

DigiBete, a Novel Chatbot to Support Transition to Adult Care of Young People/Young Adults with Type 1 Diabetes Mellitus: Outcomes from a Prospective, Multi-method, Non-randomised Feasibility and Acceptability Study

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Abstract

Background: Transition to adult healthcare for young people and young adults (YP/YA) with Type 1 Diabetes Mellitus (T1DM) starts around 11 years-of-age, but transition services may not always meet their needs. Post-transition many YAs are reluctant to request diabetes self-management support, this can lead to increased anxiety and deterioration in diabetes control and quality of life. Chatbots increasingly offer social support in daily life so could also provide diabetes self-management support, but there is a lack of co-developed, evidence-based, developmentally appropriate chatbots. Therefore, the DigiBete Chatbot, the first user-led, clinically approved transition chatbot for YP/YA with T1DM was recently developed

Objective: Study objectives were to (1) evaluate the DigiBete Chatbot in four English diabetes services for YP/YA, and (2) assess the feasibility of a future full trial of the chatbot

Methods: YP/YA received password-protected access to the chatbot and were encouraged to use it ad libitum. YP/YA completed web-based questionnaires (the Mobile App. Rating Scale (MARS), the Hospital Anxiety and Depression Scale (HADS), the Short-Form 36 (SF36), and the System Usability Scale (SUS) at baseline, 2-weeks and 6-weeks to evaluate quality of life, anxiety and depression and chatbot usability and acceptability. After 6-weeks, YP/YA and parents participated in individual qualitative interviews to ascertain their views on the chatbot's design, content and usability. Parents also discussed the chatbot's potential to enable their child to become autonomous in T1DM self-management. Healthcare professionals (HCPs) participated in focus groups to determine their views on the chatbot and their perceived role in supporting its use if it became standard practice. Data were analyzed using descriptive statistics and Framework Analysis

Results: Eighteen YP/YA enrolled. YP/YAs' SUS and uMARS scores demonstrated improvement from baseline to the second timepoint in perceived ease of use, functionality and confidence, and most viewed the chatbot as highly usable with over 50 percent finding it easy to navigate. Some modifications were recommended to increase accessibility. HADS anxiety scores were higher than the depression scores and overall, there was no significant change across the 3 time points for all SF36 domains. Four

parents, 24 HCPs and 12/18 YP/YA completed qualitative interviews. Questionnaire uptake/outputs and the emergent qualitative themes: Living with T1DM, Using the Chatbot and Refining the Chatbot, indicated that the study measures are feasible to use, the chatbot is acceptable and functional, and with refinements incorporating our results, could beneficially support YP/YA during transition. Users scored the chatbot as 'good' to 'excellent' for being engaging, informative and aesthetically pleasing, and would use it again.

Conclusions: Study results specify minor refinement of the chatbot and further investigation in a full cohort study prior to it's wider clinical use. Our research design and methodology could also be transferred to the development, evaluation and use of chatbots for other chronic conditions. Clinical Trial: Not relevant

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Original Manuscript

DigiBete, a Novel Chatbot to Support Transition to Adult Care of Young People/Young Adults with Type 1 Diabetes Mellitus: Outcomes from a Prospective, Multi-method, Non-randomised Feasibility and Acceptability Study

Data access statement:

All relevant data are within the manuscript and its Multimedia Appendix files.

Background

Introduction

Type 1 diabetes mellitus (T1DM) is a serious chronic condition that affects about 40 million people worldwide; the second most common pediatric condition, it affects 1 in 700 children and young people, with around 29,000 young people in the United Kingdom (UK) living with T1DM¹. Diabetes care is a priority in the UK National Health Service (NHS) Long Term Plan, reinforcing the need to improve the quality of care for children and young people with T1DM through bespoke quality improvement [2,14]. However, transition (the purposeful and planned process of supporting young people and young adults (YP/YA) with T1DM to move from child to adult services), is poorly developed in many regions. In addition, there is a major gap in our knowledge of transition readiness among YP/YA with chronic conditions³. After transition, young adults (YA) can experience significant deterioration in their diabetes control, raised anxiety levels and reduced quality of life [3-8] all of which are a considerable challenge for the YA and their families and a burden on the NHS [1].

Young people and young adults with T1DM are expected to learn about and perform multiple clinical self-management tasks. These include monitoring blood glucose levels, managing complex insulin calculations and insulin pumps, planning dietary intake relative to insulin requirements, and managing prescription requests, as well as planning healthcare in sometimes unfamiliar primary and secondary care services while integrating self-management with daily activities such as education, employment and socializing. Blood glucose control in T1DM substantially declines among 18- to 30-year-olds, with only 14% meeting the required level. As a result, one-third show evidence of early diabetes-related complications by the time of transition and a 2.5-fold elevated risk of poor glycemic control by the time of their first adult health service visit. Critically, poorly controlled T1DM can cause acute life-threatening complications such as diabetic ketoacidosis (DKA) and disabling chronic complications, including both micro and macro vascular disease [9].

Potential for user-led chatbots to support transition to adult health care

The highest rates of DKA are seen in 15- to 20-year-olds [10] (the age when they are transitioning between NHS pediatric and adult services). Thus, poor transition has devastating consequences in terms of quality of life, increased morbidity and mortality risk, and a dysfunctional level of care. Conversely, a systematic review demonstrated that adequate support for YP throughout the transition results in improved glycemic control,

improved clinic attendance, fewer episodes of hospitalization, lower rates of hypoglycaemia, better self-management, and increased knowledge of T1DM, suggesting that intervention during this critical time is fundamental for improved clinical outcomes [11]. A recent scoping review [12] analyzed research that examined the ways digital health technologies (DHT) were used (i) to support YP with chronic conditions during transition, and (ii) to establish YPs' needs, experiences and challenges when transitioning. The review found that a combination of DHT was used to support the transition of YP with chronic conditions to adult health care. Barriers to successful transition were reported and YP described the importance of social relationships and transition readiness, and expressed the need for individualized interventions that acknowledged social factors such as work and college. Notably, no supportive chatbots with components to help YP/YA with T1DM were identified [12].

