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Development and delivery of a brief family behavioral intervention to support continuous glucose monitor use in young children with type 1 diabetes

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Abstract

Background: Despite potential glycemic benefits of continuous glucose monitor (CGM) use in young children with type 1 diabetes, psychosocial and behavioral challenges may interfere with sustained use. We developed a 5-session family behavioral intervention (FBI) to support CGM use.

Objective: We report on the multi-step development of the FBI, training interventionists, implementation in a 14-site clinical trial, and participant satisfaction.

Methods: A multidisciplinary team created the FBI based on mixed-methods (i.e., survey data, qualitative research) preliminary work with parents of young children. Investigators trained non-physician staff to deliver the 5 sessions per an intervention manual. Trial participants received the FBI either during the first (FBI group, $n = 50$) or second 6-months (Crossover group, $n = 44$) of the 1-year trial. Investigators listened to session recordings to rate intervention fidelity, and participants rated satisfaction with the FBI.

Results: The complete 5-session FBI was delivered to 89% of participants, in-person (73%) or by telephone (23%). Sessions lasted 23 min on average, and fidelity was high across sessions. Over 80% of participants rated very high satisfaction with all aspects of the FBI and offered few recommendations for improvement.

Conclusions: Having been developed based on experiences and input of families of young children with type 1 diabetes, the FBI represented a novel behavioral approach to enhance sustained CGM use during a challenging developmental period. Evidence of strong feasibility and acceptability supports its potential for implementation in research and clinical care. As diabetes technologies evolve, the FBI may continue to be refined to address parents' most relevant concerns.

1 | INTRODUCTION

There are many unique challenges associated with type 1 diabetes management in very young children. In this age group, the burden of management is primarily assumed by parents and other caregivers (hereafter referred to as "parents"), who must administer insulin and monitor glucose levels while accounting for unpredictable eating habits, varying degrees of physical activity, and limited ability to collaborate with the young child. Continuous glucose monitoring (CGM) may reduce some of these challenges while offering benefits, including improved glycemic outcomes[1] and psychosocial outcomes.[2] Previous work has supported the use of CGM in young children.[3,4] However, there is longstanding evidence of parental distress related to diabetes management in young children[5] and challenges in adopting a new diabetes management device.[6,7]

The Strategies to Enhance New CGM Use in Early Childhood (SENCE) 14-site trial tested CGM efficacy in 143 youth age 2– < 8 years with type 1 diabetes,[8] comparing CGM to traditional blood glucose monitoring using finger sticks. To address known challenges to sustained CGM use after initiation,[6,7] SENCE included a family behavioral intervention (FBI). In the SENCE trial, participants were randomized to one of three groups, and the FBI was delivered to two of the three study groups.[8,9] One group started CGM and received CGM education with the FBI in the initial 26 weeks of the study (referred to as "FBI group," $n = 50$). The FBI interventionist delivered behavioral and psychosocial support to parents to address common barriers to CGM use and to promote optimal CGM device use initiation and maintenance. It was designed based on evidence from other age groups that psychosocial/behavioral interventions that specifically address barriers to device use can facilitate device uptake and success as well as clinical outcomes.[10] We expected the FBI would be associated with psychosocial benefits for parents and glycemic benefits for children. A second group used fingerstick blood glucose monitoring in the first half of the study, and then received the FBI when they began on CGM in the second half of the study, after the 26-week data collection was complete (referred to as "Crossover group," $n = 44$). A third group started CGM and received CGM education and never received the FBI; these participants are, therefore, not reported on in this manuscript. Full SENCE inclusion/exclusion criteria, recruitment details, randomization processes, and participant data are reported in the full trial baseline and outcomes papers.[8,9]

The primary outcomes of the SENCE trial at 6 months indicated both CGM groups (with and without the FBI) reduced time in hypoglycemia (<70 mg/dl) and the FBI group improved parents' self-reported diabetes burden and fear of hypoglycemia.[8] In light of these promising outcomes, particularly for participants receiving the FBI, the aim of this paper is to provide further details on the FBI. We report the development process of the FBI, the protocol for training and supervising interventionists, and outcomes related to intervention delivery and satisfaction.

