




BMJ Open Impact of virtual care on health-related quality of life in children with diabetes mellitus: a systematic review protocol

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To cite: Rajan R, Kshatriya M, Banfield L, *et al*. Impact of virtual care on health-related quality of life in children with diabetes mellitus: a systematic review protocol. *BMJ Open* 2022;**12**:e053642. doi:10.1136/bmjopen-2021-053642

► Prepublication history and additional supplemental material for this paper are available online. To view these files, please visit the journal online (<http://dx.doi.org/10.1136/bmjopen-2021-053642>).

Received 22 May 2021

Accepted 24 January 2022

ABSTRACT

Introduction Diabetes mellitus is the most common endocrine disorder in children, and the prevalence of paediatric type 1 and type 2 diabetes continue to rise globally. Diabetes clinical care programs pivoted to virtual care with the COVID-19 pandemic-driven social distancing measures. Yet, the impact of virtual care on health-related quality of life in children living with diabetes remains unclear. This protocol reports on the methods that will be implemented to conduct a systematic review to assess the health-related quality of life and metabolic health impacts of virtual diabetes care.

Methods and analysis We will search MEDLINE, Embase, EMCare, PsycInfo, Web of Science, and the grey literature for eligible studies. We will screen title, abstract, and full-text papers for potential inclusion and assess the risk of bias and the overall confidence in the evidence using the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) approach. A meta-analysis will be conducted if two studies report similar populations, study designs, methods, and outcomes.

This systematic review will summarise the health-related quality of life outcomes for virtual diabetes care delivery models.

Ethics and dissemination No ethics approval is required for this systematic review protocol as it does not include patient data. The systematic review will be published in a peer-reviewed journal and presented at international conferences.

PROSPERO registration number CRD42021235646.

INTRODUCTION

Diabetes mellitus is the most common endocrinopathy in children.¹ Over 1.1 million children and youth are living with type 1 diabetes mellitus (T1DM) globally.^{2,3} While the global prevalence of type 2 diabetes mellitus (T2DM) has not been fully measured, the prevalence rates are estimated to be up to 5330/100 000 children,⁴ and paediatric T2DM rates are steadily rising in parallel with its main driver, obesity.^{2,5}

Diabetes care and outcomes have been transformed over the past few decades with the development of new insulins, insulin delivery systems, and glucose monitoring

Strengths and limitations of this study

- This systematic review protocol includes a detailed reporting of the methods to assess health-related quality of life outcomes with virtual diabetes care in paediatric patients, and guides future policy directions in implementing virtual care in this population.
- The use of virtual care models and their impact on diabetes outcomes is a relatively novel area of care, and having data on their impact is critical to justify scalability.
- If there is high heterogeneity, it will not be feasible to conduct a meta-analysis to estimate effect size.

devices.^{6–12} In addition, outpatient-based multidisciplinary care have become the norm, and several guidelines recommend quarterly clinic visits.^{6 7 10 11 13 14} This care approach, while beneficial, is labor-intensive, costly, and can be disruptive to caregivers' work schedules and school time for children, with a negative impact on health-related quality of life (HRQOL).^{13 15 16}

Since the start of the COVID-19 pandemic, a seismic shift in diabetes care took place; multidisciplinary care needed to shift swiftly to virtual platforms due to social distancing measures to protect patients and manage finite healthcare resources.^{17 18} While it is unclear whether virtual care has had a negative impact on outcomes, the full implications of this shift in care delivery are starting to emerge.¹⁸

Virtual care for diabetes during the COVID-19 pandemic is building on existing trends of increased access to remote care using web-based (eHealth) and mobile-based (mHealth) platforms. These platforms included telephone, Skype for Business, and Zoom that allow audio and video communications between patients, families, and healthcare providers.^{17 19} The online platforms of continuous glucose monitoring devices and insulin pumps were leveraged



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for sharing accurate glycaemic control and management data with healthcare providers.^{17 18 20 21} eHealth refers to internet, virtual reality, or digital gaming applications that allow users to monitor, manage, or learn more about their health through video, text, or interactive learning media.^{22–24} mHealth refers to portable or wireless applications such as text messaging, mobile-compatible applications (apps), wearable devices, or the use of social media.^{22 23 25} The integration of virtual care modalities into healthcare is quite promising due to their relatively low cost, scalability, and association with successful patient engagement, satisfaction with communication with healthcare teams, and the facilitation of access to specialised care and diabetes monitoring.^{26 27}

While focus on virtual interventions to improve glycaemic control is important, this improvement may impact HRQOL as the responsibilities associated with this care approach may be burdensome for patients and their families.⁸ The eHealth and mHealth approaches increase patient involvement in their care but there is also a need for familiarity with technical aspects of these care modalities.^{27 28} There is currently no existing evidence synthesis of the impact of virtual interventions on HRQOL in children living with diabetes.