The DigiBete Chatbot

The current feasibility study forms part of a phased approach to the development and evaluation of the DigiBete Chatbot, a complex intervention [13] for YP/YA with T1DM. DigiBete is an existing video platform and application (app.) that provides support for diabetes management in YP/YA. It was founded and is run by families living with T1DM, and is a social enterprise funded by NHS England with all content clinically approved (www.digibete.org). The DigiBete Chatbot prototype was co-designed and developed in collaboration with YP/YA, parents and healthcare professionals (HCPs) in four NHS hospital diabetes services in England (two pre-transition and two post-transition). All content was quality assured by a Consultant Paediatrician who specialises in Type1 Diabetes in YP/YA.

Based on the UK National Institute for Health and Care Excellence (NICE) Evidence Standards Framework for Digital Health Technologies (DHTs). The novel DigiBete Chatbot is set at NICE DHT tier 2 (level 1) and tier 3a (level 2) requirements. To our knowledge this is the first chatbot to have been rigorously co-designed and evaluated with YP/YA with T1DM. This study was framed by self-management theory, the COM-B (capability, opportunity, motivation-behavior change) approach, and the associated behavior change wheel, which provides a basis for understanding the issues and problems surrounding self-management and applying these to intervention design [1,8,15,25,26]. The DigiBete Chatbot supports users through reactive messaging, providing links to sources of information on T1DM, and including content for peers and HCPs. The chatbot addresses a range of topics that acknowledge barriers and enablers to self-management, offering

guidance on how to navigate life, while developing physically and emotionally, socializing, and becoming increasingly independent. A more detailed explanation of the DigiBete Chatbot development is being reported elsewhere.

This Study

Patient and public involvement

Patient and public involvement (PPI) was central to our study design and delivery. Members of the pre-existing DigiBete Expert User Group who are YP/YA with T1DM had informed development of the DigiBete platform and app. and advised on this current study. For example, EUG members guided development of recruitment materials and processes, content and design of initial chatbot resources, and dissemination. To avoid any conflict of interest, EUG members were not eligible to participate in the current study.

The purpose of this paper is to build on a recent scoping review [12] and present the results of a feasibility study that addressed two objectives:

[1] to evaluate DigiBete Chatbot, the first user-led, age and developmentally appropriate, clinically approved transition chatbot for 11- to 24-year-olds with T1DM including underserved, seldom heard and vulnerable groups, and

[2] to assess the feasibility and acceptability of a future study of DigiBete Chatbot in terms of recruitment, retention, data collection procedures and performance of study measures in this population.

Methods

We conducted a prospective multi-method, non-randomized feasibility and acceptability study to enable YP/YA, HCPs and parents to access the DigiBete Chatbot and associated online materials and allow researchers to collect feedback from participants through validated questionnaires and qualitative interviews. As this was a feasibility study, a power calculation was not required, and significance was not calculated because of the small sample size [21].

Recruitment

In the four NHS diabetes services (two pediatric and two adult centers), those eligible to participate were YP/YA aged 11-24 years, parents of participating YP and all HCPs in the clinical multi-disciplinary teams. Clinical teams, under the supervision of local Principal Investigators, used patient databases to identify eligible patients and requested permission to refer them to the researcher. Thrive by Design (a collective of specialist service designers and researchers who ensure inclusivity in NHS research by engaging underserved, seldom heard and vulnerable groups) also supported recruitment and data collection. Researchers sent the study invitation letter and (developmentally appropriate) participant information sheet to interested participants, explaining the purpose of the study, who the investigator was, timings of the online survey, and that they would be invited to participate in a semi-structured interview at the end of their 6-week chatbot trial, which data were stored and where and for how long. Where interest was indicated by individuals approached, the researcher then arranged to speak to them online or by telephone to answer queries and explain the process for providing digital (adult) informed consent, or assent for young people <16 years. After study completion participants received an online shopping voucher to thank them for their time.

Intervention

Before accessing the DigiBete Chatbot, participating YP/YA were contacted by a member of the chatbot development team who was not a member of the evaluation team, to explain the process of accessing and navigating the chatbot.

Participating YP/YA received password-protected access to the DigiBete Chatbot (provided by a DigiBete developer who was not a member of the evaluation team and who monitored DigiBete Chatbot usage) for 6-weeks to allow them to ask questions, and they were

encouraged to use it as often as they wished. To enable this, at the point of consent/assent for DigiBete Chatbot evaluation, the researchers collected participants' demographic details, including the email address that the YP/YA had previously given to DigiBete when they registered for access to the DigiBete web platform and app. From their secure NHS email addresses, the researchers then forwarded the individual emails to the DigiBete team, who confirmed that the email address was consistent with the one held on record by DigiBete and arranged for the participant to have special access to the chatbot that appeared on their own DigiBete app for the duration of the study.

