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Chatbot for young people with type 1 diabetes mellitus

Submission date	Recruitment status	[_] Prospectively registered
02/08/2021	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
15/02/2022	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
01/05/2025	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol

Background and study aims
Type 1 diabetes causes the level of glucose (sugar) in your blood to become too high. It happens when your body cannot produce enough of a hormone called insulin, which controls blood glucose. You need daily injections of insulin to keep your blood glucose levels under control. Our team of doctors, nurses, young people (YP), parents/guardians, researchers, and technologists plan to create a new way of helping YP with type 1 diabetes to become confident at self-managing their diabetes when they move ('transition') from children's to adult healthcare. To do this, we will develop a YP friendly diabetes chatbot (software for online chat), with avatars and linked videos.

Who can participate?
YP aged 11-25 years with type 1 diabetes

What does the study involve?
In this project, we will first ask participants to take part in a focus group, interview, or workshop to help us develop the chatbot and extra materials. We will also ask health professionals to take part in a focus group.
Once the chatbot is ready, we will ask 40 YP aged 11-25 years with diabetes to use the chatbot on a mobile phone or DigiBete website (https://www.digibete.org/) for 6 weeks. We will ask them to fill in online questionnaires before, during, and after the 6-week trial. We will also ask them to take part in an interview after the trial to tell us what they thought about using the chatbot.

What are the possible benefits and risks of participating?
Participants may enjoy talking about their experiences of diabetes with other young people, hearing about other people's experiences of living with and managing type 1 diabetes, as well as actively contributing to the creation of a valuable resource that will help others in the future. Participants may also enjoy using the chatbot and sharing their experiences of using the chatbot. Participants will also receive a shopping voucher for taking part in each phase of the study. There is the potential that the interviews, focus groups, workshops, and questionnaires included in this research may include content that could be distressing to participants. To minimise the risk of distress, participants will be informed that they do not have to answer any questions they

do not feel comfortable answering and that they have the right to withdraw from the study at any point.

Where is the study run from?
Sheffield Children's NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
December 2020 to March 2024

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

Who is the main contact?
Professor Paul Dimitri, paul.dimitri@nhs.net
Jacob Branchflower, jacob.branchflower@nihr.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof Paul Dimitri

Contact details
The Academic Unit of Child Health
Damer St. Building
Sheffield Children's NHS Foundation Trust
Western Bank
Sheffield
United Kingdom
S10 2TH
+44 (0)114 271 7354
paul.dimitri@nhs.net

Type(s)
Scientific

Contact name
Dr Jacob Branchflower

ORCID ID
http://orcid.org/0000-0002-8099-5663

Contact details
Project Manager
Clarkson St
Broomhall
Sheffield
United Kingdom
S10 2TH

-
jacob.branchflower@nihr.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
092053

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 49396, NIHR201629, IRAS 092053

Study information

Scientific Title
The development of a chatbot to support successful transition to adult care of young people with type 1 diabetes mellitus

Study objectives
Our team of doctors, nurses, young people (YP), parents/guardians, researchers, and technologists plan to create a new way of helping YP with type 1 diabetes to become confident at self-managing their diabetes when they move ('transition') from children's to adult healthcare. To do this, we will develop a YP friendly diabetes chatbot (software for online chat), with avatars and linked videos.
It is hypothesised that regularly using the chatbot for six weeks will improve anxiety levels, depression levels, and health-related quality of life.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/06/2021, East of Scotland Research Ethics Service (Ninewells Hospital & Medical School, Tayside Medical Science Centre (TASC), Residency Block, Level 3, George Pirie Way, Dundee, DD1 9SY, UK; +44 (0)1382 383871; tay.eosres@nhs.scot), ref: LR/21/ES/0056

Study design
Interventional non randomized

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)

Internet/virtual

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

Interventions
This registration focuses on Work Package 7, however all the WPs are described for background information.