The objectives of this systematic review protocol are to report on the methods of a systematic review to determine the effectiveness of eHealth and mHealth interventions in maintaining or improving HRQOL, glycaemic control, overweight and obesity, and assess their impact on adverse events in children living with diabetes. Also, we aim to determine patient and caregiver satisfaction, and the acceptability and feasibility of virtual care modalities.

Research questions

Primary

In children with diabetes, does the use of eHealth and mHealth interventions, when compared with in-person care, maintain or improve HRQOL?

Secondary

In children with diabetes, do virtual interventions maintain or improve glycaemic control, body mass and reduce adverse diabetes-related outcomes when compared to in-person care? Is virtual care usable and acceptable for this population?

METHODS

The methodology for this protocol has been reported based on the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) guideline^{29 30} (online supplemental file 1). This protocol has been registered with PROSPERO. We aim to complete this systematic review between October 2021 and March 2022.

Patient and public involvement

Patients and/or the public were not involved in the design, conduct, reporting or dissemination plans of this research.

Search strategy

This review's search strategies will be developed by a Senior Health Sciences Librarian (LB), who has expertise in designing systematic review search strategies. A sample Ovid MEDLINE search strategy is reported in [table 1](#). Our searches will run on the following platforms: Ovid MEDLINE, Ovid Embase (Elsevier), Ovid EMCare (Elsevier), PsycInfo, and Web of Science (Clarivate). The grey literature searches will be done using ProQuest Dissertations and Theses A&I and ClinicalTrials.gov.

Inclusion criteria

We will include studies that recruited boys and girls ages 2–18 years, from all ethnicities and diagnosed with T1DM or T2DM. The diagnosis of diabetes is established using standardised criteria, with a random or a 2-hour post oral glucose tolerance test ≥ 11.1 mmol/L (200 mg/dL), or a fasting glucose level of ≥ 7.0 mmol/L (126 mg/dL).⁶

Children at all pubertal stages based on Tanner staging,^{31 32} glycaemic control levels (using HbA1c) and body mass index (BMI) z-scores will be included. Children treated with insulin injections of all insulin types and regimens (multiple daily injection regimens, two times a day regimens, insulin mixes) will be included. We will also have children on insulin pump therapy regardless of pump type and those using glucometers or continuous glucose sensors as applicable.

We will include studies from all geographic locations, languages, and publication timing.

The eligible study designs to be included in this systematic review are randomised and non-randomised comparative studies. We will exclude protocol papers, case reports, and commentaries. Eligible studies which are not published in English will be translated using google translate.

Children with comorbid autoimmune conditions (e.g. Hashimoto's thyroiditis, Graves' disease, coeliac disease), as well as children with diabetes-related complications including neuropathy, nephropathy, and retinopathy will be included.

This review will include interventions that deliver diabetes care via eHealth and mHealth approaches. Diabetes education and care refers to personalised patient and caregiver engagement to monitor and promote glycaemic control and limit comorbidities.^{7 10} eHealth refers to the Internet, virtual reality, or digital gaming applications that allow users to monitor, manage, or learn more about their health through video, text, or interactive learning media.^{22–24} mHealth refers to portable or wireless applications such as text messaging, mobile-compatible applications (apps), wearable devices, or the use of social media.^{22 23 25} These applications also allow for user engagement with health monitoring, management, and learning.^{24 25 33}

Comparator groups will be reported if available. These groups will include patients receiving usual care ; this approach includes diabetes education and care delivery via in-person clinic visits with diabetes healthcare teams.