2 | METHODS

2.1 | Intervention development

We used a multi-step approach aligned with the Intervention Mapping framework[11] to design the SENCE FBI. The Intervention Mapping steps include working with a planning group to understand the target population, establishing the behavioral targets and desired outcomes of the intervention, determining the intervention theories and practical components, producing intervention materials, developing intervention delivery protocols, and specifying the evaluation design and plan.

We first conducted a mixed-methods assessment of the experiences of parents of young children in relation to type 1 diabetes management, and specifically related to technology use. Using data from over 500 families of children age <7 years old in the T1D Exchange Clinic Registry database, we found high levels of parental burden and family impact related to their child's diabetes, especially fears of health complications, concerns about diabetes management being "off track," disrupted family sleep, and impact on parental work arrangements.[12] Many parents were worried about their children having hypoglycemic events, particularly overnight, and were more comfortable with higher glucose targets.[13] Parental concerns were particularly pronounced in families of children using insulin pumps and CGM,[12–14] highlighting the need for behavioral support to address parental and family challenges of diabetes management—especially related to device use—in early childhood.

We then conducted individual semi-structured interviews at four core SENCE study team sites (Indiana, Connecticut, Massachusetts, Texas) with parents of children <8 years old with type 1 diabetes to guide intervention development. As detailed in published results of these interviews,[15–17] trained research staff conducted interviews with 79 families using a semi-structured interview guide to learn about parents' experiences with using diabetes management technologies with young children. Interviews were professionally transcribed then analyzed using hybrid thematic analysis to identify overarching themes to guide development of the FBI. Overall, parents described substantial emotional burdens related to managing diabetes for their child, including sadness, frustration, and distress from having to explain diabetes to their child. Many parents noted that it was difficult to find and trust additional caregivers to manage diabetes care, and they requested education from a healthcare provider to help them

TABLE 1 FBI sessions

Session	Title	Content
1	Getting Used to CGM—Common Questions and Tips	• Discussion of expectations of CGM • Pain prevention/management strategies for sensor insertion
2	CGM and Glucose Ups and Downs	• Education about how CGM can provide information about glucose fluctuations, signs of hyper/hypoglycemia • Identifying and managing emotional responses to CGM use • Communication strategies for discussing high and low glucose levels with child
3	Life with CGM	• Integrating CGM into daily life, coping with challenges (e.g., glued to display, information overload, alert fatigue, CGM burnout) • Problem-solving strategy
4	CGM Away from Home and with Other Caregivers	• Communicating with other people about CGM • Helping child talk about CGM with people • Teaching other caregivers about using CGM, establishing communication plan
5	Moving Forward with CGM	• Review previous session key points and address questions • Recognize successes and offer encouragement for continued CGM use

manage their own distress and obtain effective support from others.[15] Specific to CGM use, parents of children who currently or previously used CGM highlighted multiple benefits of CGM use, including reduced worry about hypoglycemia, appreciating having more information about blood glucose trends, better sleep, and more comfort leaving their children in the care of others.[17] They also described challenges including pain at insertion, skin reactions, feeling overwhelmed at the amount of data generated, and disruptions from the CGM alerts.[17] Parents who had not used diabetes devices (pumps, CGM) described specific concerns about their child not wanting to wear a device or about the financial burden of the technology but were interested in using them if those concerns could be addressed.[16] Together, our preliminary research identified specific issues to target in a behavioral intervention to support CGM use in young children, including factors related to child acceptance (e.g., understanding diabetes and devices, device wear issues) and parent experiences (e.g., distress management, concerns about glycemic extremes, responding to data flow, communicating with other caregivers).