Measures

At baseline we collected demographic data from the YP/YA (age, sex, postal code, and ethnicity). The following measures: the user version of the Mobile App Rating Scale (uMARS) [16]; the Hospital Anxiety and Depression Scale (HADS) [17], the Short-Form 36 (SF-36) [18] and a modified version of the System Usability Scale (SUS) [19, 27, 28] were administered electronically to the participating YP/YA at three time-points: before using the chatbot time zero (T0), time 1 (T1) 2 weeks, and, time 2 (T2) 6 weeks after first using the chatbot. All questionnaires were imported into Qualtrics^{XM} software, and a secure questionnaire database was created for data collection and analysis. The usability and technical functionality of the electronic survey was tested by YP/YA advisors before fielding the questionnaires. The researchers allocated each study participant with a unique, anonymised study number/identifier and YP/YA participants were reminded of this at every communication during the chatbot evaluation. YP/YA also received email messages linking them to the questionnaire database, they accessed the database via their unique identifier then entered the relevant study timepoint (T0, T1, T2) and received access to the correct questionnaires for that timepoint. Non-completers received one reminder after 2-weeks. This Multimedia Appendix xxxxx shows details about the measures used.

Qualitative interviews/focus groups

After T2, YP/YA were invited to participate in a qualitative interview to ascertain their views on the DibiBete Chatbot's design, content and usability. In addition, parents of participating YP were invited to participate in qualitative interviews to explore their views on the chatbot's potential to enable their child to become autonomous in self-management, and focus groups were conducted with HCPs to determine their views on the chatbot's content and their role in supporting if it was later deemed suitable to become part of standard care delivery. During interviews/focus groups with parents and HCPs, the chatbot was demonstrated by the researchers, and participants were invited to suggest questions (which the researcher typed in) and discuss the answers generated. Interviews were conducted online and focus groups online, or in-person in a quiet room in the hospital by researchers trained in these methods. Recruitment commenced September 2023 and follow up ended February 2024.

Data analysis

Quantitative data were analysed using descriptive statistics. Qualitative data were analyzed using Framework Analysis; themes derived during qualitative data collection and analysis supplemented interview topics with new lines of inquiry [20].

Ethical considerations

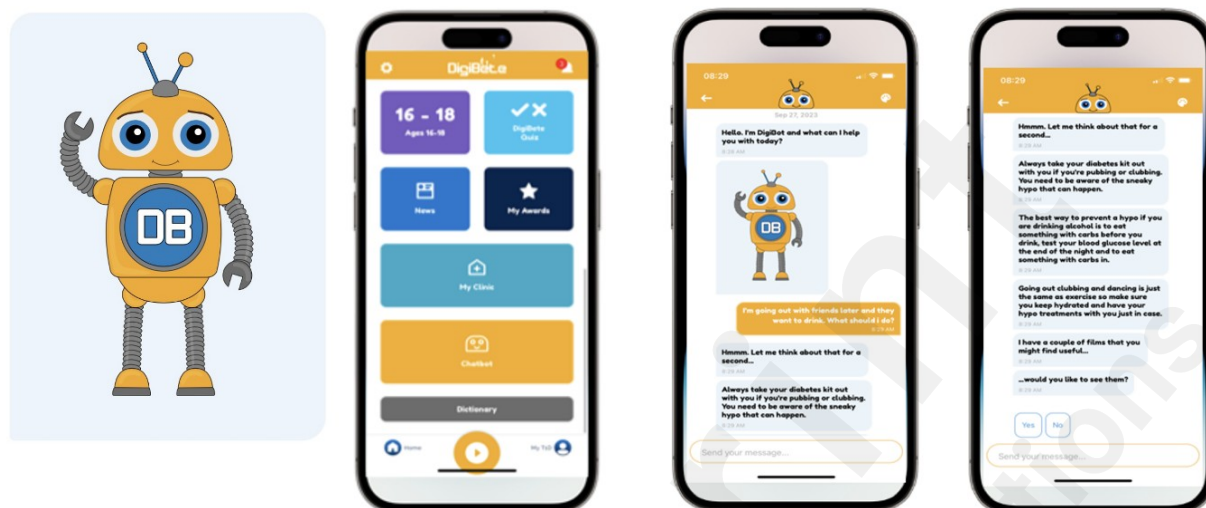
The NHS Research Ethics Committee (the Integrated Research Application System - IRAS Reference:292053), the Lead NHS Trust Research and Innovation Department and the Ethics Committee at the researchers' university approved this study. Data were collected and retained in accordance with the Data Protection Act 2018. Consent/assent forms and investigator site files were electronic. All data were managed in accordance with the data management plan of the lead/corresponding author's university. Study documents were stored in a secure location during the study and will be retained for a period of 5 years. Audio recordings of qualitative interviews/focus groups were encrypted. Data from the focus groups, interviews and questionnaires are stored in password-protected files on a university server. The raw data were only shared with researchers working on the relevant work packages. Electronic data were transferred using encrypted devices according to standard University data-protection policies. No person-identifiable information was used in the reporting.

Results

Eighteen YP/YA with T1DM (12 female) assented/consented to participate. The mean age was 17 (SD = 4.52) years. The mean number of years since diagnosis was 7.94 (SD=5.57).

Figure 1 illustrates screenshot examples from the chatbot as viewed by participants:

Figure 1: Screenshot examples from the DigiBete Chatbot as viewed by feasibility study YP/YA users:



Participants' engagement with study procedures varied. Overall, 72% of the recruited YA/YP fully completed the study, 11% partially completed it, and 17% did not engage in the study. Twenty-five HCPs and four parents participated in the individual or group interviews, see this Multimedia Appendix xxxx for more detail about participant characteristics. Semi-structured interviews (n=16) were conducted online and focus groups (n=4) online or in-person in a quiet room in the hospital, at dates/times convenient to the participants, by experienced qualitative researchers who facilitated discussions based on topic guides. Discussions were digitally recorded, and transcripts were anonymized and coded by the researchers.

