Feasibility and Effectiveness of an AI-Powered Carbohydrate Counting Educational Platform to Support Parents of Children with Type 1 Diabetes: A Multicentre Randomized Controlled Trial

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Principal Investigator:

Zainab Al-Abadla, BSN, MSc, BC-ADM

Health Education Practitioner, Pediatric Diabetes and Endocrinology Department

Al Jalila Children's Hospital, Dubai, United Arab Emirates

Co-Investigators:

Dr. MoezAlIslam Faris, Professor of Human Nutrition and Dietetics, applied science private university, Jordan

Mrs. Mariam Dabbus , Clinical dietician, Pediatric Diabetes and Endocrinology Department, Al Qasimi Hospital, Sharjah, UAE

Mrs. Hind Al Zarooni, Clinical dietician, Pediatric Diabetes and Endocrinology Department, Al Jalila Children's Hospital, Dubai, UAE

Supervisor

Dr. Hussain Alsaffar, Consultant Paediatric Endocrinologist at Sultan Qaboos University Hospital - University Medical City, Oman

Summary

Type 1 diabetes (T1D) management in children requires precise carbohydrate counting to optimize glycemic control and prevent acute and chronic complications. Parents of children with T1D face substantial challenges in accurately estimating carbohydrate content, with error rates frequently exceeding 20-30%, directly impacting postprandial glucose control. Despite the critical importance of carbohydrate counting accuracy, current educational approaches remain resource-intensive, time-limited, and often inaccessible to families in underserved areas. Recent advances in conversational artificial intelligence (AI), particularly the emergence of conversational artificial intelligence and large language model technologies, offer new opportunities to deliver scalable, personalized, and accessible education. However, there is limited evidence regarding the feasibility, acceptability, and effectiveness of using newly developed AI-powered educational platforms for structured diabetes education.

This multicenter randomized controlled feasibility trial aims to evaluate the feasibility and acceptability of using the AI-powered carbohydrate counting educational platform, as an educational support tool to improve carbohydrate counting accuracy among parents of children aged 2–12 years with T1D. Grounded in Social Cognitive Theory and the Health Belief Model, the intervention leverages AI-powered educational platform capabilities to provide interactive, personalized, and accessible educational support. The study will assess feasibility outcomes (recruitment, retention, adherence), acceptability (usability, satisfaction), and preliminary effectiveness (carbohydrate counting accuracy, parental self-efficacy, and glycemic control). This study will explore whether the AI-powered carbohydrate counting educational platform can effectively help parents learn accurate carbohydrate counting for their child's diabetes management.

1. Introduction

Type 1 diabetes (T1D) represents one of the most prevalent chronic conditions in childhood, affecting approximately 1.5 million children and adolescents worldwide, with incidence rates increasing by 2-3% annually (Schoelwer et al., 2024). The cornerstone of T1D management involves matching insulin doses to carbohydrate intake through a process known as carbohydrate counting, which requires families to accurately estimate the carbohydrate content of all foods and beverages consumed. This complex cognitive and practical skill directly influences postprandial glycemic excursions, overall glycemic control, and long-term health outcomes (Deeb et al., 2017). However, substantial evidence demonstrates that both children with T1D and their caregivers struggle with carbohydrate counting accuracy, with error rates frequently exceeding 20-30% (Smart et al., 2010), (Mehta et al., 2009).

The burden of diabetes management falls disproportionately on parents, particularly for younger children who lack the developmental capacity for independent self-management. Parents must navigate complex nutritional information, estimate portion sizes, account for hidden carbohydrates, and make real-time insulin dosing decisions multiple times daily. This cognitive load occurs within the context of competing family demands, variable food environments, and often limited access to specialized diabetes education resources (Pulgaron et al., 2014). Traditional carbohydrate counting education, typically delivered through time-limited clinic visits with certified diabetes educators, faces significant scalability challenges and may not provide the ongoing, contextual support families need in their daily lives (Spiegel et al., 2012).

Recent advances in artificial intelligence, particularly AI-powered educational platform technologies powered by natural language processing and machine learning, offer unprecedented opportunities to transform diabetes education delivery. AI-powered educational platform systems can provide personalized, interactive, and continuously available educational support that adapts to individual learning needs and contexts (Voiculescu et al., 2024). Unlike static educational materials or generic mobile applications, AI-powered educational platform can engage in dynamic dialogue, answer specific questions, provide immediate feedback, and deliver just-in-time learning tailored to real-world situations families encounter. Despite this transformative potential, rigorous evidence

regarding the feasibility, acceptability, and effectiveness of AI-powered educational platform for carbohydrate counting education in pediatric diabetes remains absent from the literature.

This research proposal presents a multicenter randomized controlled feasibility trial designed to address this critical evidence gap. The study will evaluate a theory-driven, newly developed AI-powered carbohydrate counting educational platform to support parents of children aged 2–12 years with T1D in developing and maintaining accurate carbohydrate counting skills. By integrating principles from Social Cognitive Theory and the Health Belief Model with the capabilities of AI-powered educational platform technology, this intervention represents a practical and innovative approach to addressing a persistent challenge in pediatric diabetes care. The findings will provide essential evidence regarding the feasibility of conducting a definitive efficacy trial and preliminary signals of effectiveness, while advancing our understanding of how AI-powered educational platforms can be optimally implemented to support complex health behaviors in chronic disease management.

2. Background and Theoretical Framework

2.1 Type 1 Diabetes in Children and the Critical Role of Carbohydrate Counting

Type 1 diabetes is an autoimmune condition characterized by the destruction of pancreatic beta cells, resulting in absolute insulin deficiency and lifelong dependence on exogenous insulin therapy. In children, optimal glycemic control requires intensive insulin management strategies, typically involving multiple daily injections or continuous subcutaneous insulin infusion via insulin pumps. Contemporary diabetes management guidelines emphasize the importance of matching prandial insulin doses to carbohydrate intake, a strategy that has been associated with improved glycemic control, reduced glycemic variability, and enhanced quality of life (Tascini et al., 2018).

Carbohydrate counting involves three fundamental competencies: (1) identifying foods and beverages that contain carbohydrates, (2) accurately estimating portion sizes, and (3) calculating total carbohydrate content using nutritional information or reference databases. Research has consistently demonstrated that accurate carbohydrate counting is a critical determinant of postprandial glycemia in children and adolescents with T1D on insulin pump therapy (Deeb et al., 2017). Even modest errors in carbohydrate estimation can result in significant glycemic excursions, with systematic underestimation leading to postprandial hyperglycemia and overestimation increasing hypoglycemia risk (Reiterer et al., 2018), (Roversi et al., 2021).

The developmental context of childhood adds additional complexity to diabetes management. Young children have limited capacity for self-management, placing primary responsibility on parents and caregivers. As children mature, the gradual transition of diabetes management tasks from parents to children represents a critical developmental process that must be carefully supported to maintain glycemic control and prevent diabetes-related distress (Holtz et al., 2018). Throughout this developmental trajectory, parental knowledge, skills, and self-efficacy in carbohydrate counting remain foundational to successful diabetes management.

2.2 Current Challenges in Carbohydrate Counting Education

Despite the recognized importance of carbohydrate counting, substantial evidence indicates that children with T1D and their caregivers demonstrate poor accuracy in estimating carbohydrate content. Smart et al. (2010) found that children and caregivers had mean percentage errors exceeding 20% when estimating carbohydrate content of meals and snacks, with accuracy deteriorating over time despite ongoing diabetes management experience. Notably, the study revealed that longer duration of carbohydrate counting was associated with greater errors, suggesting that initial education may not be sufficient to maintain accuracy over time. Large meals were systematically underestimated while snacks were overestimated, indicating systematic biases in estimation strategies.

Multiple factors contribute to carbohydrate counting inaccuracy. Kawamura et al. (2015) identified that inexperienced individuals demonstrated particular difficulty with high-calorie dishes containing high carbohydrate content, while even experienced individuals struggled with seasoned rice and mixed dishes. The study highlighted that education and training for physicians and dieticians who provide carbohydrate counting instruction are often inadequate, potentially limiting the quality of patient education. Pulgaron et al. (2014) demonstrated that parental health literacy significantly influences glycemic control in young children with diabetes, with lower health literacy associated with poorer understanding of carbohydrate counting principles and worse glycemic outcomes.

Traditional educational approaches face significant limitations in addressing these challenges. Spiegel et al. (2012) conducted a randomized nutrition education intervention to improve carbohydrate counting in adolescents with T1D and concluded that more intensive education might be required to improve accuracy and nutrition management. However, intensive, individualized education delivered by certified diabetes educators is resource-intensive, expensive, and often inaccessible to families in rural or underserved areas. Lee et al. (2022) found that while carbohydrate counting education improved glycemic control, the decrease in HbA1c was insufficient, and effects varied by baseline glycemic management, suggesting that traditional education alone may be inadequate for many families.

