IT • Able to communicate in English
Exclusion criteria Focus Groups	• <13 years old • ≥24 years old • No T1D diagnosis • No way of accessing IT even if solutions offered by STEADFAST team. • Unable to communicate in English
Treatment duration	N/A
Follow-up duration	N/A
Planned study period	8 months
Study Objectives and Outcome Measurements	Successfully work with young people, their families and our partners to develop robust, meaningful and enriched PPIE and IG models which foster public confidence and trust in research requiring large-scale, sensitive,

	unconsented data linkage. Feedback forms will be circulated alongside participant compensation to measure success. Involve and engage under-represented communities to develop this framework; particularly young people, those from socio-economically disadvantaged backgrounds and ethnic minority backgrounds; targeting 50% involvement from under-represented groups. A report will be written, detailing the descriptive data of participants to identify the percentage representing under-represented groups. Under-represented groups include, for example, those from ethnic minority groups, socio-economically disadvantaged backgrounds, the LBTQ+ community and those under 18. This study will focus on socio-economic background and ethnicity. • Socio-economic status will be recorded by mapping the participants postcode against the English Index of Multiple Deprivation Map 2019, Welsh Index of Multiple Deprivation Map 2019, and Scottish Index of Multiple Deprivation Map 2019. • Ethnicity will be measured using the UK Government list of ethnic groups, as recommended by the Office for National Statistics. Participant's age and gender will also be recorded, but not as a measure of under-representation in this study. Develop a toolkit for PPIE and IG which can be more broadly applied to research investigating the relationship between health/biomedicine with characteristics beyond health e.g., employment, justice, social services. This will be measured by the successful development of the toolkit, as evaluated by stakeholders at the end of the project.

	Disseminate and evaluate our findings and develop recommendations for the UKRI cross-council research infrastructure, enabling our project to have broad impact. Dissemination will be measured in the format of reports from focus groups and stakeholder groups. We also aim to publish the findings in a peer reviewed journal. The project will be delivered through four work packages: <u>WP1: Project Management and Governance (lead: Cardiff University, JT)</u> • Milestones: Refine project plan (M1); set up Project Board (M1), monthly meetings; establish PPIE Advisory Group (M2); 3x PPIE Advisory Group Meetings (M3-M8). <u>WP2: Patient and Public Involvement and Engagement (lead: Diabetes UK, PPIE lead)</u> • Milestones: Focus group recruitment (M3); Focus groups held (M5); Outputs disseminated (M6). Target 50% diverse representation. <u>WP3: IG and PPIE Toolkit development (lead: Cardiff University, PPIE lead)</u> • Milestones: 'beta' version of IG and PPIE toolkit developed (M5); 2x stakeholder workshops (M6); IG and PPIE toolkit finalised (M7). <u>WP4: Communication, Dissemination and Evaluation (co-leads: Cardiff University, Diabetes UK)</u> • Milestones: Kick-off comms (M2); Infographic and video developed (M7); partners showcase IG and PPIE toolkit (M8); final evaluation report (M8).
Intervention	N/A

3 Study summary & schema

3.1 Study schema



3.2 Participant flow diagram

3.3 Study lay summary

Diabetes is a common long-term health condition affecting 40,000 children and young people in the UK, requiring daily management. The four UK home nations have legal commitments to support young people with medical conditions in their education. However, there are significant challenges in providing evidence to support interventions. Wide public understanding and strong support are critical for the use of sensitive data in research, such as health and education data. Young people are particularly challenging to engage in such conversations. Researchers at Cardiff University, charity Diabetes UK and partners previously developed a data access framework and set up a Young People with Diabetes Panel to support research into education outcomes for young people with diabetes. At the same time, the DARE UK programme (funded by UK Research and Innovation) is exploring ways to improve research involving data from different areas.

The STEADFAST project will build on this work. We will explore the best ways to inform, engage and involve young people, their families and the wider public in important issues around the use of their sensitive data for research. 50% of participants will come from under-represented groups. The

perspectives of young people living with diabetes informed this application and our project will be co-produced with them. We will develop our findings into a toolkit for use across other health conditions and social impacts. This will inform the DARE programme and have broader impact, for example enabling research to support children with asthma at school or young people with epilepsy in employment.

4 Background

Approximately 40,000 children and young people live with diabetes in the UK (primarily type 1 diabetes) with prevalence increasing in young people (1). Diabetes requires daily management by people living with diabetes and their families e.g., insulin, blood glucose monitoring, diet, exercise, mental health (2–5). Poor long-term management leads to serious complications, which can significantly impact quality of life and NHS costs.

Research between health and characteristics beyond health (e.g., education outcomes for young people with diabetes) requires large-scale linkage of sensitive data without consent. Strong information governance ('IG') and meaningful public and patient involvement and engagement ('PPIE') are essential to gain public trust and support for such research. However, this presents particular challenges. One must find a legal basis to process data, gain agreement from data providers, repositories, and secure regulatory approvals. PPIE must be meaningful and there should be no surprises for the wider public around how their data are used. PPIE for young people and under-represented groups is particularly challenging.