Quantitative findings

Table 1 shows the three time-points for administration of questionnaires, and the number of YA/YP who assented/consented and completed the questionnaires.

Table 1: Questionnaire administration time-points and number of completions

Questionnaires	T0 (before)	T1 (2 weeks)	T2 (6 weeks)
HADS	● (N=15)	● (N=15)	● (N=14)
SF-36	● (N=15)	● (N=15)	● (N=14)
SUS		● (N=15)	● (N=14)
uMARS			● (N=14)

System Usability Score (SUS)

Participants were required to answer all the SUS items. The scores were calculated using the method recommended by Hagglund and Scandurra (2021) [22]. As reported in Table 2, each item was scored from 0 to 4 (with 4 being the most positive response). Scoring SUS involved the 2 initial steps:

1. For odd-numbered positive statements: subtract 1 from the user response.
2. For even-numbered negative statements: subtract the user responses from 5

Two types of calculations were performed: 1) calculating the mean value of all individual answers (Table 2), and 2) calculating the mean of all answers at T1 and T2 (Table 2).

As demonstrated in Table 2, most items had a mean score above 3.0. At T1, six items scored above the mean of 3.0, whereas at T2, eight items scored above the mean of 3.0.

There was a reduction in the score for Item 6 in relation to the consistency of the responses given by the chatbot. There was no change in the scores for Items 4 and 10.

Table 2: Mean SUS score of the DigiBete chatbot for individual items at T1 and T2

Item	Modified SUS statement	T1 (15 participants)	T2 (14 participants)
1	I think that I would like to use the chatbot frequently	2.1	2.3
2	I found the chatbot unnecessarily complex	3.4	3.6
3	I thought the chatbot was easy to use	3.5	3.7
4	I would need the support of a technical person	3.9	3.9
5	I found the various functions in the chatbot were well integrated	2.6	3.1
6	I thought there was too much inconsistency in the chatbot	2.9	2.4
7	most people would learn to use this system very quickly	3.7	3.9
8	I found the system very cumbersome to use	3.3	3.4
9	I felt very confident using the chatbot	2.9	3.5
10	I needed to learn a lot of things before I could get going with the chatbot.	3.9	3.9
Number of items scored above 3.0		6	8

To calculate the mean and median of all scores, the scores for each item were then added together and multiplied by 2.5 to obtain the final score. The final score ranged from 0 to 100, with higher scores indicating better usability.

The mean and median of the final score were then calculated: at time-point 1 the mean was 80.5 and the median was 82.5; at time point 2, the mean was 85.2 and the median was

86.3. The results can be interpreted using Lewis and Sauro's interpretation [19] where:

- An SUS score of 80.5 (at T1) was designated as good or an A- grade.
- An SUS score of 85.2 (at T2) was designated as the best imaginable or an A+ grade.

Usability improved between T1 (two weeks) and T2 (six weeks).

Mobile Application Rating Scale: user version (uMARS)

Table 3 provides a detailed breakdown of the number of questions in each category and the highest scores obtained in each category. Based on participants' responses, the mean score and mean percentage were calculated. All questions were mandatory for participants to answer.

Table 3: Question breakdown according to category

Category	Number of questions	Highest total score that can be obtained	Mean score for each category	Percentage of the mean score
Engagement	5	25	17.43	69.7
Functionality	4	20	17.86	89.3
Aesthetics	3	15	12.93	86.2
Information	4	20	15.92	79.6
App subjective quality	4	20	12.79	64.0
Perceived impact	6	30	19.79	66.0

The mean quality app score is 16.03. This was calculated by adding the mean scores for Engagement, Functionality, Aesthetics and Information categories and dividing them by 4.

Table 4 shows the mode of participants' responses (5-point Likert scale plus an N/A response option) for the Engagement, Functionality, Aesthetic and Information categories; most responses scored 4 or 5. The Functionality category achieved the highest percentage of scores of 4 and 5 (96.43%). The Engagement category had the lowest percentage of scores of 4 and 5 (57.14%). Two respondents selected the N/A response option in the Information Category indicating that they received no information regarding the quality and quantity of the content, availability of visuals, and credibility of the sources contained in the chatbot to answer their questions. These results indicate that although over 50 percent of participants found the DigiBete Chatbot easy to navigate and use, it needs further modifications to make it more accessible for some users.

Table 4: Mode of participants' responses

Scale /	1	2	3	4	5	N/A	Total
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Categories	Inadequate				Excellent		responses
Engagement: <i>Entertainment, interest, customization, interactivity, target group.</i>	4	7	19	31	9	0	70
Functionality: <i>Performance, ease of use, navigation, gestural design</i>	0	1	1	25	29	0	56
Aesthetics: <i>Layout, graphics, visual appeal.</i>	0	0	4	21	17	0	42
Information: <i>Quality of information, quantity of information, visual information, credibility of source.</i>	0	3	10	22	19	2	54

Table 5 lists the subjective quality item ratings, 85.72% would potentially recommend the chatbot and 14.29% of the participants would recommend it. More than half of participants (64.29%) would not pay for the DigiBete Chatbot. Over 50% of users rated the chatbot as 4- or 5-star.