Furthermore, carbohydrate counting education typically occurs in clinical settings removed from the contexts where families actually prepare and consume meals. This disconnect between learning environment and application context may limit transfer of knowledge and skills to real-world situations. Families need ongoing support to address novel foods, restaurant meals, social situations, and the myriad practical challenges that arise in daily diabetes management (Ranasinghe et al., 2018).

2.3 Theoretical Framework

This intervention is grounded in two complementary theoretical frameworks: Social Cognitive Theory (SCT) and the Health Belief Model (HBM), which together provide a comprehensive foundation for understanding and promoting health behavior change in chronic disease management.

Social Cognitive Theory (Bandura, 1986) posits that behavior change results from dynamic interactions between personal factors, environmental influences, and behavior itself, a

concept known as reciprocal determinism. Central to SCT is the construct of self-efficacy, defined as an individual's confidence in their ability to successfully perform a specific behavior. Self-efficacy is developed through four primary sources: mastery experiences (successful performance of the behavior), vicarious experiences (observing others successfully perform the behavior), verbal persuasion (encouragement and feedback from credible sources), and physiological and emotional states. In the context of carbohydrate counting, parental self-efficacy represents a critical determinant of accurate estimation and consistent application of carbohydrate counting skills.

The AI-powered educational platform intervention leverages SCT principles by providing: (1) mastery experiences through interactive practice with immediate feedback on carbohydrate estimation accuracy, (2) vicarious learning through case examples and scenarios demonstrating successful carbohydrate counting strategies, (3) verbal persuasion through positive reinforcement and encouragement tailored to individual progress, and (4) emotional support through empathetic responses that acknowledge the challenges of diabetes management. The AI system's ability to provide personalized, adaptive feedback creates opportunities for repeated mastery experiences that build self-efficacy over time.

The Health Belief Model (Rosenstock, 1974) proposes that health behaviors are influenced by individuals' perceptions of disease threat (perceived susceptibility and severity) and their evaluation of behavioral responses (perceived benefits and barriers). Applied to carbohydrate counting, parents must perceive that inaccurate carbohydrate counting poses a significant threat to their child's health (perceived susceptibility to poor glycemic control and long-term complications; perceived severity of diabetes-related outcomes) and believe that improving carbohydrate counting accuracy will reduce this threat (perceived benefits) while being feasible to implement (low perceived barriers).

The AI-powered educational platform intervention addresses HBM constructs by: (1) providing education about the relationship between carbohydrate counting accuracy and glycemic outcomes, reinforcing perceived susceptibility and severity, (2) demonstrating concrete benefits of accurate carbohydrate counting through personalized feedback linking estimation accuracy to glucose patterns, and (3) reducing perceived barriers by offering accessible, convenient, and stigma-free education that fits into families' daily routines. The AI system can also provide cues to action, timely prompts and reminders that encourage engagement with carbohydrate counting education at opportune moments.

The integration of SCT and HBM provides a robust theoretical foundation for intervention design, ensuring that the AI-powered educational platform addresses multiple determinants of behavior change through evidence-based mechanisms. This theory-driven approach distinguishes the proposed intervention from atheoretical technology applications and provides a framework for understanding how and why the intervention may influence carbohydrate counting accuracy and related outcomes.

2.4 AI-powered educational platform in Healthcare Education

AI-powered educational platform, also known as chatbots or virtual assistants, represents a class of artificial intelligence systems designed to engage in natural language dialogue with users. These systems leverage natural language processing (NLP), machine learning, and knowledge representation to understand user inputs, generate contextually appropriate responses, and maintain coherent conversations over multiple turns. Recent advances in large language models and transformer architectures have dramatically improved AI-powered educational platform capabilities, enabling more natural, contextually aware, and helpful interactions.

In healthcare, AI-powered educational platform offers several unique advantages for patient education and support. First, AI-powered educational platform provides 24/7 availability, allowing users to access information and support whenever needed, without scheduling constraints or wait times. Second, AI systems can deliver highly personalized content tailored to individual knowledge levels, learning preferences, and specific circumstances. Third, conversational interfaces reduce barriers to information access by allowing users to ask questions about diet in natural language rather than navigating complex menus or searching through static content. Fourth, AI systems can provide judgment-free environments where users feel comfortable asking questions they might hesitate to raise with healthcare providers due to embarrassment or perceived time constraints. Finally, AI-powered educational platform offers exceptional scalability, potentially reaching large populations at relatively low marginal cost once developed.

Emerging evidence suggests promise for AI-powered educational platform in diabetes care, though rigorous evaluation remains limited. Swallow et al. (2025) evaluated DigiBete, a chatbot designed to support transition to adult care for young people with T1D, in a prospective, multi-method, non-randomized feasibility study. The study found that DigiBete was an essential and valuable educational resource, serving as a trusted source of information. However, the study did not report specific clinical outcomes such as HbA1c changes or glycemic control metrics. Boggiss et al. (2025) examined the usability and feasibility of COMPASS, a self-compassion chatbot for youth living with T1D, finding acceptable usability and feasibility, though again without clinical outcome data.

Importantly, existing AI-powered educational platform applications in diabetes have primarily targeted adolescents and young adults with T1D themselves, focusing on general diabetes education, transition support, or psychosocial outcomes rather than specific skill development. No published studies have evaluated AI-powered educational platform specifically designed to support parents in developing carbohydrate counting skills for pediatric diabetes management. This represents a critical gap, as parents are the primary managers of diabetes care for young children and face distinct educational needs and challenges compared to adolescent patients.

Furthermore, most existing diabetes chatbots have been evaluated through feasibility or usability studies rather than rigorous randomized controlled trials with clinical outcomes. While these preliminary studies provide valuable insights into acceptability and user experience, they do not establish effectiveness or provide the evidence base needed for

clinical implementation and reimbursement. The proposed study addresses these gaps by conducting a rigorous feasibility trial that will inform a subsequent definitive efficacy trial, following the Medical Research Council framework for developing and evaluating complex interventions.

3. Literature Review and Research Gaps

3.1 Carbohydrate Counting Accuracy in Pediatric Populations

A substantial body of evidence documents poor carbohydrate counting accuracy among children with T1D and their caregivers, with significant implications for glycemic control. Mehta et al. (2009) demonstrated that carbohydrate counting accuracy, defined as parent estimates within 10 grams of dietitian-calculated values, was significantly associated with glycemic control in children with T1D. Parents who accurately estimated carbohydrate content had children with lower HbA1c values, establishing a direct link between estimation accuracy and clinical outcomes.

Smart et al. (2010) conducted a comprehensive assessment of carbohydrate counting accuracy in 104 children and their caregivers, finding mean percentage errors of 23% for meals and 34% for snacks. Critically, the study revealed that teaching carbohydrate counting in gram increments did not improve accuracy compared to using 10-gram portions or 15-gram exchanges, suggesting that the method of instruction may be less important than other factors. The finding that longer duration of carbohydrate counting was associated with greater errors challenges assumptions about learning curves and highlights the need for ongoing education and skill reinforcement.

Deeb et al. (2017) examined the relationship between carbohydrate counting accuracy and postprandial glycemia in children and adolescents using insulin pump therapy. The study found that accurate carbohydrate counting (within 20% of dietitian assessment) was an important determinant of postprandial glucose control, with inaccurate counting associated with greater glycemic excursions. This research underscores the clinical significance of even moderate estimation errors and the importance of interventions to improve accuracy.

Modeling studies have quantified the impact of carbohydrate counting errors on glycemic outcomes. Roversi et al. (2021) used in silico trials to assess how carbohydrate counting errors affect glycemic control in open-loop T1D management, finding that both systematic and random errors in carbohydrate estimation had adverse effects on time in range, hyperglycemia, and hypoglycemia. The study demonstrated that even small systematic biases (e.g., consistently underestimating by 10%) could substantially degrade glycemic control over time. Reiterer et al. (2018) similarly showed that carbohydrate counting errors significantly impact glycemic control, with the magnitude of effect depending on error type and magnitude.

Recent comparative studies have evaluated technological approaches to improve carbohydrate estimation accuracy. Alfonsi et al. (2020) conducted a pilot randomized

controlled trial of a carbohydrate counting app using image recognition for youth with T1D. The iSpy app reinforced a structured approach to carbohydrate counting by helping users identify food items, determine portion sizes, and account for hidden carbohydrates. While the study demonstrated feasibility and acceptability, it was conducted at a single tertiary pediatric center with limited generalizability. Baumgartner et al. (2024) compared carbohydrate estimation accuracy of two commercially available smartphone applications versus estimation by individuals with T1D, finding that technology-assisted estimation could improve accuracy for some food types but remained imperfect, particularly for mixed dishes.