4.1 Rationale for current study

The four UK home nations each have a legislative commitment to support young people with medical conditions in their education (6), yet the evidence base to develop and evaluate interventions remains weak (7). Barriers to linkage from health data to educational outcomes and characteristics beyond health, are considerable. Previous and current research led by Cardiff University funded by MRC 2016-2020 and ADRUK 2021-22, 'The personal cost of health conditions in childhood' has established: (i) an innovative information governance ('IG') framework for large-scale data linkage across health and education, with diabetes as the exemplar (ii) a proof-of-concept data linkage across diabetes and education records (iii) research engagement for the approach beyond diabetes. Diabetes UK supported the project through outreach to young people and their families, building on its Diabetes Research Steering Groups (DRSGs) (8). The DRSGs co-produce research priorities with people living

with diabetes, clinicians and healthcare professionals, a model that has stimulated wide interest. Frameworks exist for public involvement in research e.g., NIHR Involve (9), UK Standards for Public Involvement (10), but these do not specifically address large-scale unconsented data-driven research or engagement with young people. Trustworthy IG is critical; high-profile projects GP Data for Planning and Research and Spectrum10K have been deferred following patient concerns. Research that does not involve diverse groups may be biased or less impactful (11),(12).The Information Commissioner's Office states that data from children and young people needs 'particular protection' but does not provide guidelines. Our project aims to address these gaps, further co-producing our novel IG and PPIE models with young people and stakeholders, using education outcomes in diabetes as a case-study to support UK large-scale cross-sector research.

5 Study objectives/endpoints and outcome measures

Aim 1. Work with young people, their families and our partners to develop robust, meaningful and enriched PPIE and IG models which foster public confidence and trust in research requiring large-scale, sensitive, unconsented data linkage. Feedback forms will be circulated alongside participant compensation to measure success.

Aim 2. Involve and engage under-represented communities to develop this framework; particularly young people, those from socio-economically disadvantaged backgrounds and BAME communities; targeting 50% involvement from under-represented groups. A report will be written, detailing the descriptive data of participants to identify the percentage representing under-represented groups. These data will include deprivation level of home postcode, ethnicity, gender, age. Under-represented groups include, for example, those from ethnic minority groups, socio-economically disadvantaged backgrounds, the LBTQ+ community and those under 18. This study will focus on representation based on socio-economic background and ethnicity.

- Socio-economic status will be recorded by mapping the participants postcode against the English Index of Multiple Deprivation Map 2019, Welsh Index of Multiple Deprivation Map 2019, and Scottish Index of Multiple Deprivation Map 2019.
- Ethnicity will be measured using the UK Government definition of ethnic groups, as recommended by the Office for National Statistics.
- Participant's age and gender will also be recorded, but not as a measure of under-representation in this study.

Aim 3. Develop a toolkit for PPIE and IG based on Aims 1-2 which can be more broadly applied to research investigating the relationship between health/biomedicine with characteristics beyond health e.g., employment, justice, social services. This will be measured by the successful development of the toolkit.

Aim 4. Disseminate and evaluate our findings and develop recommendations for the UKRI cross-council research infrastructure, enabling our project to have broad impact. Dissemination will be measured in the format of reports from focus groups and stakeholder groups. We also aim to publish the findings in a peer reviewed journal.

The project will be delivered through four work packages:

- WP1: Project Management and Governance (lead: Cardiff University, JT)
    - Milestones: Refine project plan (M1); set up Project Board (M1), monthly meetings; establish PPIE Advisory Group (M2); 3x PPIE Advisory Group Meetings (M3-M8).
- WP2: Patient and Public Involvement and Engagement (lead: Diabetes UK, PPIE lead)
    - Milestones: Focus group recruitment (M3); Focus groups held (M5); Outputs disseminated (M6). Target 50% diverse representation.
- WP3: IG and PPIE Toolkit development (lead: Cardiff University, PPIE lead)
    - Milestones: 'beta' version of IG and PPIE toolkit developed (M5); 2x stakeholder workshops (M6); IG and PPIE toolkit finalised (M7).
- WP4: Communication, Dissemination and Evaluation (co-leads: Cardiff University, Diabetes UK)
    - Milestones: Kick-off comms (M2); Infographic and video developed (M7); partners showcase IG and PPIE toolkit (M8); final evaluation report (M8).

5.1 Primary outcomes measure(s)

Successful diabetes PPIE engagement, based on numbers of participants attending focus groups and targets for participation by under-represented groups based on socio-economic background and ethnicity.