Table 5: Subjective app quality

Subjective chatbot quality uMARS items	Value (N=14)
Would you recommend the DigiBete Chatbot to people who might benefit from it?	
1: Not at all	0 (0%)
2	0 (0%)
3: Maybe	6 (42.86%)
4	6 (42.86%)
5: Definitely	2 (14.29%)
How many times do you think you would use the DigiBete Chatbot in the next 12 months if it was relevant	

to you?	
1: None	0 (0%)
2: 1-2	0 (0%)
3: 3-10	7 (50%)
4: 10-50	6 (42.86%)
5: >50	1 (7.14%)
Would you pay for the DigiBete Chatbot?	
1: Definitely not	9 (64.29%)
2:	2 (14.29%)
3:	3 (21.43)
4:	0 (0%)
5: Definitely yes	0 (0%)
What is your overall (star) rating of the DigiBete Chatbot?	
1: One of the worst apps I've used	0 (0%)
2:	0 (0%)
3: Average	6 (42.84%)
4:	6 (42.86%)
5: One of the best apps I've used	2 (14.29%)

Hospital Anxiety and Depression Scale (HADS)

The HADS results showed that anxiety sub-scale values were higher than those of the depression sub-scale (Table 6). Specifically, some participants reported a borderline or abnormal anxiety score (higher mean for anxiety), whereas their depression scores were within the normal range. The anxiety scale also had higher maximum values, which were within the abnormal range. One participant had an anxiety score close to the maximum abnormal range (values of 19 and 20).

Most participants reported a normal range of depression scores at all time points. However, between the anxiety and depression sub-scales, the anxiety sub-scale achieved a higher percentage of participants at the time points: 26.67% at T0 and T1 and 35.71% at T2. Only 6.67% were classed as 'abnormally' depressed at T0 and T1 while no participant was considered 'abnormally' depressed at T2.

Table 6: HADS – percentage of participants with normal, borderline and abnormal levels of depression and anxiety

	T0 (N=15)		T1 (N=15)		T2 (N=14)	
	Depression	Anxiety	Depression	Anxiety	Depression	Anxiety
Normal	93.33	53.33	93.33	60.00	92.86	64.29
Borderline	0.00	20.00	0.00	13.33	7.14	0.00
Abnormal	6.67	26.67	6.67	26.67	0.00	35.71

36-Item Short Form Survey Instrument (SF-36)

YPs and YAs were required to answer all 36 questions at all time points. Table 7 shows the average and SD of YPs/YAs scores across the three time points for each health domain. The Physical Functioning domain had consistently high mean scores with no significant change observed between the time points. This could indicate that YPs/YAs can perform basic activities (e.g. walking) and instrumental activities of daily living (e.g. bathing and dressing). Items in this domain also include perceived participants' ability to perform vigorous activities, such as running and lifting heavy objects, and moderate activities such as moving a table and bowling.

The domain Energy Fatigue, however, has two mean values, which are the lowest in comparison to the mean values in other domains. In this domain, the YPs/YAs were asked questions related to their emotional well-being (feeling energetic, lively and enthusiastic) and physical well-being (feeling worn out and tired). Low scores in this domain could indicate that they are feeling drained and demotivated.

Overall, there was no significant change across the 3 time points for all the domains.

Table 7: SF-36 domains and mean and SD results at three timepoints

Scale	T0 (N=15)		T1 (N=15)		T2 (N=14)	
Domain	Mean	SD	Mean	SD	Mean	SD
Physical Functioning (PF)	92.33	9.42	92	8.62	91.43	12.16
Role limitations due to Physical health (RP)	80.00	30.18	88.33	20.85	83.93	33.41
Role limitations due to Emotional health (RE)	77.78	32.53	80.00	37.37	80.95	33.88
Energy/Fatigue (EF)	61.67	24.03	62.00	19.71	56.79	23.66
Emotional Well-being (EW)	69.07	19.85	70.13	20.50	68.86	23.70
Social Functioning (SF)	85.00	23.24	82.50	24.91	86.61	24.25
Bodily Pain (BP)	83	15.12	83.50	15.26	83.93	16.60
General Health (GH)	59.33	15.91	63.00	13.73	65.36	16.69

Qualitative findings

A total of 41 participants (N=6 x YP (11-15 years); 6 x YA (16-24), 4 x parents, and 25 x HCPs) participated in an individual or focus-group interview. The full Framework of themes/sub-themes derived from qualitative data analysis is available in this Multimedia Appendix xxxx. Below, we present summary narratives juxtaposed with verbatim quotations to

illustrate the derived themes:

Living with T1DM:

YP and YA spoke of the shock of diagnosis and the overwhelming information related to it, as one YA described:

I think my parents took it harder than I did, and no one really knew about it. Dad struggled Lockdown [Covid] difficult straight after diagnosis.

Also, her parents thought the diagnosis was wrong at first, so when it was confirmed correct:

...that was quite sad. but after that, once I'd accepted it, found it quite insightful. It was hard, get used to it, [but] becomes second nature.

(YA aged 22 years, diagnosed aged 19 years)

YP/YA acted as peer support and educators for those around them and were aware that learning more about the YP/YA's condition may be stressful for others; they generally accepted living with T1DM and could not remember a time before diagnosis, although some indicated frustration about the inconvenience of self-management.

Parents showed awareness of future needs as their child moved towards independence, and they were pleased with how their child coped:

He's done very well to adapt to it

(Parent of 13-year-old, diagnosed at 9 years)

Using the DigiBete Chatbot:

The participants were positive about the chatbot, its benefits to users and those around them. It provides reassurance, generally offers accurate advice and has potential as an educational tool for others. A short, easy to read format was preferred, and all found it straightforward to use. Preference for short text messages and videos over links to websites and PDFs was indicated by YP/YAs and HCPs. Some participants indicated that the DigiBete chatbot was not their only source of T1DM information and reassurance, and that they may not rely on it in an emergency.