3.2 Educational Interventions for Carbohydrate Counting

Despite the recognized importance of carbohydrate counting education, evidence regarding effective educational interventions remains limited and inconsistent. Spiegel et al. (2012) conducted a randomized nutrition education intervention for adolescents with T1D, comparing standard care to an intensive intervention involving additional dietitian visits and educational materials. While the intervention group showed trends toward improved knowledge, the study concluded that even more intensive education might be required to meaningfully improve carbohydrate counting accuracy and nutrition management. This finding highlights the challenge of achieving lasting behavior change through traditional educational approaches.

Donzeau et al. (2020) evaluated the effects of advanced carbohydrate counting education on glucose control and quality of life in children with T1D. The advanced carbohydrate counting group received structured education on carbohydrate counting principles, while the control group received traditional dietary education. The study found small improvements in metabolic control and quality of life scores associated with advanced carbohydrate counting education, though effects were modest. The authors noted that the intervention required substantial resources and specialized expertise, raising questions about scalability and accessibility.

Lee et al. (2022) examined the effect of carbohydrate counting education in children and adolescents with T1D, finding that while education improved glycemic control, the decrease in HbA1c was insufficient, and effects varied by baseline glycemic management. For patients with already well-controlled diabetes, traditional education provided minimal additional benefit, suggesting that more advanced or personalized approaches may be needed for this population. The study highlights the heterogeneity of educational needs and the importance of tailoring interventions to individual circumstances.

Marigliano et al. (2013) investigated nutritional education and carbohydrate counting in children with T1D treated with continuous subcutaneous insulin infusion, examining effects on dietary habits, body composition, and glycometabolic control. The study found that structured carbohydrate counting education could improve dietary quality and glycemic outcomes, but required ongoing reinforcement to maintain effects over time. This finding aligns with Smart et al.'s (2010) observation that carbohydrate counting accuracy deteriorates over time, emphasizing the need for continuous rather than one-time educational interventions.

Ranasinghe et al. (2018) examined the association between parents' knowledge of carbohydrate counting and glycemic control in children with T1D, finding a significant positive correlation. Parents with better carbohydrate counting knowledge had children with better glycemic control, independent of other factors. This research underscores the critical importance of parent education and suggests that interventions targeting parental knowledge and skills may be particularly impactful for pediatric populations.

A consistent theme across carbohydrate counting education research is the challenge of providing intensive, individualized, and ongoing education within resource-constrained healthcare systems. Traditional approaches rely heavily on certified diabetes educators, who are in limited supply and unevenly distributed geographically. Clinic-based education is time-limited and may not address the contextual challenges families face in real-world settings. These limitations create a compelling rationale for scalable, technology-enabled educational approaches that can provide continuous support tailored to individual needs.

3.3 Digital Health and mHealth Interventions in Pediatric Diabetes

The proliferation of mobile health (mHealth) technologies has generated substantial interest in digital interventions to support pediatric diabetes management. Multiple studies have evaluated mobile applications designed to improve various aspects of diabetes self-management, with mixed results regarding clinical effectiveness.

Klee et al. (2018) conducted a randomized double-crossover study of a patient-designed do-it-yourself mobile device app for children and adolescents with T1D. The intervention resulted in significant HbA1c reduction, particularly in patients with initial HbA1c >8.0%, without increasing hypoglycemia prevalence. Quality of life scores were not modified. This study demonstrates that well-designed mobile interventions can improve glycemic outcomes, though the specific mechanisms of effect and optimal design features remain unclear.

Castensøe-Seidenfaden et al. (2018) evaluated the "Young with Diabetes" smartphone app in a 12-month randomized controlled trial. Contrary to expectations, HbA1c was significantly higher in the intervention group compared to controls, and app usage was low (mean 10.5 days over 12 months). This study highlights the critical importance of user engagement and the risk that poorly designed or inadequately supported digital interventions may fail to achieve intended benefits or potentially cause harm through distraction from evidence-based care.

Chatzakis et al. (2019) conducted a randomized controlled trial of the Euglyca mobile application in children and adolescents with T1D, finding beneficial effects on glycemic control and treatment satisfaction. The app provided comprehensive diabetes management support including glucose tracking, insulin dose calculation, and educational content. Laptev et al. (2022) evaluated remote monitoring using a mobile application for adolescents with T1D, finding significant decreases in HbA1c (-0.5%), increased time in target glucose range (+5.3%), decreased glucose variability (-3.1%), and improved quality of life (+2.9 points). These positive findings suggest that mobile interventions with appropriate features and support can improve clinical outcomes.

However, most mHealth interventions in pediatric diabetes have focused on comprehensive diabetes management platforms rather than specific skill development such as carbohydrate counting. Alfonsi et al. (2020) represents a notable exception, evaluating an image recognition app specifically for carbohydrate counting. While the study demonstrated feasibility and acceptability, it was a small pilot study at a single center, and the app focused on image-based estimation rather than education to improve manual estimation skills. The app's food database was not comprehensive, and the study did not assess whether using the app improved users' carbohydrate counting knowledge or accuracy when not using the technology.

A systematic review and meta-analysis of telemedicine interventions for children and adolescents with T1D found only marginal, non-significant improvements in glycemic control at three months, which were not sustained at six months (Pélicand et al., 2020). Few studies evaluated patient satisfaction, diabetes-related quality of life, or severe hypoglycemic episodes, showing no significant differences. This meta-analysis highlights the limited evidence base for digital health interventions in pediatric diabetes and the need for more rigorous, theory-driven research.

Importantly, most mHealth interventions have targeted adolescents and young adults rather than parents of younger children. Holtz et al. (2018) developed a protocol for an mHealth app to transition diabetes care from parents to teens, recognizing the importance of developmentally appropriate interventions. However, interventions specifically designed to support parents in developing and maintaining diabetes management skills, particularly carbohydrate counting, remain largely absent from the literature.

3.4 AI-powered educational platform in Diabetes Care

The application of AI-powered educational platform to diabetes care represents an emerging area with limited but growing evidence. Voiculescu et al. (2024) provided an overview of natural language AI models and pediatric T1D, discussing how chatbots might help with diabetes self-management and patient education. The authors highlighted the potential for AI-powered educational platform to provide accessible, personalized, and continuous support, but noted the absence of rigorous evaluation studies.

Swallow et al. (2025) conducted a prospective, multi-method, non-randomized feasibility and acceptability study of DigiBete, a chatbot designed to support transition to adult care for young people with T1D. The study found that DigiBete was perceived as an essential and valuable educational resource and a trusted source of information. Participants appreciated the 24/7 availability, non-judgmental responses, and ability to ask questions they might not feel comfortable raising with healthcare providers. However, the study did not report clinical outcomes such as HbA1c changes or glycemic control metrics, and the non-randomized design limits causal inference.

Boggiss et al. (2025) examined the usability and feasibility of COMPASS, a self-compassion chatbot for youth living with T1D. The study found acceptable usability and feasibility, with participants reporting that the chatbot helped them develop more compassionate self-talk

regarding diabetes management challenges. However, like the DigiBete study, COMPASS focused on psychosocial outcomes rather than specific diabetes management skills, and clinical outcomes were not assessed.

Alloatti et al. (2021) described the AIDA Project, which developed a conversational agent for diabetes management. The project emphasized the importance of natural language interaction and personalized responses, but provided limited evaluation data regarding effectiveness or user outcomes. Bernier et al. (2018) conducted a usability study of the New-Onset Diabetes Educator, a digital tool to educate children and caregivers about diabetes at diagnosis. While usability was acceptable, the tool was not a AI-powered educational platform system and focused on initial diagnosis education rather than ongoing skill development.

Neerincx et al. (2019) explored socio-cognitive engineering of a robotic partner for children's diabetes self-management, examining how social robots might support diabetes education and motivation. While not strictly AI-powered educational platform, this work highlights the potential for interactive, dialogue-based systems to engage children and families in diabetes management. However, the research remained largely conceptual and developmental, without clinical outcome evaluation.

A critical gap in the AI-powered educational platform literature is the absence of interventions specifically designed to teach complex procedural skills such as carbohydrate counting. Existing chatbots have focused primarily on general diabetes education, psychosocial support, or comprehensive management platforms. None have systematically applied principles of skill acquisition and mastery learning to develop AI-powered educational platform systems that progressively build competence in carbohydrate estimation through interactive practice, feedback, and reinforcement.

Furthermore, existing AI-powered educational platform applications in diabetes have primarily targeted adolescents and young adults with T1D themselves, rather than parents of younger children. This represents a significant gap, as parents are the primary diabetes managers for young children and face distinct challenges and educational needs. Parents require not only knowledge about carbohydrate counting principles but also practical skills in estimating portions, accounting for recipe variations, and making real-time decisions in diverse food environments.

3.5 Identified Gaps and Study Rationale

The literature review reveals several critical gaps that provide strong rationale for the proposed research:

Gap 1: Absence of AI-powered educational platform Interventions for Carbohydrate Counting Education. Despite substantial evidence documenting poor carbohydrate counting accuracy and its impact on glycemic control, no studies have evaluated AI-powered educational platform specifically designed to teach and reinforce carbohydrate counting skills. Existing digital interventions have focused on image recognition tools or comprehensive management platforms rather than interactive educational systems that build competence through dialogue, practice, and feedback.