Experts in behavioral health and diabetes at two of the core study sites (Texas Children's Hospital and Joslin Diabetes Center)

designed the FBI targets, materials, and protocol based on these mixed-methods results. Table 1 outlines the FBI content targets for each session. Given our findings related to parents' concerns about low blood glucose levels and the pervasiveness of parental fear of hypoglycemia identified in previous research,[5,18–21] we emphasized this topic throughout. Intervention sessions introduced skills for emotion regulation, relaxation, problem solving, and communication. To maximize potential for implementation in the context of routine diabetes care, we designed brief (20–30 min) sessions. The timing was intended to be convenient for the family, delivered along with a study CGM education visit when possible, and flexible to be delivered in-person or by telephone, per participant preference. Interventionists were intended to be non-physician, non-psychologist members of the diabetes care or research teams (e.g., nurses, educators, social workers, coordinators), whom the study team trained to use a semi-scripted handbook for interventionists to maximize consistency (available upon request to the corresponding author). We also created handouts for participating families to follow along with the intervention content and skills in session, and to keep for reference later (Data S1). Staff at the two development sites role-played the sessions and revised the manuals to minimize redundancy, maximize participant engagement, and enhance flow.

2.2 | Intervention training and delivery

Prior to study launch, interventionists from all sites completed an intensive 2-day training on location at the Texas Children's Hospital site. Training consisted of an orientation to the rationale for the intervention, familiarization with the intervention manual and materials, modeling of the intervention sessions by investigators who created the intervention and role-playing each of the sessions in small groups with live feedback from the investigators and other interventionists-in-training. Sites and interventionists that joined the study later received training and role-play with feedback from investigators via telephone before delivering the intervention. Each site had 1–3 interventionists.

All FBI sessions were audio-recorded, and the length and mode of delivery (in person or telephone) were documented. A team of four investigators at Texas Children's Hospital and Joslin Diabetes Center (two psychologists, one physician, one psychology fellow), who developed the intervention content and format, monitored the fidelity with which interventionists delivered the FBI sessions at each site (FBI group only). Staff at the coordinating center (Jaeb Center for Health Research) sent the review team audio recordings of the first session completed at each site. They also sent one additional session per site, of a randomly selected participant's 4th session. This was selected because the 4th intervention session occurred at 13 weeks, which was halfway through the 6-month study period, which allowed reviewers to monitor fidelity further into the intervention delivery process. Investigators from the intervention development team reviewed the recordings and independently completed a standard

TABLE 2 Satisfaction ratings

FBI satisfaction item	Combined	FBI group	Crossover group
Helped me get used to using CGM	87%	86%	87%
Helped me understand the challenges of CGM use	84%	81%	87%
Helped me manage the challenges of CGM use	86%	86%	85%
Increased my confidence in managing my child's diabetes with CGM	87%	83%	90%
Were additionally helpful to me beyond what we learned in the basic CGM education meetings	83%	84%	82%
Helped me explain CGM to others involved in my child's care	82%	81%	82%
Helped me improve my child's diabetes control	81%	84%	79%
Were a good use of my time	88%	86%	90%
The booklet was helpful	80%	78%	82%
I have used the strategies I learned in the FBI sessions to help with using CGM with my child	83%	84%	82%

rating form of intervention fidelity, assessing the session completeness, interaction between participant and interventionist, adherence to the script, and pace. Each item was scored on a 3-point scale (e.g., Item: "Interventionist followed script" Responses: "1: Minimal," "2: Half the time," "3: Mostly"). The reviewers then discussed and came to consensus on the ratings via teleconference and returned a single rating form per session to the coordinating center. Summary feedback from the first reviewed session per site was sent to Site PI to share with the interventionist. We did not send feedback on the fourth session unless major concerns were noted. Booster trainings were available if needed.

2.3 | Satisfaction assessments

At the end of the study, all participants completed a satisfaction survey developed for this study about participation overall and specifically about the parts of the intervention they received. For the FBI and Crossover groups, the post-study satisfaction survey included questions about their impressions of the FBI sessions and materials. Ten items were rated on a 0–4 scale (strongly disagree to strongly agree). There were also open-ended questions about satisfaction with the intervention and recommendations for improvement. Quantitative ratings were tabulated overall and by group, and text responses were reviewed for content by the investigators.