One YP thought the chatbot might be useful when he is out with friends, and while he

seemed confident about managing his T1DM, he thought he may need further advice with self-management in the future, for example to calculate alcohol units in a specific drink:

Yeah because, like drinking alcohol maybe?
(11-year-old boy, diagnosed at 2-years)

Without exception, YP, YA and parents would recommend the DigiBete Chatbot to others because they liked its accessibility, together with the reassurance and knowledge it provides. Generally, HCPs received the chatbot positively and thought it might fill a gap by addressing questions typically not asked in the clinic by YP/YA. As one HCP said, patients may, for example ask:

'What happens if I give too much insulin?' or 'Can I lose weight by not taking insulin?'. It's those unsaid things [often] not asked in clinic.

(Clinical Psychologist)

However, some HCPs were more reserved about recommending it in its current stage of development, citing safety and accuracy concerns. For example, some were concerned about the accuracy of some information provided, given the wide age range of prospective users. Some HCPs were also worried that some terminology used by the YP/YA when asking questions of the chatbot may be interpreted incorrectly. One HCP said they would:

...like to see safety mechanisms built in before recommending its use...

(Consultant Paediatrician)

Refining the DigiBete Chatbot:

The appearance of the chatbot was well received by participants, although options for customization of the avatar were suggested (this finding corresponds with results from the uMARS). Participants recommended further refinement of the accuracy of chatbot responses with options to tailor or streamline responses by age, comprehension abilities, language preference and voice activation. These recommendations are consistent with the results of the uMARS which also indicate that the chatbot needs further modification, with improvements to enable users to customize it and make it more entertaining. See this Multimedia Appendix xxxx for participants' qualitative suggestions for ways to improve the

chatbot, and the developers' responses regarding the feasibility of integrating these suggestions in a future version of the chatbot.

The complexity of responses could be reduced to encourage engagement with the information provided. For example, some said that there was a need for the chatbot to supply short, text-based answers first, rather than what they sometimes received in response to their questions, which could be lengthy and complicated information. Participants suggested that safety issues around mental health and emotional support should be enhanced by referencing correct support in a timely manner. Suggestions for expanding content focused on the provision of reassurance, accurate contemporary information while recognizing users' developmental stage, and potential for experimentation alongside peers. For instance, one Diabetes Nurse was concerned that those with: ... *English as a second language may struggle* and that YP/YA may think they are talking directly with their clinical team via the chatbot; this respondent highlighted a need to be clear that the diabetes team are not available 24/7, so they:

...may need DigiBete Chatbot to remind them in bold, big message flashing up and give contact numbers.

This HCP also said it would be helpful if information about meals and carbohydrates in food outlet chains was linked to the chatbot, as YP/YA may be embarrassed to request this information when eating out.

The chatbot could encourage compliance with medications, clinic attendance or engagement with specialist teams. The difficulty of deciding what information to include in the chatbot was acknowledged, along with the extensive age range of potential users. Additionally, other suggestions for future chatbot enhancement were extracted from the qualitative data (Multimedia Appendix xxxx,

Discussion

Principal Findings

To our knowledge this is the first national (UK/NHS) or international self-management chatbot to be co-designed, developed and evaluated by patients living with T1DM during their transition journey, parents and HCPs [1-12]. The results reported here will inform the design and delivery of a future large-scale cohort study to assess the acceptability, functionality and usability of the DigiBete Chatbot when assessed by 11–24-year-olds with T1DM. This will potentially pave the way for development of a fully functional, NHS approved, age and developmentally appropriate online and app-based chatbot to 'go live'

after the end of the cohort study.

The DigiBete Chatbot addresses the identified lack of personalized supported self-management tools available for 11-24 yr olds with T1DM and other chronic conditions [8, 12, 23, 24]. Our reactive conversational agent offers content (messaging and additional multimedia resources) that is age and developmentally appropriate and clinically approved. The DigiBete Chatbot was co-designed and co-developed with and for YP/YA with T1DM as they transitioned from child to adult health services, providing them with informational support to enhance their knowledge, skills, and confidence in navigating their T1DM self-management journey [8, 25]. Scores from the SUS, designed to measure users' perception of the usability of a system, indicated improvement from baseline to the second timepoint, with improvements in perceived ease of use, functionality and confidence. This demonstrates that participants viewed the chatbot as highly usable. Having used the chatbot for 6 weeks, YA/YP who were more likely to use it in the future, found that its functions were well integrated, became more confident in using it and perceived the chatbot to operate in a consistent way. This aligns with the consolidated star rating from the uMARS showing that more than fifty percent of participants allocated the DigiBete Chatbot 4 or 5 stars out of 5, with no respondents rating the app below 3 out of 5 stars.

After using the chatbot, participants scored it highly in the domains of engagement, functionality, aesthetics and the information provided, with lower overall scores in the subjective quality and perceived impact. Functionality scored highly, suggesting that the chatbot met the intended needs of users in relation to performance, ease of use, navigation and gestural design. Despite this, feedback from the HADS questionnaire demonstrates that the chatbot is unlikely to have a significant impact on depression and anxiety over the short time scale applied to the feasibility study. This aligns with the lower score for the perceived impact in the uMARS questionnaire. Similarly, from the SF-36 results, the chatbot did not impact physical or emotional well-being and did not improve social functioning, although there was a trend towards improvement in general health.