We will deliver our four objectives across one pre-development phase and eight work packages:

PRE-DEVELOPMENT PHASE (months 1-4)
The pre-development phase includes the project scoping review, applying for relevant approvals, and study set up.

WORK PACKAGE 1: CO-DESIGN 1 (months 4-6)
During work package 1, we will conduct the initial focus groups that are required to develop the first iteration of the chatbot and supporting materials. This work package therefore includes conducting four focus groups with YP with T1DM who are cared for by one of four NHS sites.

We will also conduct informal interviews and one half day workshop with YP and their families who are more socially and digitally excluded. The interviews and workshop will focus on the possible barriers and enablers in terms of life context (e.g., disabilities, language, culture, poverty, mental health), digital skills and confidence, as well as accessibility of digital resources, communication between health care professionals and YP/parents/carers, and current services.

WORK PACKAGE 2: REPORT (months 7-9)
A report combining the scoping review and findings from work package 1 will inform the development of the first version of the chatbot in work packages 3 and 4.

WORK PACKAGE 3 & 4: PRODUCT DEVELOPMENT 1 (months 9-12)
The first version of the chatbot and supporting materials will be produced. The chatbot will be curated (relevant information and topics selected and organised) by the research team. IBM will also deliver training to the research team so they can independently manage the chatbot in the future.

During work package 4, we will reconvene the half day workshop with socially and digitally excluded YP/families from work package 1. We will draw on existing examples including NHS-WDP (Widening Digital Participation) which will include digital skills development, access to the internet and Wi-Fi, community connections, videos, text reminders, reward and recognition, peer support, and coaching. This workshop will also focus on what enhancements might help to lift the barriers to YP benefitting from the chatbot.

WORK PACKAGE 5: CO-DESIGN 2 (months 13-14)
During work package 5, we will reconvene the four focus groups from work package 1. These focus groups will focus on assessing the usability, functionality, and content of the chatbot and supporting materials.
We will also conduct four focus groups with health care professionals (6-8 professionals per site). These focus groups will focus on assessing the chatbot from a professional point of view.

WORK PACKAGE 6: PRODUCT DEVELOPMENT 2 (months 15-16)
In this work package, IBM, DigiBete, and the subcontractors will make the changes to the chatbot and supporting materials as determined by work packages 4 and 5.

WORK PACKAGE 7: FEASIBILITY STUDY (months 17-27)
We will conduct a short feasibility trial to explore the accessibility, usability, and acceptability of the chatbot for YP with T1DM. We will invite 32-40 YP (8-10 at each NHS site) to take part in the feasibility study. At baseline (T0), we will collect background data for YP (age, sex, postal code, ethnicity). At baseline (T0), 2 weeks (T1), and 6 weeks (T2), YP will use their digital device to complete a set of standardised measures using a secure web-application.

At the end of the 6-week trial, we will conduct individual interviews with YP as well as focus groups with health professionals and parents/guardians to obtain rich qualitative data in addition to the questionnaire data:

Interviews
All YP who completed the feasibility trial will be asked to take part in a 30 - 60 minute interview. YP will be able to bring a parent or guardian to this interview if they would like to.

Health care professional focus groups
Health care professional focus groups will be conducted to determine views on administering, teaching, and supporting the platform as well as to assess the impact they perceive it had on clinical management. There will be four health professional focus groups, one at each site.

Parent/guardian focus groups
Parent/guardian focus groups will also take place to explore their views on the strengths and limitations of a chatbot for their child becoming more autonomous in self-management. The parent focus groups at each site will comprise the parents of the YP participating in the feasibility trial with a maximum of 10 per group.

WORK PACKAGE 8: DISSEMINATION (months 28-30)
The study team will work closely with the Expert User Group to maximise the study outputs:
1. Work with YP to disseminate findings of this work to peers and families, accounting for socially and digitally excluded groups, in an innovative and engaging way (work package 7 focus groups and interviews will address this);
2. A report as per standard NIHR contract to the relevant authority;
3. Summary of study findings on NIHR Children and Young People MedTech Co-operative and DigiBete websites;
4. Study published in an open-access, high-quality, peer-reviewed scientific journal; and
5. Conference presentations.