Gap 2: Limited Focus on Parent Education in Digital Diabetes Interventions. Most mHealth and AI-powered educational platform interventions have targeted adolescents and young adults with T1D, neglecting parents of younger children who bear primary responsibility for diabetes management. Parents have distinct educational needs, learning preferences, and contextual challenges that require tailored intervention approaches. The absence of parent-focused AI-powered educational platform interventions represents a significant missed opportunity to support the primary caregivers of children with T1D.

Gap 3: Lack of Theory-Driven Intervention Design. Many digital health interventions in diabetes have been developed without explicit grounding in behavior change theory, limiting their effectiveness and our understanding of mechanisms of action. The proposed intervention addresses this gap by systematically applying Social Cognitive Theory and the Health Belief Model to guide intervention design, content development, and evaluation.

Gap 4: Insufficient Evidence from Rigorous Trials. Most AI-powered educational platform applications in diabetes have been evaluated through feasibility or usability studies rather than randomized controlled trials with clinical outcomes. While preliminary studies provide valuable insights, they do not establish effectiveness or provide the evidence base needed for clinical implementation. The proposed feasibility trial represents an essential step toward definitive efficacy evaluation.

Gap 5: Limited Understanding of Optimal AI-powered educational platform Design for Skill Development. Existing AI-powered educational platform systems in healthcare have primarily focused on information provision and psychosocial support rather than procedural skill development. The optimal design features, interaction patterns, and pedagogical approaches for using AI-powered educational platform to teach complex skills like carbohydrate counting remain unknown. The proposed study will generate critical insights into effective AI-powered educational platform design for health behavior skill development.

Gap 6: Scalability and Accessibility Challenges in Traditional Education. Traditional carbohydrate counting education relies on resource-intensive, clinic-based instruction by certified diabetes educators. This approach faces significant scalability limitations and creates access barriers for families in rural or underserved areas. AI-powered educational platform offers potential to dramatically increase access to high-quality education, but this potential remains unrealized without rigorous development and evaluation.

These gaps collectively demonstrate the need for the proposed research. By evaluating a newly developed AI-powered educational platform specifically designed to support parents in developing carbohydrate counting skills, this study addresses a critical unmet need in pediatric diabetes care. The feasibility trial design follows best practices for complex intervention development and will generate essential evidence to inform a subsequent definitive efficacy trial. The research has potential to transform how carbohydrate counting education is delivered, dramatically increasing access to personalized, continuous support for families managing pediatric T1D.

4. Research Aims and Hypotheses

Primary Aim

To assess the feasibility and acceptability of the AI-powered carbohydrate counting educational platform as an educational tool for carbohydrate counting for parents of children aged 2-12 years with type 1 diabetes.

Primary Study Outcomes (Feasibility Outcomes)

1. **Recruitment feasibility:** Ability to recruit 80 parent-child dyads (40 per arm) within 12 months across two study sites
2. **Retention feasibility:** Retention rate ≥80% at 3-month follow-up
3. **Intervention adherence:** ≥70% of intervention participants engage with the AI-powered carbohydrate counting educational platform for at least 10 sessions over the 3-month intervention period
4. **Data completeness:** ≥85% completeness for primary outcome measures at baseline and 3-month follow-up

Feasibility Success Criteria: As this is a feasibility randomized controlled trial, the primary outcomes of the study are feasibility- and implementation-related outcomes rather than clinical efficacy outcomes. Measures of carbohydrate counting accuracy, glycemic outcomes, and parental self-efficacy are considered exploratory preliminary effectiveness outcomes intended to inform the design, outcome selection, and sample size estimation of a future definitive efficacy trial. The trial will be deemed feasible if at least 3 of 4 primary feasibility outcomes are met. Meeting all four criteria will indicate high feasibility for a definitive trial.

Secondary Aims

Aim 2: To assess the acceptability of the AI-powered carbohydrate counting educational platform among parents of children with type 1 diabetes.

Hypotheses:

- H2a: ≥75% of intervention participants will rate the AI-powered carbohydrate counting educational platform as "acceptable" or "highly acceptable" on the Acceptability of Intervention Measure (AIM)
- H2b: ≥70% of intervention participants will report that they would recommend the AI-powered carbohydrate counting educational platform to other parents of children with T1D

Aim 3: To examine preliminary effectiveness signals of the AI-powered carbohydrate counting educational platform intervention on carbohydrate counting accuracy, parental self-efficacy, and glycemic outcomes.

Hypotheses:

- H3a: Parents in the intervention group will demonstrate greater improvement in carbohydrate counting accuracy (percentage of estimates within 20% of dietitian assessment) from baseline to 3 months compared to the control group (effect size $d \geq 0.4$
- H3b: Parents in the intervention group will show greater increases in diabetes management self-efficacy scores from baseline to 3 months compared to the control group (effect size $d \geq 0.3$)
- H3c: Children in the intervention group will show greater improvement in time in range (70-180 mg/dL) from baseline to 3 months compared to the control group (effect size $d \geq 0.3$)
- H3d: Children in the intervention group will demonstrate greater reduction in HbA1c from baseline to 3 months compared to the control group (effect size $d \geq 0.3$)

Aim 4: To explore moderators and mediators of intervention effects to inform optimization for a definitive trial.

Research Questions for aim 4:

- RQ4a: Do intervention effects vary by child age, diabetes duration, baseline glycemic control, or parental health literacy?
- RQ4b: Is the relationship between intervention exposure and outcomes mediated by changes in parental self-efficacy, as predicted by Social Cognitive Theory?
- RQ4c: What patterns of AI platform usage (frequency, duration, topics discussed) are associated with greater improvements in carbohydrate counting accuracy?

5. Methodology

5.1 Study Design

This study employs a multicenter, parallel-group, randomized controlled feasibility trial design with 1:1 allocation to intervention or enhanced usual care control. The study duration is 12 weeks, with assessments at baseline, week 6 (mid-intervention), and week 12 (post-intervention). The 12-week timeframe was selected to balance the need for sufficient exposure to the intervention to observe preliminary effects while maintaining feasibility for a pilot study. This duration aligns with previous feasibility studies of digital health interventions in pediatric diabetes (Alfonsi et al., 2020), (Boggiss et al., 2025).

The study follows the CONSORT extension for randomized pilot and feasibility trials and adheres to the Medical Research Council framework for developing and evaluating complex

interventions (Schulz et al., 2010; Eldridge et al., 2016). As a feasibility trial, the primary focus is on assessing whether a definitive efficacy trial is warranted and can be successfully conducted, rather than on definitive hypothesis testing. Therefore, the study is not powered to detect definitive clinical effectiveness, and all clinical outcome analyses will be considered exploratory and hypothesis-generating. However, preliminary effectiveness signals will be examined to inform sample size calculations, refinement of outcome measures, and the design of a future definitive efficacy trial.

The study will use a quantitative randomized controlled feasibility trial design to assess feasibility, acceptability, usability, and preliminary effectiveness of the AI-powered carbohydrate counting educational platform.

5.2 Study Setting and Sites

The study will be conducted at two geographically and institutionally distinct pediatric diabetes centers in the United Arab Emirates, representing diverse clinical settings and patient populations:

Site 1: Al Jalila Children's Hospital

A large tertiary academic children's hospital located in an urban setting in Dubai. The hospital serves as a national referral center for pediatric subspecialty care and provides comprehensive, multidisciplinary diabetes and endocrinology services, including advanced diabetes technologies, structured education programs, and specialized dietetic support.

Site 2: Al Qasimi Hospital

A major government-based hospital serving a diverse pediatric population in the Emirate of Sharjah. The pediatric diabetes service delivers comprehensive endocrinology care to children and adolescents from both urban and semi-urban communities, offering routine diabetes management, nutritional counseling, and family-centered education within a public healthcare setting.

This multi-site design enhances the generalizability of findings by capturing variation in healthcare delivery models, patient demographics, and clinical workflows across two key pediatric diabetes centers in the UAE.

Each site will have a designated site principal investigator (PI), research coordinator, and certified diabetes educator who will support recruitment, data collection, and intervention delivery. Site PIs will participate in regular coordination meetings to ensure protocol adherence and address implementation challenges.