However, as the chatbot was only available to each user for a six-week period it is likely that this period is too short to demonstrate a significant impact on the overall physical, emotional and social health of YP/YA. Furthermore, given that this was a feasibility study, the small number of responses may have been insufficient to demonstrate impact on emotional and physical well-being. In future studies, a longer trial period with more

participants to assess impact in the domains of the HADS and SF-36 may provide a more realistic view of impact. In the qualitative assessment, users recognized that the chatbot could identify issues around mental health and emotional wellbeing and suggested that 'safety-netting' within the chatbot could support timely referral and so was required. Responses in uMARS also demonstrated that the chatbot was aesthetically pleasing to users, although in future developments, participants would like the ability to customize the chatbot based upon their personal preferences. Reassuringly, all participants would recommend the chatbot and would use it again within the following 12 months.

Qualitative data demonstrates that participants were positive about the chatbot, its benefits to users and those around them. It provides reassurance, generally gives accurate advice and has potential as an educational tool for YA/YP with other health conditions. All YP/YA and parents would recommend it to others and HCPs also received the chatbot positively, however, more work was required by some HCPs to develop it further from its current form. Quantitative analysis demonstrates that the chatbot was usable, and over time, YP/YA gained confidence in its use. Users particularly liked the functionality and information provided. However, the areas of improvement cited include the need for more technical information and support when using the chatbot.

Before proceeding further, we recommend improving the usability of the DigiBete Chatbot by, for example, enabling it to remember each user at return visits, recording detail relating to user characteristics to assist the persuasive conversational capacity of the intervention, accommodating user language choices in their conversational dialogue and supporting customization and personalization. Given the ubiquitous use of smartphones and increasing popularity of chatbots in daily life for YP/YA, chatbots such as DigiBete may also be an increasingly popular and scalable solution to promote confident and competent self-management during transition by YP/YA living with other chronic conditions⁷. For example, YP/YA with Juvenile Arthritis or chronic kidney disease [29, 30] also often experience high levels of self-management support needs before and during transition to adult healthcare; these needs could be addressed by tailored chatbots such as the DigiBete Chatbot.

Strengths and limitations

The study design was strengthened by basing it on the Template for Intervention Description and Replication (TIDieR) checklist, Multimedia Appendix xxxx details this as a

guide, and using a multi-method design in which qualitative data helped to foster insights into factors underpinning quantitative data. The feasibility testing enabled us to refine and put study procedures in place, incorporate inclusion and exclusion criteria and processes for tracking enrolment and data collection, and evaluate the performance of measures in a sample drawn from the target population for a future full scale study, train research staff in administering study procedures, including participant identification and referral, recruitment, enrolment, data collection, and teaching participants how to use the chatbot. The DigiBete Chatbot has the potential to beneficially affect patients' self-reported self-management outcomes and a full-scale study of its usability and acceptability following iterative changes to the chatbot based on the reported findings was found to be feasible.

The study has some limitations, for example While the primary source of identification and recruitment of participants was clinical appointments, this process could be further strengthened in the future by clinicians inviting existing DigiBete App users via the app. In addition, there was a relatively small sample size and limited diversity regarding digital exclusion and ethnic diversity. There are also limitations to the reactive chatbot's content/functionality and content recommendations, some of these recommendations cannot yet be achieved owing to the current technological capabilities of the chatbot. Most data were collected remotely which was convenient for most participants during the Covid pandemic. Although questionnaire completion rates were less than optimum, the measures could be used in a future full study with small amendments. For example, the respondent burden for the SF-36 was high as it involves eight domains across 36 items, but this could be reduced to 17 items by selecting only the three most relevant domains: physical function (10 items), social function (2 items) and mental health (5 items).

Conclusions

The impact of chatbots in T1DM care remains unclear. Prior to examining the DigiBete Chatbot's effectiveness in the future, its usability, acceptability and impact on users' psychological well-being in the target YP/YA population were examined. The DigiBete Chatbot was deemed usable, acceptable and feasible for delivery. Our results warrant some refinement of the chatbot based on the recommendations reported here and further investigation prior to its wider use in clinical practice. Our research design and methodology could also be transferred to the development and evaluation of chatbots for YA/YP living with other chronic conditions before and after transition.

On the premise of this feasibility study, the plan is to rebuild the DigiBete Chatbot to meet identified user needs and preferences and progress to a national cohort study to assess the usability, feasibility and acceptability of a modified chatbot, with a view to proceeding to roll-out for national/international use on the established DigiBete platform (<https://www.digibete.org>).

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- The multidisciplinary team worked with industry partners including Digibete and IBM to develop a chatbot and multi-media resources on transition on the established DigiBete T1DM platform that could provide YP with information in an acceptable form. Our PPI work ensured that the information and chatbot met the needs of YP/YA and allowed the chatbot and media to be modified and evaluated accordingly.

Conflict of interests

A potential conflict of interest is that co-author Maddie Julian is also a DigiBete developer, however, she was not involved in participant recruitment, data collection or analysis and did not view any data until they were anonymised. The remaining authors declare no conflicts of interest with respect to the research and/or publication of this article.

Abbreviations

DHT	Digital health technologies
DKA	Diabetic ketoacidosis
EUG	Expert User Group
HADS	Hospital Anxiety and Depression Scale
HCPs	Health care professionals

NHS	National Health Service
NICE	National Institute for Health and Care Excellence
SF36	Short-Form 36
SUS	T0
T1	Time 1 (2 weeks)
T2	Time 2 (6 weeks)
T1DM	Type 1 Diabetes Mellitus
UK	United Kingdom
uMARS	user version of the Mobile App Rating Scale
YP/YA	Young people and young adults

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Authors' Contributions

PD conceived and planned the study with input from VS, MJ, FC, AS, RZ, SD and AR. JH and EM distributed the questionnaires and analysed the data. JH, EM, VS, HM, JB and JMK conducted and analysed the interviews/focus groups. VS, PD, JB, JH, HM and EM drafted the manuscript; PD, JH, EM, JB, AR, FC, HM, AS, RZ, MJ and JMK provided feedback on the manuscript. All authors approved the final version of the manuscript for submission.