Intervention Type
Behavioural

Primary outcome measure

At baseline, 2 weeks and 6 weeks:
1. Usability measured using The System Usability Scale (SUS)
2. Acceptability measured using The Mobile App Rating Scale (MARS)

Secondary outcome measures
At baseline, 2 weeks and 6 weeks:
1. Anxiety and Depression measured using The Hospital Anxiety and Depression Scale (HADS)
2. Health-Related Quality of Life measured using The Short-Form 36 (SF-36)

3. Young people's, parent/carers', and health professionals' experiences and perspectives will be measured using qualitative focus groups and interviews at the end of the study. We will use Framework to analyse qualitative data; Framework is a systematic method for handling large qualitative data sets by iterating between: collecting data, identifying themes, coding/labelling data, identifying categories, and possible interpretations. Constant comparison of data, supplemented by regular project management group discussions, will open up meaning.

Overall study start date
01/12/2020

Completion date
31/03/2024

Eligibility

Key inclusion criteria
1. Aged 11 - 25 years
2. Diagnosed with type 1 diabetes mellitus (T1DM)
3. Cared for by the Diabetes Clinical Teams at one of four NHS sites (Sheffield Children's Hospital, Leeds Children's Hospital, Royal Liverpool University Hospital, University Hospitals Birmingham)
4. Fluent in spoken English
5. Familiar with using a PC, smartphone, or tablet (DigiBete operates on 96% of mobile phones supporting apps up to Android 7 and IOS from iPhone 6. (For YP who do not have access to any of these devices we will provide them with the equipment to support their involvement with the trial.)
6. If in paediatric diabetes services: expected to transfer to adult NHS diabetes service
7. If in adult diabetes services: transferred from a paediatric NHS diabetes services
8. The exact inclusion criteria for digitally and socially excluded YP will be determined by the scoping review currently being undertaken by mHabitat

Participant type(s)
Patient

Age group
Mixed

Lower age limit
11 Years

Upper age limit

25 Years

Sex
Both

Target number of participants
Planned Sample Size: 249; UK Sample Size: 249

Total final enrolment
79

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/06/2021

Date of final enrolment
31/10/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Sheffield Children's NHS Foundation Trust
Western Bank
Sheffield
United Kingdom
S10 2TH

Study participating centre
St James University Hospital
Beckett Street
Leeds
United Kingdom
LS9 7TF

Study participating centre
Royal Liverpool University Hospital
Royal Liverpool University Hospitals NHS Trust
Prescot Street

Liverpool
United Kingdom
L7 8XP

Study participating centre
University Hospitals Birmingham NHS Foundation Trust
Mindelsohn Way
Edgbaston
Birmingham
United Kingdom
B15 2GW

Sponsor information

Organisation
Sheffield Children's NHS Foundation Trust

Sponsor details
Western Bank
Sheffield
England
United Kingdom
S10 2TH
+44 (0)1142717000
gillian.gatenby@nhs.net

Sponsor type
Hospital/treatment centre

Website
https://www.sheffieldchildrens.nhs.uk/

ROR
https://ror.org/02md8hv62

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF)

Funder Name
National Institute for Health Research (NIHR) (UK)

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

Publication and dissemination plan
The study team will work closely with the expert user group to maximise the study outputs:
• Work with young people to disseminate findings of this work to peers and families, accounting for socially/digitally excluded groups, in an innovative and engaging way;
• A report as per standard NIHR contract to the relevant authority;
• Summary of study findings on NIHR CYP MedTech and DigiBete websites;
• Study published in an open-access, high-quality, peer-reviewed scientific journal within one year of the overall trial end date; and
• Conference presentations.

Intention to publish date
01/03/2025

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Preprint results		17/04/2025	01/05/2025	No	No