5.3 Participant Eligibility and Recruitment

Inclusion Criteria (Parent/Caregiver):

- Parent or primary caregiver of a child aged 2-12 years with type 1 diabetes
- Primary responsibility for carbohydrate counting and insulin dosing decisions for the child

- English-speaking
- Access to a smartphone (iOS or Android) with internet connectivity
- Willing and able to provide informed consent and complete study procedures

Inclusion Criteria (Child):

- Age 2-12 years at enrolment
- Diagnosis of type 1 diabetes for ≥ 1 months
- Using intensive insulin therapy (multiple daily injections or insulin pump)
- Using carbohydrate counting for insulin dosing
- HbA1c 7.0-10.0% (53-86 mmol/mol) at most recent clinic visit (within past 3 months)

Exclusion Criteria:

- Child has significant developmental delays or medical conditions that substantially alter nutritional requirements or carbohydrate metabolism (e.g., celiac disease, cystic fibrosis)
- Parent has significant cognitive impairment that would preclude participation
- Family planning to move out of the study area within the next 6 months
- Participation in another diabetes intervention study
- Previous participation in structured carbohydrate counting education program within the past 3 months

Recruitment Strategy:

Recruitment will occur through a clinic-based recruitment channel, where research coordinators will review clinic schedules to identify potentially eligible families. Eligible families will be approached during routine diabetes clinic visits, provided with study information, and invited to participate. Healthcare providers will also refer potentially eligible families to the research team.

After informed consent and baseline assessment, participants will proceed to randomization as described in Section 5.5.

5.4 Sample Size Justification

As a feasibility trial, formal power calculations for hypothesis testing are not appropriate. Instead, sample size is based on precision for estimating feasibility parameters and preliminary effect sizes. The proposed sample size is consistent with methodological recommendations for pilot and feasibility randomized controlled trials, which suggest that approximately 30–40 participants per study arm are generally sufficient to estimate feasibility parameters, assess intervention acceptability, and generate preliminary effect size estimates

for planning a future definitive trial (Julious, 2005; Whitehead et al., 2016; Eldridge et al., 2016).

Target Sample Size: 80 parent-child dyads (40 per arm)

Rationale:

1. **Feasibility parameter estimation:** With 40 participants per arm, we can estimate proportions (e.g., retention rate, adherence rate) with 95% confidence intervals of approximately ±15%. For example, if 80% retention is observed, the 95% CI would be 65-95%, providing adequate precision to assess feasibility.
2. **Preliminary effect size estimation:** With 40 participants per arm and assuming 20% attrition, 32 participants per arm will complete the study. This provides 80% power to detect a large effect size ($d = 0.8$) for continuous outcomes at $\alpha = 0.05$. While the study is not powered for definitive hypothesis testing, this sample size allows preliminary estimation of clinically meaningful effect sizes that would justify a larger efficacy trial.
3. **Feasibility and resource considerations:** The proposed sample size is achievable within the study timeline and budget while providing sufficient data to address feasibility aims. Recruiting approximately 27 pairs per site over 12 months (approximately 2-3 per month) is realistic based on clinic volumes and previous recruitment experiences.

5.5 Randomization and Allocation Concealment

Following completion of baseline assessments, eligible parent-child pair will be randomized 1:1 to the intervention or control group using a computer-generated randomization sequence. Randomization will be stratified by site and child age group (2-6 years vs. 7-12 years) to ensure balance across these important factors.

The randomization sequence will be generated by the study statistician using a permuted block design with randomly varying block sizes (4, 6, or 8) to prevent prediction of future allocations. The sequence will be concealed using a secure, web-based randomization system (Sealed Envelope Simple Randomiser) that reveals allocation only after participant eligibility is confirmed and baseline data are entered.

Research coordinators conducting baseline assessments will be blinded to the randomization sequence. After randomization, blinding of participants and research staff is not possible due to the nature of the intervention. However, outcome assessors for the carbohydrate counting accuracy assessment (dietitians reviewing food records) will be blinded to group allocation. Data analysts will remain blinded to group allocation until the primary analysis is complete.

5.6 Intervention Development and Description

Intervention Name:

AI-Powered Carbohydrate Counting Education Platform

Intervention Platform:

The intervention will utilize a newly developed AI-powered carbohydrate counting educational platform specifically designed for parents of children with type 1 diabetes. The platform will integrate conversational artificial intelligence with evidence-based carbohydrate counting education to provide personalized, interactive, and accessible educational support. The platform will be developed collaboratively by the research team in consultation with pediatric endocrinologists, diabetes educators, registered dietitians, and technical developers to ensure clinical accuracy, usability, and safety. The platform will undergo internal testing and validation by the research team prior to participant enrollment to ensure functionality, safety, and educational accuracy.

The AI-powered carbohydrate counting educational platform will operate under predefined educational boundaries established by the clinical research team, with all educational content reviewed and supervised by certified diabetes educators and registered dietitians.

Theoretical Foundation:

The intervention is grounded in Social Cognitive Theory (SCT) and the Health Belief Model (HBM), as described in Section 2.3. These frameworks guide how parents interact with the AI, how educational content is framed, and how confidence, motivation, and behaviour change are supported through conversational engagement.

Intervention Adaptation and Use:

Parents will be guided on how to effectively use the AI-powered carbohydrate counting educational platform to:

- Practice carbohydrate counting through interactive conversations;
- Request feedback on meal estimations;
- Learn strategies for portion estimation and nutrition labelling;
- Reinforce key concepts through guided prompts and examples.

Registered dietitians will review AI-assisted logs to verify accuracy and provide feedback, ensuring educational fidelity and safety.

1. Stakeholder-informed use case definition

Input from parents of children with type 1 diabetes and certified diabetes educators will be used to:

- Identify common carbohydrate counting challenges
- Define realistic parent questions and scenarios
- Establish boundaries for appropriate educational use of the AI
  This input will inform standardized guidance prompts and recommended interaction strategies for participants.

2. Content framework and clinical guardrails

Evidence-based carbohydrate counting content will be defined and curated by the study team, including certified diabetes educators, pediatric endocrinologists, and registered dietitians. This framework will guide parents on how to use the AI-powered carbohydrate counting educational platform to support learning in the following areas:

- Fundamentals of carbohydrate counting (food identification, nutrition labels, databases)
- Portion estimation strategies (visual cues, household measures, common portions)
- Practical application (restaurants, packaged foods, home-prepared meals, ethnic cuisines)
- Problem-solving in real-world situations (school meals, social events, travel)
- Understanding the relationship between carbohydrate counting accuracy and glycemic outcomes

The AI-powered carbohydrate counting educational platform will be used as an interactive educational support platform, not as a medical decision-making tool.

3. Conversational guidance and prompt standardization

Participants in the intervention arm will receive:

- Structured onboarding on how to ask effective questions
- Examples of recommended prompts (e.g., “Help me estimate carbohydrates in this meal and explain your reasoning”)
- Guidance on verifying outputs using food labels, logs, and dietitian feedback

This approach ensures:

- Consistency of use across participants
- Alignment with SCT principles (practice, feedback, confidence-building)
- Reduction of variability in AI interactions

4. Human oversight and validation

Parents will be instructed to document meals and AI-assisted carbohydrate estimates in diet diaries.
These logs will be reviewed by registered dietitians, who will:

- Verify accuracy of AI-assisted estimates
- Provide corrective feedback when needed
- Ensure patient safety and educational fidelity

All AI-generated educational responses related to carbohydrate counting will be periodically monitored and reviewed by certified diabetes educators and registered dietitians throughout the study period to ensure clinical accuracy, consistency, and patient safety. Any incorrect or potentially misleading educational content identified during monitoring will be corrected immediately, and participants will receive clarification from the research team when necessary. The AI-powered carbohydrate counting educational platform will function strictly as a supervised educational support tool and will not independently provide insulin dosing recommendations or medical decision-making advice.

5. Delivery format

Participants will access the AI-powered carbohydrate counting educational platform using their own devices through a secure web-based or mobile-compatible interface.

6. Orientation and feasibility testing

Before study launch:

- A brief orientation session will train participants on appropriate and safe use of the AI-powered carbohydrate counting educational platform for educational purposes
- A small pilot group (n ≈ 10 parent–child dyads) will be used to:
    - Assess feasibility of platform use
    - Identify common issues or misunderstandings
    - Refine participant guidance materials prior to the main feasibility trial

Key Methodological and Ethical Clarification

The AI-powered carbohydrate counting educational platform is used solely as an educational support tool to reinforce carbohydrate counting concept, not as a source of clinical or insulin dosing advice.
It does not replace:

- Clinical judgment
- Insulin dosing decisions
- Professional dietary counseling

Participants will be explicitly informed that medical decision-making remains under the guidance of healthcare professionals.

Intervention Components

1. Structured AI-Supported Learning

Parents will use the AI-powered carbohydrate counting educational platform as an interactive educational tool to support progressive learning in carbohydrate counting. Educational engagement will be guided by a structured content framework provided by the study team and will focus on:

- Carbohydrate counting fundamentals
- Portion size estimation
- Advanced and real-world carbohydrate counting challenges

Through guided prompts and examples, parents will receive:

- Conversational explanations of key concepts
- Interactive examples and practice questions
- Immediate explanatory feedback
- Tailored learning suggestions based on prior interactions

2. Practice With Feedback and Verification

Parents may enter food items or meals and request assistance in estimating carbohydrate content. The AI educational platform will provide:

- Estimated carbohydrate values with step-by-step reasoning
- Identification of potential estimation errors
- Practical tips to improve future estimates
- Supportive and encouraging feedback

All AI-assisted estimates will be recorded in diet logs and reviewed by registered dietitians to ensure accuracy, reinforce learning, and maintain patient safety.