Table 1 Ovid MEDLINE search strategy

#	Searches
1	Child/
2	child*.mp.
3	Adolescent/
4	adolescen*.mp.
5	Pediatrics/
6	pediatric*.mp.
7	paediatric*.mp.
8	teen*.mp.
9	preadolescen*.mp.
10	preteen*.mp.
11	or/1–10
12	Diabetes Mellitus, Type 2/or Diabetes Mellitus, Type 1/or Diabetes Mellitus/
13	(T1D or T1DM or T2DM or T2D or NIDDM or IDDM).mp.
14	diabet*.mp.
15	or/12–14
16	Telemedicine/
17	telemedicine.mp.
18	tele-medicine.mp.
19	mhealth.mp.
20	ehealth.mp.
21	virtual health.mp.
22	Mobile Applications/
23	teleconsult*.mp.
24	web-based.mp.
25	mobile-based.mp.
26	Social media/
27	social media.mp.
28	twitter.mp.
29	telemonitor*.mp.
30	Remote Consultation/
31	iphone.mp.
32	computers/ or computers, handheld/ or smartphone/
33	smart phone*.mp.
34	smartphone*.mp.
35	computer*.mp.
36	laptop*.mp.
37	((remote or web or virtual or online) adj2 (consult* or appointment*)).mp.
38	((web or virtual or online) adj2 (education or communit* or platform*)).mp.
39	ipad.mp.
40	(android adj3 (tablet* or device* or phone*)).mp.
41	or/16–40
42	Comparative Study/

Continued

Table 1 Continued

#	Searches
43	comparative stud*.mp.
44	cohort studies/ or prospective studies/ or retrospective studies/
45	cohort stud*.mp.
46	Observational Study/
47	observation* stud*.mp.
48	nonrandom*.mp.
49	non-random*.mp.
50	Randomized Controlled Trial/ or Randomized Controlled Trials as Topic/
51	randomized controlled trial*.mp.
52	Random Allocation/
53	random*.mp.
54	Clinical Trial/
55	clinical trial.mp.
56	retrospective.mp.
57	prospective.mp.
58	or/42–57
59	11 and 15 and 41 and 58
60	remove duplicates from 59

These visits include a review of glucose trends in logbooks or sensor downloads, a review of insulin regimens for injectors and pump settings for children on insulin pumps, dietary guidance, physical activity recommendations, and emotional and mental health screening and supports.^{15 19} Also, information and education about life-style factors are included in these visits.^{15 19}

We will include studies that report on the HRQOL, measured by diabetes HRQOL questionnaires. These include the Pediatric Quality of Life Inventory^{34 35} or the Diabetes Quality of Life for Youth Questionnaire.³⁶ Other questionnaires, such as the proxy formats of general HRQOL questionnaires for parents and families and others, will also be included. Studies that have failed to report one or more measured outcomes will not be excluded.

Exclusion criteria

We will exclude studies on boys and girls with other types of diabetes including Maturity Onset Diabetes of the Young, gestational diabetes mellitus, and cystic fibrosis-related diabetes, among others. Children receiving medications that can drive hyperglycaemia, such as steroids and immunosuppressants, will also be excluded.

OUTCOMES MEASURES

Critical outcome

This systematic review's critical outcome includes the maintained or improved HRQOL, as measured by

diabetes HRQOL questionnaires, or proxy formats of the questionnaires used to measure HRQOL.

Important outcomes

Important outcomes of this study include:

1. Maintained or improved glycaemic control, as measured by HbA1c, logbook glucose readings or glucose sensor-based data, for example, DexCom G6,³⁷ FreeStyle Libre II sensors³⁸ or others. While the target HbA1c level for people with diabetes is usually <7.5% for T1DM and ≤6.5%–7% for T2DM, goals that are adjusted to participants' needs will be accepted.^{6 7 39 40}
2. Changes in body mass as measured by assessing BMI z-scores or BMI percentiles pre-intervention and post-intervention changes.
3. The number and severity of morbidities. These morbidities include hypoglycaemia (glucose levels ≤3.9 mmol/L (70 mg/dL)) and hyperglycaemia (glucose levels ≥13.3 mmol/L (240 mg/dL)). Also, the occurrence of ketosis, assessed via measurement of blood beta-hydroxybutyrate or urine acetoacetate and using manufacturer-specific reporting measures including quantitative or semiquantitative testing as applicable will be reported. We will also assess rates of diabetic ketoacidosis (defined as hyperglycaemia with blood glucose >11 mmol/L (200 mg/dL), venous blood gas-based pH <7.3, serum bicarbonate <15 mmol/L and the presence of ketones (β-hydroxybutyrate ≥3 mmol/L in blood, moderate-large ketonuria).^{6 41} If no specific values were reported to establish the diagnosis of

hypoglycaemia, hyperglycaemia, ketosis, and diabetic ketoacidosis, the above events would be included as a dichotomous outcome.

4. Patient and family satisfaction, and their perceptions of the usability and acceptability of the virtual intervention from relevant questionnaires, which include measures to assess frequency and ease of use and desire for continued application after the study has ended.