To have successfully developed the IG and PPIE toolkit, based on numbers of stakeholders attending stakeholder workshops and their qualitative feedback on the toolkit

6 Study design and setting

Successful development of the IG and PPIE toolkit through PPIE engagement and collaboration. The duration of study: Eight months (January 2022 – August 2022).

The project will be delivered through seven methods:

(1) We will actively engage, inform, and involve under-represented communities (young people aged 13-24, socio-economically disadvantaged groups, ethnic minorities). To achieve 50% representation of under-served groups, we will co-create communication materials with Diabetes UK, Egality Health and their network of community-based organisations and young people. These will be shared via their community social media channels (e.g., TikTok, Instagram), local radio, and community meetings. The success of these methods will be evaluated and incorporated in the IG and PPIE toolkit.

(2) We will establish a patient and public advisory group of c.10 young people living with diabetes, chaired by Susie Marques, PPIE Chair. Appointment to the group will be openly advertised through Diabetes UK and Egality Health's networks. The Advisory Group will meet online three times during the project. We will use accessible, plain English and participants will be compensated for their time.

(3) Insight gathering, engagement, and involvement of young people. We will explore key issues related to use of large-scale, sensitive unconsented data to support research via focus groups, run at different times of day to enable diverse participation (with 4-6 participants per focus group, aiming for 60 participants). We will explain and seek views on three overall topics: Types of data, current access to data through IG frameworks; anonymised data; public benefit and trust, including who is considered trust worthy both now and in the future IG topics will include legal basis for processing; Control of Patient Information (COPI) notices; Section 251 approvals; anonymisation; the 'research to education database' framework; Digital Economy Act. Data types include data controlled by private companies (e.g., continuous glucose monitoring devices); sensitive non-health data (e.g., employment records); use of data with limited consent for processing (e.g., diabetes registries, clinical study, or survey data). Data usage topics include commercial research with a profit-making motive, expectations of how their data might be used versus what would not be expected, linkage to non-health data. Future uses include transition from emergency data access arrangements for the Covid-19 pandemic, methodologies with inherent biases (e.g., machine learning), scope for opting-out. Public benefit and trust will explore scenarios under which these uses would be trusted or not and will

be a dialogue between young people and data controllers and researchers. The focus groups will be facilitated by Diabetes UK and supported by Egality Health. Facilitators will use open ended questions and statements e.g. “I am happy for my data to be used for public health benefit” to encourage discussion between participants on their knowledge, experiences, and point of view. The focus groups will be held virtually, recorded, and transcribed. Analysis will compare discussions, themes, and minority opinions.

(4) Based on this insight, we will develop an accessible, plain English IG and PPIE toolkit. This will explain the approach and methods, providing templates for applying our novel IG and PPIE approach to relevant research via a written document and short video.

(5) We will test, iterate, and evaluate the toolkit through two stakeholder workshops, involving the project partners and DARE programme stakeholders. We will co-produce research questions/ scenarios through which the toolkit could be more broadly applied.

(6) We will capture and disseminate the project findings, developing a short report, video, and infographic. These will be reviewed by the PPIE Advisory Group and project partners. They will be widely communicated and disseminated. Following the project end we will write up the results for publication in a journal.

(7) We will evaluate the project success against objectives and anticipated impact through an informal reflective evaluation by the project team and partners, and through feedback from the project stakeholders through the second of two stakeholder workshops.

6.1 Risk assessment

A Study Risk Assessment has been completed to identify the potential hazards associated with the study and to assess the likelihood of those hazards occurring and resulting in harm. This risk assessment includes:

- The known and potential risks and benefits to human subjects
- How high the risk is compared to normal standard practice
- How the risk will be minimised/managed

This study has been categorised as low risk. The study does not impact the level of care received. A copy of the study risk assessment may be requested from the Study Manager.

7 Participants

7.2 PPIE Advisory Group

Up to ten young people (18-24 years old) living with Type 1 Diabetes will make up the PPIE Advisory Group. The PPIE Advisory Group is already established, as members were part of a previous research programme with Diabetes UK and Cardiff University. The group will meet online three times during the project to advise and input into the programme, including co-producing materials for the focus groups. New members to the PPIE Advisory Group will additionally be welcomed through open recruitment through Diabetes UK and Egality Health's networks. We will use accessible, plain English and participants will be compensated for their time (£25 money/voucher per hour). The PPIE Advisory Group members are not study participants.

7.3 Focus Groups

There will be a maximum of 60 participants across the focus groups, with each focus group session being held twice in order to maximise attendance from under-represented groups. There will be a maximum of six participants (children and young people with T1D) per focus group. Focus group participants will attend focus groups with peers of a similar age.

The Focus Groups will meet online via Microsoft Teams and these sessions will be recorded for transcription and further analysis. We will use accessible, plain English and participants will be compensated for their time (£25 money/voucher per hour). At the end of the focus groups participants will be asked to complete a feedback form. Recordings / transcripts from these meetings will be retained for the full study retention period.