3. Natural-Language Question Answering

Participants may ask questions about carbohydrate counting at any time using natural language (for example, clarification about mixed meals or portion sizes). Responses are intended to be:

- Educational and explanatory
- Aligned with evidence-based nutrition principles
- Adapted to the parent's level of understanding and context

The AI-powered carbohydrate counting educational platform will function strictly as an educational support tool, not as a source of medical or insulin-dosing advice.

4. Scenario-Based Learning and Problem Solving

Parents will be encouraged to explore realistic, everyday scenarios using guided prompts, such as meals at school, restaurants, or social events. The AI-powered carbohydrate counting educational platform will help parents:

- Break down complex meals
- Think through estimation strategies
- Apply carbohydrate counting principles in practical contexts

This supports skill transfer from theory to real-world application.

5. Self-Monitoring and Reflection

Rather than automated in-app tracking, progress will be supported through:

- Parent self-reflection on learning and confidence
- Review of food logs and AI-assisted estimates over time
- Feedback from dietitians during study check-ins

This approach emphasizes learning, confidence building, and accuracy rather than competition or gamification.

6. Individualized Learning Focus

Based on interaction patterns and common challenges identified through logs and discussions, parents will be encouraged to focus on specific areas for improvement (e.g., portion estimation, mixed dishes, eating outside the home). Personalized learning goals will be supported through:

- Suggested prompt examples
- Dietitian feedback
- Targeted practice activities

Intervention Support

Participants will receive:

- An initial onboarding session (15–20 minutes) conducted by the research team to explain appropriate and safe educational use of the AI-powered carbohydrate counting educational platform and review example prompts
- Written guidance outlining recommended usage, boundaries, and verification steps
- Ongoing support via email or phone for technical or study-related questions
- A mid-intervention check-in (approximately 6 weeks) to review experiences, address concerns, and reinforce appropriate use

5.7 Control Condition

Enhanced Usual Care: Control group participants will receive enhanced usual care consisting of:

1. **Standard diabetes education:** Continued access to routine diabetes education provided by their clinical care team, including certified diabetes educators, as per usual care at their clinic.
2. **Educational materials:** Provision of high-quality, evidence-based written educational materials on carbohydrate counting, including:
    - Printed guide to carbohydrate counting fundamentals
    - Portion size visual reference guide
    - List of reputable online resources and mobile apps for carbohydrate information
    - Access to the same educational content provided in the intervention, but in static PDF format rather than through AI-powered educational platform
3. **Attention control:** Control participants will receive the same frequency of contact from research staff (onboarding, mid-intervention check-in, outcome assessments) to control for attention effects.

This enhanced usual care control condition was selected to provide a rigorous comparison that isolates the specific effects of the AI-powered educational platform delivery modality while ensuring that control participants receive meaningful educational support. By providing the same educational content in static format, we can assess whether the interactive, personalized, and adaptive features of AI-powered educational platform provide added value beyond content alone.

5.8 Outcome Measures

Primary Feasibility Outcomes:

1. **Recruitment rate:** Number of eligible families approached, number consented, time to reach target enrollment
2. **Retention rate:** Proportion of enrolled participants completing 3-month follow-up assessment
3. **Data completeness:** Proportion of participants with complete data for primary outcome measures at each timepoint

Secondary Acceptability Outcomes:

1. **Acceptability of Intervention Measure (AIM):** 4-item validated scale assessing perceived acceptability of the intervention (Weiner et al., 2017). Scores range from 4-20, with higher scores indicating greater acceptability.

2. **System Usability Scale (SUS):** 10-item validated scale assessing perceived usability of the AI-powered carbohydrate counting educational platform (Brooke, 1996). Scores range from 0-100, with scores >68 considered above average usability.

3. **Net Promoter Score (NPS):** Single-item measure asking "How likely are you to recommend the AI-powered carbohydrate counting educational platform to other parents of children with type 1 diabetes?" on a 0-10 scale. Scores 9-10 are "promoters," 7-8 are "passives," and 0-6 are "detractors."

Exploratory Preliminary Effectiveness Outcomes

Main Effectiveness Outcome:

1. **Carbohydrate counting accuracy:** Participants will complete a standardized carbohydrate counting assessment at baseline and 3 months. The assessment involves estimating carbohydrate content of 10 standardized meals/snacks presented via photographs with portion size references. A certified diabetes educator/registered dietitian will calculate the actual carbohydrate content. Accuracy is defined as the percentage of estimates within 20% of the actual value, consistent with previous research (Deeb et al., 2017). Mean absolute percentage error will also be calculated.

Secondary Effectiveness Outcomes:

2. **Parental diabetes management self-efficacy:** Self-Care Inventory-Revised (SCI-R) parent version, a validated 15-item measure assessing confidence in performing diabetes management tasks, including carbohydrate counting (Weissberg-Benchell et al., 2009). Scores range from 15-75, with higher scores indicating greater self-efficacy.

3. **Time in range (TIR):** Percentage of time with glucose 70-180 mg/dL over 14 days, assessed via continuous glucose monitoring (CGM) or downloaded glucose meter data. TIR is a key glycemic outcome recommended by international consensus (Battelino et al., 2019).

4. **HbA1c:** Glycated hemoglobin measured via point-of-care device or laboratory assay at baseline and 3 months, reflecting average glycemic control over the preceding 2-3 months.

5. **Time below range (TBR):** Percentage of time with glucose <70 mg/dL over 14 days, assessing hypoglycemia risk.

6. **Glucose variability:** Coefficient of variation (CV) of glucose values over 14 days, with CV <36% considered optimal.

7. **Parental diabetes distress:** Problem Areas in Diabetes-Parent Revised (PAID-PR), a validated 18-item measure assessing diabetes-related emotional distress in parents (Markowitz et al., 2012).

Process Measures:

1. **AI platform usage analytics:** Detailed logging of user interactions including number of sessions, session duration, topics discussed, questions asked, modules completed, and practice exercises attempted. High engagement will be defined as completion of ≥10 AI interaction sessions during the 12-week intervention period.
2. **Intervention fidelity:** Assessment of whether the AI system delivers content as intended, responds appropriately to user inputs, and maintains conversation quality.

Moderator Variables:

1. **Child age and diabetes duration**
2. **Baseline HbA1c and glycemic control**
3. **Parental health literacy:** Newest Vital Sign (NVS), a validated 6-item measure of health literacy (Weiss et al., 2005)
4. **Sociodemographic characteristics:** Parent age, education, race/ethnicity, household income, insurance type
5. **Technology proficiency:** Self-reported comfort with smartphone technology

5.9 Data Collection Procedures

Baseline Assessment (Week 0):

- Informed consent and HIPAA authorization
- Eligibility screening and confirmation
- Demographic and clinical history questionnaire
- Carbohydrate counting accuracy assessment
- Self-efficacy, quality of life, and distress questionnaires
- Health literacy assessment
- Download of CGM/glucose meter data from previous 14 days
- HbA1c measurement (if not available from recent clinic visit)
- Randomization

Intervention Period (Weeks 1-12):

- Intervention group: Access to the AI-powered carbohydrate counting educational platform with onboarding and ongoing support
- Control group: Provision of educational materials
- Both groups: Mid-intervention check-in call at 6 weeks
- Continuous collection of collection of AI platform usage data for intervention group

3-Week 12 Follow-Up Assessment:

- Carbohydrate counting accuracy assessment
- Self-efficacy, quality of life, and distress questionnaires
- Acceptability and usability measures (intervention group only)
- Download of CGM/glucose meter data from previous 14 days
- HbA1c measurement

Data Management:

All data will be collected and managed using Sealed Envelope Simple Randomiser, a secure, web-based application designed for research data management. Sealed Envelope Simple Randomiser provides audit trails, data validation, and role-based access controls to ensure data integrity and security.

Participant identifiers will be stored separately from research data using a unique study ID system. Only authorized research staff will have access to the linkage file. All data will be stored on secure, encrypted servers with regular backups. Data quality checks will be conducted regularly to identify missing data, outliers, or inconsistencies.

5.10 Data Analysis Plan

Feasibility Outcomes:

Feasibility outcomes will be analyzed descriptively using frequencies, proportions, means, and 95% confidence intervals. Success criteria will be evaluated by comparing observed values to pre-specified thresholds:

- Recruitment: Target enrollment achieved within 12 months
- Retention: ≥80% retention at 3 months
- Adherence: ≥70% of intervention participants complete ≥10 sessions
- Data completeness: ≥85% completeness for primary outcomes

Barriers to recruitment, retention, and adherence will be documented descriptively to inform protocol refinement.