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Table 1: Questionnaire administration time-points and number of completionstable 1

Questionnaires	T0 (before)	T1 (2 weeks)	T2 (6 weeks)
HADS	• (N=15)	• (N=15)	• (N=14)
SF-36	• (N=15)	• (N=15)	• (N=14)
SUS		• (N=15)	• (N=14)
uMARS			• (N=14)

Table 2: Mean SUS score for individual items at T1 and T2

Item	Modified SUS statement	T1 (15 participants)	T2 (14 participants)
1	I think that I would like to use the Chatbot frequently	2.1	2.3
2	I found the Chatbot unnecessarily complex	3.4	3.6
3	I thought the Chatbot was easy to use	3.5	3.7
4	I would need the support of a technical person	3.9	3.9
5	I found the various functions in the Chatbot were well integrated	2.6	3.1
6	I thought there was too much inconsistency in the Chatbot	2.9	2.4
7	most people would learn to use this system very quickly	3.7	3.9
8	I found the system very cumbersome to use	3.3	3.4
9	I felt very confident using the Chatbot	2.9	3.5
10	I needed to learn a lot of things before I could get going with the Chatbot.	3.9	3.9
Number of items scored above 3.0		6	8

Table 3: Question breakdown according to category

Category	Number of questions	Highest total score that can be obtained	Mean score for each category	Percentage of the mean score
Engagement	5	25	17.43	69.7
Functionality	4	20	17.86	89.3
Aesthetics	3	15	12.93	86.2
Information	4	20	15.92	79.6
App subjective quality	4	20	12.79	64.0

Perceived impact	6	30	19.79	66.0
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Table 4: Mode of participants' responses

Scale / Categories	1 Inadequate	2	3	4	5 Excellent	N/A	Total responses
Engagement: Entertainment, interest, customization, interactivity, target group.	4	7	19	31	9	0	70
Functionality: Performance, ease of use, navigation, gestural design	0	1	1	25	29	0	56
Aesthetics: Layout, graphics, visual appeal.	0	0	4	21	17	0	42
Information: Quality of information, quantity of information, visual information, credibility of source.	0	3	10	22	19	2	54

Table 5: Subjective app quality

Subjective Chatbot quality uMARS items	Value (N=14)
Would you recommend the Chatbot to people who might benefit from it?	
1: Not at all	0 (0%)
2	0 (0%)

3: Maybe	6 (42.86%)
4	6 (42.86%)
5: Definitely	2 (14.29%)
How many times do you think you would use the Chatbot in the next 12 months if it was relevant to you?	
1: None	0 (0%)
2: 1-2	0 (0%)
3: 3-10	7 (50%)
4: 10-50	6 (42.86%)
5: >50	1 (7.14%)
Would you pay for the Chatbot?	
1: Definitely not	9 (64.29%)
2:	2 (14.29%)
3:	3 (21.43)
4:	0 (0%)
5: Definitely yes	0 (0%)
What is your overall (star) rating of the Chatbot?	
1: One of the worst apps I've used	0 (0%)
2:	0 (0%)
3: Average	6 (42.84%)
4:	6 (42.86%)
5: One of the best apps I've used	2 (14.29%)

Table 6: HADS – percentage of participants with normal, borderline and abnormal levels of depression and anxiety

	T0 (N=15)		T1 (N=15)		T2 (N=14)	
	Depression	Anxiety	Depression	Anxiety	Depression	Anxiety
Normal	93.33	53.33	93.33	60.00	92.86	64.29
Borderline	0.00	20.00	0.00	13.33	7.14	0.00
Abnormal	6.67	26.67	6.67	26.67	0.00	35.71

Table 7: SF-36 domains and mean and SD results at three timepoints

Scale	T0 (N=15)		T1 (N=15)		T2 (N=14)	
Domain	Mean	SD	Mean	SD	Mean	SD
Physical Functioning (PF)	92.33	9.42	92	8.62	91.43	12.16
Role limitations due to Physical health (RP)	80.00	30.18	88.33	20.85	83.93	33.41
Role limitations due to Emotional health (RE)	77.78	32.53	80.00	37.37	80.95	33.88
Energy/Fatigue (EF)	61.67	24.03	62.00	19.71	56.79	23.66
Emotional Well-being	69.07	19.85	70.13	20.50	68.86	23.70

(EW)						
Social Functioning (SF)	85.00	23.24	82.50	24.91	86.61	24.25
Bodily Pain (BP)	83	15.12	83.50	15.26	83.93	16.60
General Health (GH)	59.33	15.91	63.00	13.73	65.36	16.69

Supplementary Files

Multimedia Appendixes

Details on measures used.

URL: <http://asset.jmir.pub/assets/994d2697c6e09d85fbf55df3ba8a7980.docx>

Participant characteristics.

URL: <http://asset.jmir.pub/assets/c29f8f8fe4ee127de4fdc42117e91e85.docx>

Framework of derived themes from qualitative data.

URL: <http://asset.jmir.pub/assets/fbde827a973e3d95492e8be6e465be38.docx>

Participants' qualitative suggestions from data.

URL: <http://asset.jmir.pub/assets/822d5a028c4faf8ec14e555b723652d8.docx>

TiDier checklist.

URL: <http://asset.jmir.pub/assets/04ad34134549e157b509cd8aa6723c50.docx>