The focus groups will explore critical issues identified in our previous research: (i) *IG framework issues* (legal basis for processing; Section 251 approvals; anonymisation; Digital Economy Act); (ii) *types of data* (e.g. continuous glucose monitoring device data controlled by private companies; sensitive non-health data e.g. employment records); *challenging data use* (research with a profit-making motive, expectations of how data might be used versus what would not be expected, linkage to non-health data), *future use of data* (e.g. COPI notices, machine learning, scope for opting-out); (iii) *public benefit and trust* (legitimate pathways for claiming real-world benefit from research).

7.3.1 Inclusion criteria

- Between the ages of 13 and 24.
- T1D diagnosis.
- Access to / enable access to IT in order to participate in the focus group(s) online – this could include access to a computer or a mobile phone with an internet connection.
- Ability to communicate in English.

7.3.2 Exclusion criteria

- <13 years old.
- ≥24 years old.
- No T1D diagnosis.
- No way of accessing IT even if solutions offered by STEADFAST team.
- Unable to communicate in English.

8 Recruitment, Screening and registration

8.1 Participant identification

Participants will be recruited openly through Diabetes UK and Egality's community networks channels. Methods will include:

- Social media posts
- Webpage
- Newsletter features

No sources of identifiable personal or clinical information will be used to identify potential participants in the research. Expressions of interest to participate in the research will be self-selecting and voluntary.

Participants will be asked to express their interest in participating in the research, directly to the DUK PPIE lead. The participant will be asked to confirm they are a young person (ages between 13-24 inclusive) with type 1 diabetes according to the inclusion/exclusion criteria. There will not be any confirmation of eligibility by a medical practitioner; although eligibility questions will be asked of the participant, responses will be accepted based on trust.

Diabetes UK will hold the participants' information and use this to monitor progress on recruitment, reporting anonymised figures back to Egality.

8.2 Screening logs

A screening log of all ineligible and eligible but not consented/not approached will be recorded and stored by Diabetes UK so that any biases from differential recruitment will be detected. In order to monitor the study targets around diversity and representation, Diabetes UK will collect diversity monitoring information including ethnicity and home postcode on study participants at the time of collecting informed consent, but not at the point of confirming eligibility in order to minimise the personal data collected from individuals. When collected by Diabetes UK logs may contain identifiable information but this will be redacted prior to being shared with the CTR. The screening log should be sent to the Diabetes UK STEADFAST PPIE Manager (steadfast@diabetes.org.uk) every 1 months (see section 19 for further detail on data monitoring/quality assurance).

8.3 Recruitment rates

A maximum of 60 participants will be recruited to the focus groups, with the aim to have 30 of these participants from under-represented groups. Recruitment will be expected at a rate of twenty per month over three months.

8.4 Informed consent

Diabetes UK will seek informed consent for participation in the study, including parental consent for those under the age of 17 as required by Diabetes UK's Safeguarding policy. All participant responses will be fully anonymised prior to publication. Required participant personal data will be held securely by Diabetes UK within their secure IT systems.

The participant's written/electronic informed consent must be obtained using the study Consent Form or relevant link, which follows the relevant Participant Information Sheet (PIS). The participant will be given sufficient time after the initial invitation to participate before being asked to sign the Consent Form. Informed consent must be obtained prior to the participant participating in the study.

Please note, only when written/electronic informed consent has been obtained from the participant (and parental consent if applicable, depending on the age of the participant) can they participate in the Focus Groups. One copy of the consent form will be given to the participant, but the original copy will be kept by Diabetes UK, if consent is obtained using the electronic form a standard email

confirming that electronic consent has been received will be sent to the participant confirming the statements they have consented to.

Members of the PPIE Advisory Group will provide informed consent to pass their contact details on to Cardiff University for reimbursement.

Egality will facilitate a communications workshop with three members of the PPIE advisory group, three community organisation CEOs/Directors, and representatives from Diabetes UK and Cardiff University. The purpose of the workshop is to co-produce research communications to engage under-represented groups. Participants will receive a brief on the objectives of the workshop and the agenda, before agreeing to take part over email. They will then receive an email invitation with a Microsoft Teams link for the meeting. At the beginning, participants will be informed that the workshop will be recorded for note taking purposes, and that they can withdraw at any time.

Helix Data Innovation will facilitate two stakeholder workshops with stakeholders from the research community, with approximately 10 participants at each workshop. The workshop participants will include a purposive sample from the project partners, the PPIE Advisory Group chair, DARE UK researchers, stakeholders from charities and interested patient groups. The purpose of the workshops will be to establish stakeholder needs around the PPIE and Information Governance toolkit, and to refine and validate the toolkit. Participants will receive a brief on the objectives of the workshop and the agenda, before agreeing to take part over email. They will then receive an e-mail invitation with a Microsoft Teams link for the meeting. At the beginning, participants will be informed that the workshop will be recorded for note taking purposes, and that they can withdraw at any time.