3 | RESULTS

3.1 | Participants

Of the 94 participants in the FBI and Crossover groups, 54% were parents of female children with T1D, with a mean child age of 5.9 ± 1.7 years at study start. Children were 64% non-Hispanic White, 17% non-Hispanic Black, 11% Hispanic, 1% Asian, and 7% more than one race/ethnicity. Of these 94 participants, 38% had public health insurance, 61% had private insurance, and 1% had no insurance, and 24% of the participant parents reported their highest education to be

high school or less. At study start, mean diabetes duration was 2.5 ± 1.9 years and 36% used an insulin pump. The trial enrolled both CGM naïve participants and those who had tried CGM in the past but not used it for at least the 3 months prior to study start (87% and 13% of the $n = 94$ in this analysis, respectively). Mean HbA1c at randomization was 8.2% ± 0.8% (66 ± 8 mmol/mol).

3.2 | Intervention delivery

We report intervention dose and format for the FBI and Crossover groups separately, and all other results are reported across groups. Overall, 89% of participants received the full dose of the intervention (i.e., 5 sessions): 96% in the FBI group and 82% in Crossover group. Most sessions (73% overall, 79% FBI group, 67% Crossover group) were conducted in-person and the remainder via telephone. The sessions lasted a mean of 23 ± 7 min, with very similar patterns by session and across both groups.

Fidelity to the intervention was high for the two sessions reviewed per site in the FBI group. The full session was completed (mean fidelity form rating = 2.96 ± 0.19) and there was high adherence to the intervention script ($M = 2.86 ± 0.36$) for almost all sessions reviewed. Parents were largely actively engaged ($M = 2.89 ± 0.31$) and interventionists were able to encourage dialogue with parents easily ($M = 2.79 ± 0.50$). Session pace was judged to be relaxed to somewhat rushed ($M = 1.71 ± 0.46$). Given the high fidelity to the intervention, no booster trainings were determined by the fidelity raters to be necessary.

3.3 | Participant satisfaction

Most participants (>80%) reported very high satisfaction with the FBI (agreed or strongly agreed with all the post-study FBI satisfaction survey questions), as outlined in Table 2. Overall, there were few written comments or suggestions. Three participants noted being satisfied with the intervention in its current form (e.g., "They were very informative, I wouldn't change anything") or offered minor suggestions for

improvement, mostly related to a few participants who felt they did not need the information because they were not having trouble using CGM (e.g., "The educator was great, the content/material just was not helpful because we had a completely positive experience using the CGM."). One participant suggested incorporating videos for visual learners and another recommended adding a website.

4 | DISCUSSION

The SENCE study's FBI was developed using a strategic, multi-step process based in stakeholder input, demonstrated strong feasibility and acceptability, and supports the promising findings of improved psychosocial outcomes and less time in hypoglycemia in the FBI group at 6 months.[8] Interventionists received standardized training and consistent feedback across multiple sites, with largely positive ratings from families across the country. The consistency of the high satisfaction among participants across the 14 sites and in both the FBI and Crossover groups suggests the intervention has potential to be useful to families regardless of their care team, location, and previous diabetes management experiences.

The intervention was delivered both in person and via telephone, and we trained interventionists remotely when needed. High intervention fidelity scores provide support for the systematic training approach and the structured, manualized intervention protocol. This suggests that the FBI is flexible in terms of both training and delivery format. This study was conducted before the rapid increase in telehealth infrastructure associated with the COVID-19 pandemic, so it was not tested using video-conferencing software. However, given the widespread and increasing use of telehealth for medical care, education, and behavioral healthcare,[22,23] the ability to successfully train interventionists to deliver the FBI remotely is promising, as this enhances the opportunities for implementation in practice and widespread reach.

A strength of the intervention was the comprehensiveness of the topics it addressed. In alignment with the Intervention Mapping framework,[11] we targeted the intervention content on lessons learned from a thorough, mixed-methods evaluation of the needs and experiences of families of young children with type 1 diabetes. Indeed, the high satisfaction ratings, high levels of participation in sessions, and few recommendations for change suggest parents found the topics useful, relevant, and engaging, without any topics being noted by participants as excessive or less helpful. However, we did not collect formal feedback from interventionists about their experiences delivering the FBI, which could have been helpful to inform future iterations of this intervention and ultimate implementation into clinical practice.