Data management

We will export search results onto Covidence,⁴² and remove duplicates and complete data screening. Data will be abstracted into a Microsoft Excel sheet. We will develop and pilot test the data abstraction form to ensure its validity.

Study selection

Two reviewers will independently assess the eligibility of titles, abstracts and full-text articles identified in the database searches for potential eligibility and inclusion in this review. Disagreements at each stage will be resolved through discussion among the reviewers. A third reviewer will resolve persistent disagreements. The 2020 PRISMA flow diagram reported in figure 1 will be used to track the process and will be included in the final paper.^{43 44}

Data abstraction

Data from included full-text articles will be abstracted independently by the two reviewers into the standardised data abstraction form. The reviewers will resolve any conflicts

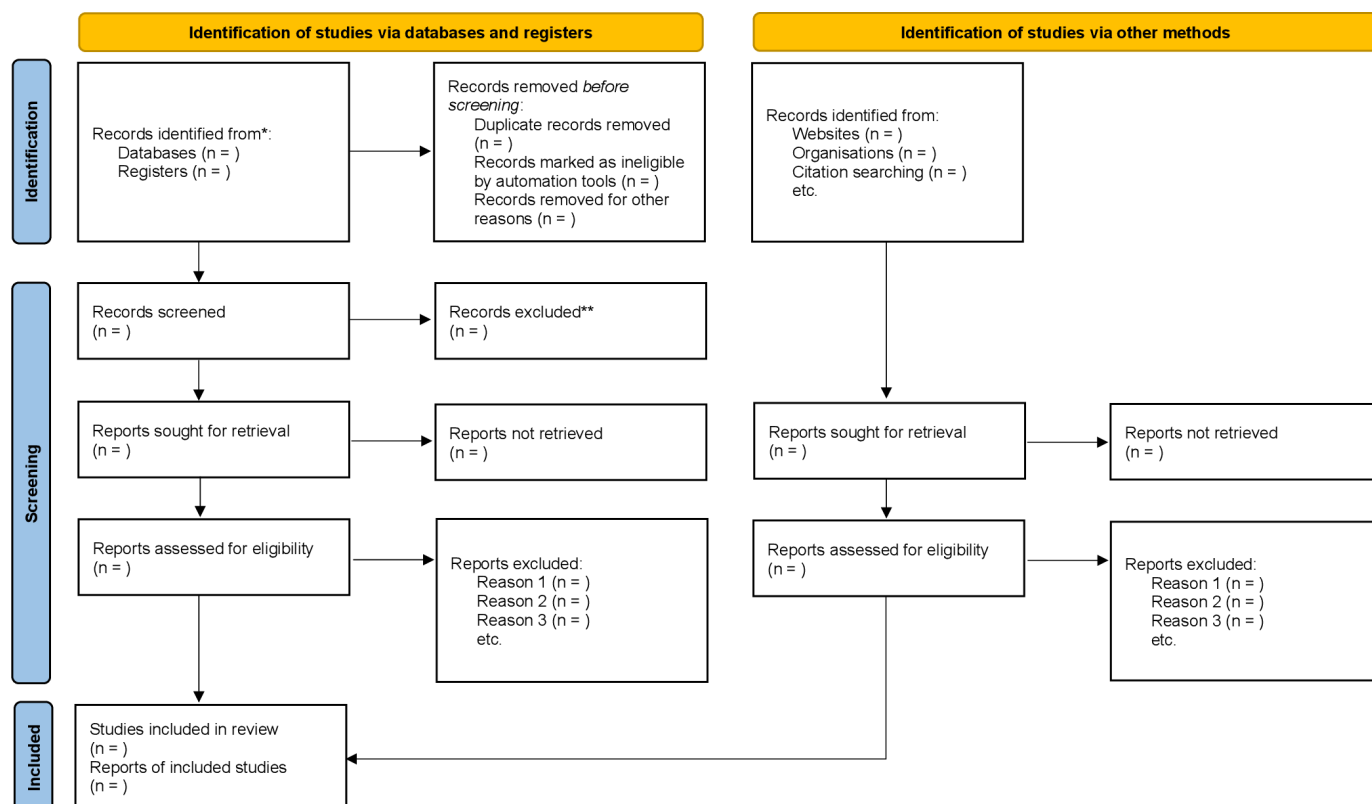


Figure 1 Flow diagram of article screening process.

through discussion, and if necessary, a third reviewer will resolve any persisting discrepancies. We will abstract data including first author's name, country, year, number of participants, age, sex, diabetes type, diabetes duration, comorbidities, insulin type and mode of delivery, and modality of glucose monitoring. Data on hyperglycaemia, hypoglycaemia, ketosis, and diabetic ketoacidosis will also be abstracted. We will abstract relevant data on the interventions including type, duration, details of delivery, HRQOL questionnaires used, HRQOL scores, glycaemic control measures, change in glycaemic control, change in BMI z-score or BMI percentile, adverse events, data on user satisfaction and the usability and acceptability of the interventions. Based on the data available, we will determine whether studies can be pooled for meta-analyses.