9 PPIE Advisory Groups and Focus Group retention

Focus Group participants will be given PIS prior to giving informed consent to participate, and PPIE Advisory Group members will be informed of the requirements of the study. Members of both groups will be asked whether they are at that time able to commit to the study needs. Participants will be financially compensated for their time, a £25 (money/voucher) per hour will be provided on completion of their participation and will be distributed by Cardiff University. PPIE representatives to the stakeholder workshops will also be financially compensated for their time.

9.1 Withdrawal

Participants have the right to withdraw consent for participation or refuse to participate in any aspect of the study at any time. The participants' care will not be affected at any time by declining to participate or withdrawing from the study.

The withdrawal of participant consent shall not affect the study activities already carried out and the use of data collected prior to participant withdrawal. The use of the data collected prior to withdrawal of consent is based on informed consent before its withdrawal.

There is specific guidance on this contained in the Participant Information Sheet but briefly:

A participant may withdraw for any reason or be withdrawn from the study for the following reasons:

- Non-compliance
- Unwilling to continue participating

In all instances participants who consent and subsequently withdraw should complete a withdrawal form (see Withdrawal Form in study pack) or the withdrawal form should be completed on the participant's behalf by the researcher based on information provided by the participant. This withdrawal form should be sent to steadfast@diabetes.org.uk any queries relating to potential withdrawal of a participant should be forwarded to steadfast@diabetes.org.uk

10 Study procedures

Participants will have the opportunity to participate in a focus group. Focus groups will be semi-structured discussions based on an interview guide, to be developed by the study team, around issues of use of sensitive unconsented large-scale data in research, using the specific issue of education outcomes for young people with type 1 diabetes as an exemplar. The focus groups will be recorded using Microsoft Teams and transcribed using Microsoft Teams automated speech-to-text software. Key themes emerging from the focus groups will be summarised and coded using qualitative thematic analysis approach (13) by the research team (CU and Diabetes UK). Anonymised quotes will be drawn out from the key themes to support the analysis and highlight specific issues, participants will be given the opportunity to review the analysis and comment on the findings. Participants are expected to participate in one focus groups lasting between one and two hours.

The results of the focus groups will be used to develop a toolkit for PPIE in research using sensitive large-scale data, in order to inform future studies. The study will explore the conditions under which large-scale data linkage would be acceptable for public benefit, in the opinion of the participants.

Two stakeholder workshops will be held to support and inform the development of the toolkit. Stakeholders will be identified from a purposive sample developed by the research team. Stakeholders include, inter alia, professionals working in and engaged in research using large-scale sensitive unconsented linked data from the following sectors and types of organisations, with a focus (but not limited to) type 1 diabetes and education outcomes; patient data interest groups, e.g. MedConfidential; medical research charities e.g. Diabetes UK, JDRF; trusted research environments e.g. Office for National Statistics, NHS Digital; DARE UK programme stakeholders involved in PPIE; the project partners. In the first workshop, participants will be asked about challenges of involving under-represented groups in research and what they would expect to see or find useful in such a toolkit. In the second workshop, participants will be asked to provide feedback on the draft toolkit. Following the second workshop, the toolkit will be refined and disseminated.

The PPIE Advisory Group members are young people with type 1 diabetes between the ages of 18 and 24. The PPIE Advisory Group is established, and members were part of a previous research programme with Diabetes UK and Cardiff University. Additional members will be welcomed through open recruitment. The Group will meet three times during the project to advise and input into the programme, including co-producing materials for the focus groups.

Egality will sub-contract three community organisations to co-produce and disseminate communications on the study, to increase engagement with under-represented groups. The organisations CEO/Directors will advise, as required, on study materials to ensure they are culturally appropriate.

At the beginning, Egality will facilitate a communications workshop with three members of the PPIE advisory group, three community organisation CEO/Directors, and representatives from DUK and Cardiff University. The purpose of the workshop is to co-produce research communications to increase engagement from under-represented groups.

11 Safety Reporting

This study has been classed as low risk with minimal participant contact, no clinical or medical interventions and no changes to care as a result of the study. As such we do not expect participants to experience any AEs/SAEs as a result of taking part. In addition, the collection of AEs/SAEs would provide little benefit and increase unnecessary burden to participants and study staff. Therefore, there will be no process in place for collecting AEs/SAEs. However, we understand that some participants may find it difficult to think/talk about their experiences and they may express emotional or

psychological distress related to their diagnosis/management of type 1 diabetes. Participants will be provided with the research team's contact details as well as those of support services where they can seek further support should they feel they require this. Diabetes UK provides a confidential helpline for people living with diabetes, their families and carers which can be accessed via https://www.diabetes.org.uk/about_us/contact_us.