Though the trial tested the intervention among families not currently using CGM, some topics may be useful for those already using CGM. For example, the module focused on explaining diabetes to others may be used when starting CGM and revisited as children age and can understand more. For parents, the module about managing data overload and alert fatigue may be relevant during periods of burnout or if families are considering stopping CGM use.[17] Additionally, as diabetes technologies change, the intervention is well positioned to be revised. For example, our intervention development research found that parents had concerns regarding duration of sensor life, adhesive reactions, calibration requirements, and sensor application procedures[17] associated with CGM devices on the market at the time. More contemporary devices that use factory-calibrated sensors with longer sensor wear and automatic injectors may address some of these challenges,[24,25] which may reduce the need to focus on pain at insertion or managing distress around inaccurate readings in future iterations of the intervention. There are some challenges associated with CGM use that may be most responsive to education or psychosocial support, rather than resolved through device improvements, such as those that are more emotional or behavioral in nature (e.g., explaining diabetes to others, feeling overwhelmed by data). Facilitating successful CGM use will likely apply to future technological advancements, such as hybrid-closed loop pumps and automated insulin delivery systems. By better understanding and addressing the common barriers and psychological challenges to CGM use from a behavioral standpoint, young children and their families may be better prepared to use future systems effectively.[26]

There are areas for potential improvement in the intervention. Given very common fear of hypoglycemia[13] it is not surprising that parents may feel more comfortable with their child having higher glucose levels especially when they are apart. Indeed, young children tend to spend many hours per day in hyperglycemia.[9] A finding of the SENCE study design work was that parents of young children using CGM reported lower limits for their target glucose ranges for their child, suggesting some potential glycemic and fear of hypoglycemia benefits of CGM use.[27] The FBI addressed parents' fear of hypoglycemia but did not heavily target strategies to reduce the risks associated with prolonged hyperglycemia. Addressing this issue more directly in future FBIs could help parents feel more comfortable with lower target glucose ranges and ultimately increase children's time in range. We also targeted the intervention to improve wear time as prior studies had suggested low prolonged use of CGM in young children. Ultimately, we found that prolonged wear time was very high across groups, including the group that did not receive the FBI.[28] Therefore, the FBI time and content directed at encouraging wear could be used instead on teaching behaviors to ameliorate hyperglycemia.

Regarding generalizability, the study was conducted primarily at diabetes care centers affiliated with large academic medical centers, parent participants were mostly mothers, and the intervention was designed and delivered only in English. However, the substantial racial, ethnic, socioeconomic, and geographic diversity across the participating sites increases potential generalizability. This is particularly notable given the lower rates of CGM availability, uptake, and sustained use in children from marginalized racial/ethnic groups.[29] As CGM technologies are now supported by clinical practice guidelines as optimal for management of young children,[30] continued advocacy to further improve access to CGM

through complete coverage of costs associated with their use is warranted.

Our sample was not necessarily typical of young children with type 1 diabetes due to the HbA1c limitation in inclusion criteria and the requirements to be new to or not currently using CGM. Considering the study sensor's long-standing availability, this limited our sample to participants who were later adopters of or had less access to technology. Thus, it is not known how satisfaction with and impact of the FBI translates to other families. Additionally, the recruitment sites did not systematically track how many families were informed about the study but did not proceed to being assessed for eligibility or enrolling in the trial, which limits the potential generalizability of the study sample.[8] Finally, the FBI had a set number of sessions and personalized follow-up was not part of the approach. A stepwise intervention with more personalization and follow-up may be needed for those who require greater support with CGM use.[31]

The SENCE trial's FBI targets many of the major stressors associated with CGM use in parents of very young children with type 1 diabetes and was associated with psychosocial benefits for parents.[8] This data-driven intervention approach offers room for expansion to increase its reach and benefits. In addition to expanding the content to address hyperglycemia prevention and issues that may emerge related to newer technologies, developmental adaptations may also be warranted to enhance its relevance for older age groups. Finally, as new technologies become widely available, this study's strategically informed approach to intervention revisions will be important to ensure that future versions of the SENCE FBI continue to easily reach and meet the needs of families using devices as part of their child's care.

AUTHOR CONTRIBUTIONS

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PEER REVIEW

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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