Acceptability Outcomes:

Acceptability measures (AIM, SUS, NPS) will be analyzed descriptively using means, standard deviations, medians, and proportions meeting acceptability thresholds.

Exploratory Preliminary Effectiveness Outcomes:

As a feasibility trial, effectiveness analyses are exploratory and hypothesis-generating rather than definitive. Analyses will follow intention-to-treat principles, with all randomized participants included in their assigned groups regardless of intervention adherence.

Exploratory effectiveness outcome: (Carbohydrate counting accuracy)

- Change from baseline to 3 months will be compared between groups using analysis of covariance (ANCOVA) adjusting for baseline accuracy, site, and child age group
- Effect sizes (Cohen's d) with 95% confidence intervals will be calculated
- Sensitivity analyses will examine per-protocol effects (participants meeting minimum adherence threshold)
- Analyzed similarly to the Exploratory effectiveness outcome using ANCOVA for continuous outcomes
- Mixed-effects models will be used to examine trajectories over time (baseline, 6 weeks, 12 weeks) where mid-intervention data are available
- Effect sizes with 95% confidence intervals will be calculated for all outcomes

Missing data:

- Multiple imputation using chained equations will be used for missing outcome data, with 20 imputed datasets
- Sensitivity analyses will compare complete case analysis to imputed data analysis

Moderator and Mediator Analyses:

Exploratory moderator analyses will examine whether intervention effects vary by:

- Child age group (2-6 vs. 7-12 years)
- Baseline HbA1c (7.0-8.0% vs. >8.0%)
- Parental health literacy (adequate vs. limited)
- Diabetes duration (<2 years vs. ≥2 years)

Moderation will be tested using interaction terms in regression models.

Exploratory mediation analyses will examine whether changes in self-efficacy mediate the relationship between intervention exposure and carbohydrate counting accuracy, consistent with Social Cognitive Theory predictions. Mediation will be tested using the product of coefficients approach with bootstrapped confidence intervals.

Usage Pattern Analysis:

AI platform usage data will be analyzed descriptively and using cluster analysis to identify distinct usage patterns (e.g., high engagement, moderate engagement, early dropout). Associations between usage patterns and outcomes will be examined using regression analyses.

Sample Size for Definitive Trial:

Data from this feasibility trial will inform sample size calculations for a definitive efficacy trial. Specifically:

- Observed effect sizes and standard deviations for the primary effectiveness outcome (carbohydrate counting accuracy) will be used to calculate required sample size for adequate power (80-90%) to detect clinically meaningful effects
- Observed retention and adherence rates will inform sample size inflation to account for attrition
- Intraclass correlation coefficients from the multi-site design will inform sample size requirements for a future cluster-randomized or multi-site trial

5.11 Ethical Considerations

Institutional Review Board Approval:

The study protocol will be submitted for review and approval by the Institutional Review Boards (IRBs) at all participating sites before any recruitment or data collection begins. Any protocol modifications will be submitted as amendments for IRB approval before implementation. The study will be prospectively registered on ClinicalTrials.gov prior to participant recruitment.

Informed Consent:

Parents/caregivers will provide written informed consent for their own participation and for their child's participation. For children aged 7-12 years, written assent will be obtained in addition to parental consent, using age-appropriate assent forms. The consent process will emphasize voluntary participation, the right to withdraw at any time without affecting clinical care, and confidentiality protections.

Privacy and Confidentiality:

All data will be de-identified using unique study IDs. Identifiable information will be stored separately from research data in secure, encrypted systems with restricted access. Study-related records and exported interaction logs will be stored on secure encrypted servers accessible only to authorized research personnel. Participants will be informed that while conversations are private, they are not confidential from the research team.

Data Security:

All electronic data will be stored on secure, HIPAA-compliant servers with encryption, access controls, and audit trails. Paper documents will be stored in locked cabinets in secure research offices. Data will be retained for 7 years following study completion, as required by federal regulations.

Risks and Benefits:

Risks: Risks are minimal and include:

- Loss of confidentiality (mitigated through robust data security measures)

- Time burden of study participation (approximately 3-4 hours total over 3 months)
- Potential frustration or distress if the AI system does not meet expectations or provides incorrect information (mitigated through careful development, testing, and ongoing monitoring)
- Possibility that focusing on carbohydrate counting could increase diabetes-related stress (mitigated through supportive, non-judgmental AI design and availability of research staff support)

Benefits: Potential benefits include:

- Access to innovative educational support for carbohydrate counting
- Improved carbohydrate counting skills and confidence
- Potential improvements in child's glycemic control
- Contribution to research that may benefit other families managing pediatric diabetes

Adverse Event Monitoring:

Adverse events, including severe hypoglycemia, diabetic ketoacidosis, or other serious medical events, will be monitored and reported according to IRB requirements. While not expected to be caused by the intervention, any adverse events will be documented and assessed for potential relationship to study participation.

Ethical Justification:

Clinical equipoise exists regarding the effectiveness of AI-powered educational platform for carbohydrate counting education, as no previous research has evaluated this approach. The control condition provides meaningful educational support (enhanced usual care with written materials), ensuring that all participants receive benefit from study participation. The feasibility trial design is ethically appropriate as a necessary step before conducting a large-scale efficacy trial.

6. Significance and Innovation

This study represents the first structured evaluation of a newly developed AI-powered carbohydrate counting educational platform used as an educational support tool for carbohydrate counting in parents of children with T1D.

The innovation lies not in creating a new AI system, but in developing a specialized AI-powered educational platform tailored for pediatric diabetes education. This approach enhances scalability, cost-effectiveness, and translational potential, paving the way for future studies on AI-powered educational platform applications in chronic disease education.

Clinical Significance:

Carbohydrate counting accuracy directly impacts glycemic control, which in turn influences risk for acute complications (hypoglycemia, diabetic ketoacidosis) and long-term complications (retinopathy, nephropathy, neuropathy, cardiovascular disease). Even modest improvements in carbohydrate counting accuracy could yield substantial clinical benefits for children with T1D. By addressing a persistent challenge in diabetes management through an innovative, scalable approach, this research has potential to improve health outcomes for the 1.5 million children and adolescents worldwide living with T1D.

Innovation in Intervention Design:

This study represents the first rigorous evaluation of existing AI-powered educational platform to teach carbohydrate counting skills to parents of children with T1D. Unlike existing digital health interventions that focus on information provision or comprehensive management platforms, The AI-powered carbohydrate counting educational platform employs interactive dialogue, personalized feedback, and adaptive learning to build procedural competence in a complex skill. The intervention's grounding in Social Cognitive Theory and the Health Belief Model distinguishes it from atheoretical technology applications and provides a framework for understanding mechanisms of behavior change.

Methodological Rigor:

The study employs a rigorous feasibility trial design following CONSORT guidelines and the MRC framework for complex interventions (Schulz *et al.*, 2010). The multi-site design enhances generalizability, while the quantitative feasibility trial design provides comprehensive evaluation of feasibility, acceptability, and preliminary effectiveness. The study will generate essential evidence to inform a definitive efficacy trial, following best practices for intervention development and evaluation.

Scalability and Access:

Traditional carbohydrate counting education relies on resource-intensive, clinic-based instruction by certified diabetes educators, who are in limited supply and unevenly distributed geographically. AI-powered educational platform offers potential to dramatically increase access to high-quality, personalized education, particularly for families in rural or underserved areas. If proven effective, The AI-powered educational platform could be disseminated widely at relatively low marginal cost, addressing health equity concerns in diabetes care.

Advancement of AI-powered educational platform in Healthcare:

This research will advance understanding of how AI-powered educational platform can be optimally designed and implemented to support complex health behavior skill development. Insights regarding effective dialogue patterns, feedback mechanisms, personalization strategies, and engagement approaches will inform future applications of AI-powered educational platform across diverse health behaviors and conditions. The study will contribute to the emerging science of human-AI interaction in healthcare education.

Parent-Centered Approach:

By focusing on parents as the primary intervention target, this research addresses a critical gap in digital health interventions for pediatric diabetes, which have predominantly targeted adolescents and young adults. Parents of young children with T1D face distinct challenges and educational needs that require tailored approaches. This parent-centered focus aligns with the developmental reality that parents are the primary diabetes managers for young children and will inform future family-centered intervention designs.

Potential for Broader Impact:

If successful, the AI-powered educational platforms approach could be adapted to support education for other complex diabetes management skills (e.g., insulin dose adjustment, sick day management, exercise management) and extended to other chronic conditions requiring complex self-management behaviors. The intervention development process and evaluation framework will provide a model for creating and testing AI-powered educational platform interventions in healthcare.

7. Limitations and Mitigation Strategies

Limitation 1: Short Follow-Up Duration

The 12-week intervention and follow-up period may be insufficient to observe sustained behavior change or long-term clinical outcomes. Carbohydrate counting is a skill that must be maintained over years, and initial improvements may not persist without ongoing support.