11.1 Safeguarding

Diabetes UK will be responsible for managing safeguarding issues in relation to study participants in the focus groups. Diabetes UK has a Designated Safeguarding Lead for the project, which will be Kamini Shah, Head of Research Funding and line manager for the Diabetes UK PPIE Manager. Diabetes UK has a Safeguarding Manager, Louise Himan, who can be contacted at safeguarding@diabetes.org.uk, and a published Safeguarding Policy, which is available online on Diabetes UK's website: https://www.diabetes.org.uk/about_us/legal-information/safeguarding

Specific safeguarding procedures have been agreed for the STEADFAST project and will be reviewed on a regular basis at weekly project team meetings as the study progresses. The following procedures have been agreed:

- All Diabetes UK staff and contractors who have contact with the study participants will be DBS checked.
- Contact with study participants will be minimised i.e., only those members of the project team which are managing recruitment, consent, withdrawal and screening procedures and who need to take part in the focus group research, will have contact with study participants.
- During focus groups, there will be breakout sessions for individual school years or age brackets to enable engagement and participation. This model has been used successfully by Diabetes UK in previous events with young people.
- Focus group participants under the age of 17 will also need to have parental consent.
- For focus group participants under the age of 17, their parents or carers will also be invited to be involved, as part of a separate group to the young people or on standby should the adolescents need support.
- The language being used will be age appropriate. A break-out room will be available to speak to a member of the Diabetes UK team if required by the young person. The participants will be able to withdraw from the focus groups and re-join the focus groups if they need to.

- For participants aged 17 and under – only first name can be used when running the focus group (e.g., their zoom profile name)
- Facilitation briefings will be held ahead of the focus groups on how to handle any sensitive situations that may come up
- Storage of data, including contents of the focus group recordings, consent forms and diversity information will require consent from both young people and, if under the age of 17, their parents.

11.2 Signposting

This is a low-risk study and we do not envisage any adverse effects from participation in the study. However, Diabetes UK provides a confidential helpline for people living with diabetes, their families and carers which can be accessed via https://www.diabetes.org.uk/about_us/contact_us. This will be signposted to focus group participants in the PIS.

12 Statistical considerations

12.1 Sample size

The target is for 50% of the cohort to be from under-represented groups. Under-represented groups include, for example, those from ethnic minority groups, socio-economically disadvantaged backgrounds, the LBTQ+ community and those under 18 or over 75.

This study will focus on socio-economic background and ethnicity.

- Socio-economic status will be recorded by mapping the participants postcode against the English Index of Multiple Deprivation Map 2019, Welsh Index of Multiple Deprivation Map 2019, and Scottish Index of Multiple Deprivation Map 2019
- Ethnicity will be measured using the UK Government list of ethnic groups, as recommended by the Office for National Statistics.
- Participant's age and gender will also be recorded, but not as a measure of under-representation in this study. Age will be collected to determine eligibility.

12.2 Missing, unused & spurious data

A report will be generated detailing the level of missing data from participants; e.g. undisclosed ethnicity.

12.3 Inclusion in analysis

Data from the online focus group discussions will be analysed by both Cardiff University and Diabetes UK.

13 Analysis

13.1 Main analysis

Qualitative data collected in the online focus groups will be, recorded and transcribed. Analysis will compare discussions, themes and minority opinions.

14 Data Management

The 'five safes' data management principles will be used throughout the project (safe data, safe people, safe projects, safe settings, safe outputs): https://www2.uwe.ac.uk/faculties/BBS/Documents/1601.pdf Cardiff University and Diabetes UK will have access to the raw data and the participant's data, in relation to the PPIE Advisory Group and study focus groups. Egality Health will support the focus groups and therefore will have access to the study participants during the focus groups but will not receive any contact details of participants. Data minimisation will be employed so that only those people in each organisation who need to access raw data (e.g., transcripts of focus groups) and personally identifiable data (e.g., consent forms, withdrawal forms) as they are participating in specific tasks, need to have access to it. For example, only those members of the research who need to actively participate in the focus groups will be present at the focus groups, and only those members of the research team undertaking the qualitative analysis of the focus groups will have access to the transcripts. Egality Health and Helix Data Innovation will have access to only aggregated or anonymised data from participant focus groups.

Egality Health and Helix Data Innovation will collect personal data in relation to the communications workshop and stakeholder workshops respectively. The recordings of these workshops will be stored for note-taking purposes for one month following each workshop and then deleted.

Consent: Personal data will be collected by Diabetes UK via recruitment, eligibility, consent and withdrawal forms. These forms will be stored for 7 years by Diabetes UK on secure servers according

to Diabetes UK's privacy policy: https://www.diabetes.org.uk/about_us/legal-information/privacy-policy

Payment: Personal data will be collected by Diabetes UK and passed to Cardiff University in order to be able to issue payment/vouchers to focus group participants and PPIE Advisory Group members. Any transferred data will use a secure transfer method i.e., via the Cardiff University Microsoft Teams project SharePoint in a private channel with restricted access.