We will e-mail the Principal Investigators cited in the publications to obtain any missing data.

Risk of bias assessment

Two reviewers will independently perform the risk of bias assessments of all randomised controlled trials using the Cochrane RoB 2.0 tool.⁴⁵ Comparative, non-randomised studies will be assessed using the ROBINS-I tool.⁴⁶ Any conflicts will be discussed, and a third reviewer will resolve any remaining disagreements.

GRADE assessment

To assess the overall confidence in the quality of evidence, we will use the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) approach.⁴⁷ Quality will be determined by study design, risk of bias, inconsistency, indirectness, imprecision, and publication bias.⁴⁷ The quality of the cumulative evidence and magnitude of the effect will be used to determine the overall strength of the meta-analysis findings if it is feasible to do so.

Statistical analysis

We will include a summary table of all eligible studies in the final review. A meta-analysis will be conducted if two or more studies of similar study design, methods, populations, interventions, and outcomes are identified. We will analyze the data of randomised trials separately from those of non-randomised comparative studies. We will report dichotomous outcomes as risk ratios or ORs and continuous variables as mean differences or standardised mean differences, with a 95% CI. A detailed qualitative synthesis of the findings will be provided in a narrative table if a meta-analysis is not possible.

If a meta-analysis is possible, we will perform a random-effects model which accounts for within-study and between-study variability. We will use the Review Manager (Revman V5.4.1) software to generate forest plots to represent the data graphically if appropriate.⁴⁸

Heterogeneity will be assessed using the χ^2 test p value with a cut-off value of 0.1 and the I^2 statistic with a cut-off value of >75% defined as considerable heterogeneity.⁴⁹ A sensitivity analysis will be performed by removing studies

with a high risk of bias to assess the impact on the meta-analysis results.⁵⁰

If appropriate, we will conduct subgroup analyses based on the type of diabetes mellitus, as participants with T1DM and T2DM have fundamentally different management goals. We will also perform subgroup analyses based on the age and sex of participants and the mode of insulin administration (injections vs pumps).

If 10 or more studies are included, we will generate a funnel plot and use Egger's test to assess small study effect. Alternatively, we will report publication bias by considering the number of relevant conference abstracts that did not have published articles.

DISCUSSION

While the number of children and youth living with diabetes is rising globally, the outcomes of these children have improved significantly over the past few decades, thanks to advances in care models and research.^{1 7-12} However, the burden of care on patients and families is high due to the complex nature of the disease and its treatment, and burnout is a challenge that patients and families struggle with.^{13 15 16} With the COVID-19 pandemic, new virtual models of care had to be adopted within a very short period of time to deliver care to these children and youth.^{17 18} While the use of virtual care has grown steadily over the past few years, its impact on HRQOL with diabetes is less well understood compared with their impact on glycaemic control. This systematic review will focus on understanding the impact of virtual diabetes care on HRQOL. As these care approaches now take an unprecedented priority in view of the pandemic, with healthcare systems and policy makers trying and balance safety with the need for delivering quality care worldwide, the data on HRQOL are crucial to help shape the future of virtual diabetes care.

As remote diabetes care and education have become viable alternatives to in-person care in the COVID-19 era, this systematic review will help develop an understanding of its effects on HRQOL outcomes in children living with diabetes, and will guide future directives on implementing virtual diabetes care.

ETHICS AND DISSEMINATION

Ethics approval is not required as we will not recruit nor include any individual patient data in this systematic review. There are no other ethical and safety considerations. The results of our systematic review will be published in a peer-reviewed journal and presented at international conferences.

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Funding The authors have not declared a specific grant for this research from any funding agency in the public, commercial or not-for-profit sectors.

Competing interests None declared.

Patient consent for publication Not applicable.

Ethics approval This study does not involve human participants.

Provenance and peer review Not commissioned; internally peer reviewed.

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