Mitigation: The 3-month duration is appropriate for a feasibility trial and aligns with previous digital health intervention studies. If the feasibility trial is successful, a definitive efficacy trial will include longer follow-up (e.g., 6-12 months) to assess sustainability of effects. The current study will collect data on usage patterns and engagement over time to inform strategies for promoting sustained engagement in a longer trial.

Limitation 2: English Language Only

The initial feasibility trial will be conducted in English only, limiting generalizability to non-English-speaking populations. This is a significant limitation given the diversity of families affected by pediatric T1D and potential health disparities in diabetes outcomes.

Mitigation: Restricting to English speakers is necessary for the initial feasibility trial to manage complexity and costs. However, the intervention is designed with multilingual expansion in mind, using modular content architecture that facilitates translation. If the feasibility trial is successful, subsequent phases will prioritize Spanish language development and evaluation, followed by additional languages based on population needs.

Limitation 3: Technology Access Requirements

The intervention requires access to a smartphone with internet connectivity, potentially excluding families with limited technology access or digital literacy. This could exacerbate health disparities if the intervention is effective but not accessible to all families.

Mitigation: Eligibility criteria require smartphone access, but the study will document technology access barriers encountered during recruitment to inform future implementation strategies. If the intervention proves effective, implementation research will explore strategies to increase access, such as providing devices to families in need, developing lower-bandwidth versions, or creating hybrid models combining AI-powered educational platform with human support for families with limited technology access.

Limitation 4: Potential for AI Errors

Despite careful development and testing, AI-powered educational platform systems can make errors, provide incorrect information, or misunderstand user inputs. Such errors could undermine trust, provide misleading education, or potentially cause harm if parents act on incorrect information.

Mitigation: The intervention development process includes extensive content validation by diabetes experts, rigorous testing, and ongoing monitoring of AI responses. The system will include disclaimers that it is an educational tool and not a substitute for medical advice, with prompts to consult healthcare providers for medical decisions. Usage data will be monitored for problematic interactions, with mechanisms for rapid response and correction. Participants will have access to research staff support to address any concerns or questions.

Limitation 5: Lack of Blinding

Due to the nature of the intervention, participants and research staff cannot be blinded to group allocation. This creates potential for performance bias (differential behavior based on group assignment) and detection bias (differential outcome assessment).

Mitigation: The primary effectiveness outcome (carbohydrate counting accuracy) will be assessed by dietitians blinded to group allocation. Objective outcomes (HbA1c, CGM data) are less susceptible to bias. The enhanced usual care control condition provides meaningful educational support, reducing expectancy effects. Data analysts will remain blinded until primary analyses are complete.

Limitation 6: Generalizability

The study will be conducted at two sites in the United Arab Emirates with families who volunteer for research participation. Findings may not generalize to families who decline participation, those receiving care in other settings, or populations in other countries with different healthcare systems and cultural contexts.

Mitigation: The multi-site design with diverse geographic regions and patient populations enhances generalizability compared to single-site studies. Detailed documentation of participant characteristics, recruitment challenges, and reasons for non-participation will inform understanding of generalizability limits. If the intervention proves effective, implementation research in diverse settings will be essential before widespread dissemination.

Limitation 7: Feasibility Trial Limitations

As a feasibility trial, the study is not powered for definitive hypothesis testing regarding effectiveness. Effect size estimates will be imprecise, and null findings may reflect insufficient power rather than true lack of effect.

Mitigation: The study is explicitly designed as a feasibility trial with primary focus on feasibility and acceptability outcomes. Effectiveness analyses are clearly framed as exploratory and hypothesis-generating. The sample size provides adequate precision for feasibility parameter estimation and will inform power calculations for a definitive trial. The study follows best practices for feasibility trials and the MRC framework for complex intervention development.

8. Dissemination and Implementation Plan

Scientific Dissemination:

Study findings will be disseminated through multiple channels to reach diverse scientific audiences:

1. **Peer-reviewed publications:** Manuscripts will be submitted to high-impact journals in diabetes care (e.g., *Diabetes Care*, *Diabetologia*, *Pediatric Diabetes*), digital health (e.g., *JMIR mHealth and uHealth*, *Journal of Medical Internet Research*), and health informatics (e.g., *Journal of the American Medical Informatics Association*). Manuscript will address: (a) feasibility and acceptability outcomes, (b) preliminary effectiveness signals, (c) exploratory findings regarding user engagement and usability, and (d) lessons learned for AI-powered educational platform intervention design.
2. **Conference presentations:** Findings will be presented at major scientific conferences.
3. **Open science practices:** De-identified data, analysis code, and study materials will be made publicly available through appropriate repositories (e.g., Open Science Framework, NIH data repositories) following publication, consistent with FAIR principles (Findable, Accessible, Interoperable, Reusable).

Stakeholder Dissemination:

Study findings will be shared with key stakeholders who can influence clinical practice and policy:

1. **Healthcare providers:** Webinars and continuing education presentations for pediatric endocrinologists, certified diabetes educators, and primary care providers will communicate findings and implications for practice.
2. **Patient advocacy organizations:** Partnerships with JDRF, American Diabetes Association, and other diabetes advocacy organizations will facilitate dissemination to families affected by T1D through newsletters, websites, and social media.

3. **Health systems and payers:** Findings will be shared with healthcare system leaders and insurance companies to inform decisions about digital health intervention adoption and reimbursement.
4. **Technology developers:** Insights regarding effective AI-powered educational platform design for health behavior education will be shared with digital health companies and AI developers through industry conferences and publications.

Implementation Planning:

If the feasibility trial demonstrates success and a subsequent efficacy trial confirms effectiveness, implementation research will be essential to translate findings into practice:

1. **Implementation science studies:** Research will examine barriers and facilitators to adoption of the AI-powered carbohydrate counting educational platform in diverse clinical settings, optimal implementation strategies, and sustainability factors.
2. **Adaptation for diverse populations:** The intervention will be adapted and evaluated for Spanish-speaking populations and other language groups, with attention to cultural tailoring and health literacy considerations.
3. **Integration with clinical workflows:** Research will explore how the AI-powered carbohydrate counting educational platform can be integrated into routine diabetes care, including referral processes, progress monitoring by clinical teams, and coordination with certified diabetes educators.
4. **Reimbursement pathways:** Engagement with payers and policy makers will explore reimbursement mechanisms for AI-powered educational platform-delivered diabetes education, potentially through remote patient monitoring codes or diabetes self-management education and support (DSMES) programs.
5. **Scalability research:** Studies will examine strategies for scaling the AI-powered carbohydrate counting educational platform to reach large populations while maintaining quality and effectiveness, including partnerships with healthcare systems, technology platforms, and community organizations.

Patient and Public Involvement:

Throughout the research process, parents of children with T1D will be engaged as partners in research design, intervention development, interpretation of findings, and dissemination planning. A parent advisory board will provide ongoing input and ensure that research remains responsive to family needs and priorities.

9. Conclusion

Type 1 diabetes management in children requires accurate carbohydrate counting to optimize glycemic control and prevent complications, yet substantial evidence demonstrates that parents often struggle with this complex skill. Traditional educational approaches face limitations in scalability, accessibility, and the ability to provide ongoing, contextual support.

AI-powered educational platform offer transformative potential to deliver personalized, interactive, and continuously available education that adapts to individual learning needs. However, rigorous evidence regarding the feasibility, acceptability, and effectiveness of using existing AI-powered educational platform tools for carbohydrate counting education in pediatric diabetes remains limited.

This multicenter randomized controlled feasibility trial evaluates a newly developed AI-powered carbohydrate counting educational platform designed specifically to support carbohydrate counting education for parents of children aged 2–12 years with T1D in developing and maintaining accurate carbohydrate counting skills. Grounded in Social Cognitive Theory and the Health Belief Model, the intervention leverages AI-powered educational platform's interactive dialogue, personalized feedback, and adaptive learning capabilities to build competence and self-efficacy. The study will assess the feasibility of conducting a definitive efficacy trial, evaluate acceptability among parents, and examine preliminary effectiveness signals for carbohydrate counting accuracy, parental self-efficacy, and glycemic outcomes.

This research represents a novel application of a newly developed AI-powered educational platform within evidence-based diabetes education. Its rigorous design, theoretical grounding, multi-site approach, and quantitative feasibility evaluation will generate essential evidence to inform future research and clinical implementation. If successful, the use of the AI-powered carbohydrate counting educational platform could address a persistent challenge in pediatric diabetes care, improve health outcomes for children with T1D, and provide a model for applying existing AI-powered educational platform technologies to support complex health behavior skill development across diverse conditions and populations.

The findings will advance scientific understanding of effective integration of existing AI-powered educational platform systems into healthcare education, inform the design of a definitive efficacy trial, and contribute to the growing evidence base for digital health interventions in pediatric chronic disease management. By focusing on parents as the primary intervention target and addressing a critical skill gap in diabetes management, this study has the potential to make a meaningful impact on the lives of families affected by type 1 diabetes.

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