Recordings and transcripts: will be collected by Diabetes UK and securely transferred to Cardiff University for analysis.

Ethnicity / Deprivation scoring: Diabetes UK and Cardiff University will have access to these personal data to ensure we are achieving the study output of 50% of participants being from underrepresented groups. Egality Health and Health Data Innovation will have access only to aggregated, anonymised data in order to monitor the representation in the study of under-represented groups.

Cardiff University and Diabetes UK are joint data controllers and Egality Health is a data processor.

14.1 Data collection

The focus groups will be facilitated by Diabetes UK and supported by Cardiff University and Egality Health. Facilitators will use open ended questions and statements e.g. "I am happy for my data to be used for public health benefit" to encourage discussion between participants on their knowledge, experiences and point of view. The focus groups will be held virtually, recorded and transcribed.

The PPIE Advisory Groups will be facilitated by PPIE Chair and supported by Diabetes UK. Facilitators will use open ended questions and statements e.g. "I am happy for my data to be used for public health benefit" to encourage discussion between participants on their knowledge, experiences and point of view.

The stakeholder workshops will be conducted by Helix Data Innovation Ltd and supported by Cardiff University and Diabetes UK. Helix Data Innovation will write an informal report describing the outputs and will share the results with Cardiff University, Diabetes UK and Egality Health. The purpose of the workshops is to provide input to and feedback on the PPIE toolkit. Stakeholders will be participating in an official capacity on behalf of their organisation or institution and their consent will be sought to record their comments and opinions on the toolkit and to share these with the group members for

the purposes of developing the toolkit. The recording will be stored for up to one month following each workshop on Helix Data Innovation's Zoom account for note taking purposes, and then deleted.

Egality meetings with community leaders will be conducted and managed by Egality. The communications workshop will be held with three community leaders, and three members of the PPIE group. The workshop will be held virtually and recorded. The recording will be stored for one month on Egality's Microsoft Teams for note taking purposes, and then deleted.

15 Protocol/GCP non-compliance

The Principal Investigator should report any non-compliance to the study protocol or the conditions and principles of Good Clinical Practice to the CTR in writing as soon as they become aware of it.

16 End of Study definition

The end of the study at sites is defined as the date of final data capture to meet the study endpoints.

CI or Study Manager must notify the main REC of the end of a clinical study within 90 days of its completion or within 15 days if the study is terminated early.

17 Archiving

The SMF and SSF containing essential documents will be archived at an approved external storage facility for a minimum of 15 years. The CTR will archive the SMF. Essential documents pertaining to the study shall not be destroyed without permission from the CI. Diabetes UK will archive any information in accordance with its published Privacy Policy. Egality and Helix Data Innovation will not hold any essential documents relating to the study; any essential documents will be passed to Cardiff University.

18 Regulatory Considerations

18.1 Ethical and governance approval

We will apply for Cardiff University School of Medicine Research Ethics Committee approval for the STEADFAST project to ensure ethical approval and governance of the primarily qualitative research in this project. We will treat participant data in accordance with UK data protection legislation and best practice. We will seek informed consent for participation in the project, including parental consent where applicable. Focus group responses will be fully anonymised prior to publication. Participant

focus group data will be held securely. We will conduct a Data Protection Impact Assessment. As part of the contract a data sharing agreement will be signed, to process participant data from the focus groups across Cardiff University, Diabetes UK.

18.2 Data Protection

The CTR will act to preserve participant confidentiality and will not disclose or reproduce any information by which participants could be identified, except where specific consent is obtained. Data will be stored in a secure manner and managed in accordance with applicable data protection laws including the UK General Data Protection Regulation 2021. Focus group responses will be fully anonymised prior to publication. Participant focus group data will be held securely. A full Data Protection Impact Assessment will be conducted for the study and is anticipated to be low risk. A data sharing agreement will be signed to govern any required data sharing across the study partners as described above.

18.3 Indemnity

Non-negligent harm: This study is an academic, investigator-led and designed study, coordinated by the CTR. The Chief Investigator, local Investigators and coordinating centre do not hold insurance against claims for compensation for injury caused by participation in a clinical study and they cannot offer any indemnity. The Association of the British Pharmaceutical Industry (ABPI) guidelines will not apply.

18.4 Study sponsorship

Cardiff University's research governance team has reviewed this study and has confirmed that no sponsor is required for this study, as there is no recruitment via, or involvement of, NHS organisations.

18.5 Funding

This study is funded by MRC-UKRI. The allocated grant number is: MC_PC_21031.

19 Study management

Project management team will meet weekly throughout study set up, every other week in the subsequent months.

Project team includes RT, LB, SM, CA, AJ, RM, JT, CD, KS, ER, PK, KS & RS

19.1 TMG (Study Management Group)

Study Management Group: RF, SM, and LB. Will meet monthly. Will also have four meetings with PPIE advisory group.

20 Quality Control and Assurance

20.1 Monitoring

The clinical study risk assessment has been used to determine the intensity and focus of central and on-site monitoring activity in the Steadfast study. This study does not require a study monitoring plan, due to its low risk and overall aims/objectives having no risk to participants or researcher.

20.2 Audits & inspections

The study may also be participant to inspection and audit by Cardiff University.

21 Publication policy

All publications and presentations relating to the study will be authorised by the Study Management Group. The aim is to publish the following:

- Protocol Paper
- Focus group analysis
- Research methodology manuscript
- PPIE toolkit

22 Milestones

M1:	Refine project plan
	Set up Project Board
M2:	Set up monthly meetings
	Establish PPIE Advisory Group
	Kick-off comms
M3–M8:	3x PPIE Advisory Group Meetings
M3:	Focus Group Recruitment
M5:	Focus Groups held
	‘beta’ version of IG and PPIE toolkit developed
M6:	2x Stakeholder Workshops

	Outputs disseminated
M7:	IG and PPIE toolkit finalised
	Infographic and video developed
M8:	Partners showcase IG and PPIE toolkit
	Final Evaluation Report

23 References

Royal College of Paediatrics and Child Health. Diabetes – RCPCH – State of Child Health [Internet]. 2020 [cited
2021 Nov 9]. https://stateofchildhealth.rcpch.ac.uk/evidence/long-term-conditions/diabetes/

2. de Cássia Sparapani V, Liberatore RDR Jr, Damião EBC, de Oliveira Dantas IR, de Camargo RAA, Nascimento LC.
Children with type 1 diabetes mellitus: Self-management experiences in school. J Sch Health [Internet]. 2017
Aug;87(8):623–9. https://onlinelibrary.wiley.com/doi/10.1111/josh.12529

3. Beckles ZL, Edge JA, Mugglestone MA, Murphy MS, Wales JKH, Guideline Development Group. Diagnosis and
management of diabetes in children and young people: summary of updated NICE guidance. BMJ [Internet]. 2016
Jan 27;352:i139. Available from: http://dx.doi.org/10.1136/bmj.i139

4. Patton SR, Noser AE, Youngkin EM, Majidi S, Clements MA. Early Initiation of Diabetes Devices Relates to
Improved Glycemic Control in Children with Recent-Onset Type 1 Diabetes Mellitus. Diabetes Technol Ther
[Internet]. 2019 Jul 1;21(7):379–84. Available from: https://doi.org/10.1089/dia.2019.0026

5. Naranjo D, Hood K. Psychological challenges for children living with diabetes. Diabetes Voice [Internet]. 2013;
Available from: https://www.idf.org/e-library/diabetes-voice/archive/38-september-2013.html?layout=article&aid=198

6. Department for Education. Supporting pupils with medical conditions at school [Internet] 2014
https://www.gov.uk/government/publications/supporting-pupils-at-school-with-medical-conditions--3

7. Oakley NJ, Kneale D, Mann M, Hilliar M, Dayan C, Gregory JW, et al. Type 1 diabetes mellitus and educational
attainment in childhood: a systematic review. BMJ Open [Internet]. 2020 Jan 26;10(1):e033215. Available from:
http://dx.doi.org/10.1136/bmjopen-2019-033215
8. Diabetes UK. Diabetes Research Steering Groups [Internet]. Diabetes UK; [cited 2021 Nov 9]. Available from:
https://www.diabetes.org.uk/research/our-approach-to-research/diabetes-research-steering-groups
9. INVOLVE – Supporting public involvement in NHS, public health and social care research [Internet]. 2018 [cited
2021 Nov 9]. Available from: https://www.invo.org.uk/
10. UK Standards for Public Involvement [Internet]. 2017 [cited 2021 Nov 9]. Available from:
https://sites.google.com/nihr.ac.uk/pi-standards/home
11. Yeoh S-A, Burke B, Castelino M, Hyndman T, Keenan A-M, Watson S, et al. Patient and public involvement in
rheumatology research: embracing the wave of change. The Lancet Rheumatology [Internet]. 2021 Aug
1;3(8):e540–2. Available from: https://doi.org/10.1016/S2665-9913(21)00184-3
12. Pii KH, Schou LH, Piil K, Jarden M. Current trends in patient and public involvement in cancer research: A
systematic review. Health Expect [Internet]. 2019 Feb;22(1):3–20. Available from:
http://dx.doi.org/10.1111/hex.12841
13. Clarke V., Braun V. (2014) Thematic Analysis. In: Teo T. (eds) Encyclopedia of Critical Psychology. Springer, New York, NY. https://doi.org/10.1007/978-1-4614-5583-7_311

24 Appendices

- Participant and parent/legal guardian/carer consent form(s)
- Participant information sheets