Tailoring Resources to Help Children and Parents Manage Type 1 Diabetes

Elizabeth Cox, MD, PhD; Mari Palta, PhD; Betty Chewning, PhD; Tim Wysocki, PhD; Tosha Wetterneck, MD, MS; Rosanna Fiallo-Scharer, MD

1University of Wisconsin–Madison, Madison, Wisconsin
2Nemours Children’s Clinic, Jacksonville, Florida
3Medical College of Wisconsin, Milwaukee, Wisconsin

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A. ABSTRACT

**Background:** The 165,000 US children with type 1 diabetes (T1D) face a lifetime of self-management decisions to delay or prevent complications while maintaining quality of life (QOL) for themselves and their parents. Although efficacious resources exist to support self-management, most children with diabetes struggle with achieving glycemic control targets. Experts recommend family-centered self-management approaches that attend to each family’s self-management challenges. Currently, no system-level method exists to identify and address each family’s self-management barriers, resulting in ineffective or wasted resources. The validated PRISM (Problem Recognition in Illness Self-management) tool could be used as part of an intervention to tailor family-centered self-management resources by helping each family and its clinicians identify and address self-management barriers.

**Objectives:** To assess the impact of family-centered tailoring of diabetes self-management resources on glycemic control, parent and child QOL (primary outcomes), and fear of hypoglycemia (secondary outcome).

**Methods:** Conducted in partnership with families, clinicians, clinic administration, and advocacy organizations, our pragmatic trial enrolled children aged 8-16 with T1D and their parent(s) at 2 sites. Participating families were randomized to receive either tailored self-management resources (intervention) or usual care. Our intervention (1) used PRISM to identify families’ self-management barriers, (2) tailored self-management resources to the identified barrier, and (3) coordinated group-based delivery of the tailored resources over 9 months to optimize convenience, efficiency, and sustainability. We used validated measures to assess A1c, parent and child QOL, and fear of hypoglycemia during the 12-month intervention period and for the subsequent year. We used mixed effects models with repeated measures of study outcomes over time to examine the intervention’s impact.

**Results:** Among 363 potentially eligible families, 267 (74%) consented to participate. Ultimately, 108 families were randomized to usual care and 106 to receive the intervention. Among the participating children, 44% were aged 8-12 and 56% were aged 13-16. About half of the children were female (49%) and 84% identified as non-Hispanic white. Mean diabetes duration was 5.4 years (SD 3.3) and 14% had an A1c < 7.5%. Attendance at intervention group sessions was high, with 69% of families attending at least 3 of the 4 sessions. Our analyses demonstrated no overall intervention effect on A1c, QOL for the child or parent, or on fear of hypoglycemia during or after the intervention. However, in prespecified subgroup analyses, intervention group teenagers (aged 13-16) at one site had a significantly better A1c trajectory in the year postintervention than teenagers who received usual care (mean A1c was lower by 0.059% [95% CI, 0.11-0.01] per month). At this same site, parents of intervention group children aged 8-12 had a significantly better QOL trajectory during the intervention than parents of those who received usual care (mean parent QOL was greater by 0.61 points [95% CI, 0.05-1.17] per month).
Conclusions: Although the intervention did not significantly affect outcomes as hypothesized, findings suggest best practices for the process of delivering self-management resources and that the intervention might improve outcomes in select settings.

Limitations: The trial was conducted at 2 clinical sites, which could limit generalizability of findings.
B. BACKGROUND

More than 165,000 US children live with type 1 diabetes (T1D), requiring intensive self-management, including insulin injections or pumps, blood glucose monitoring, dietary management, and physical activity. The number of children with T1D has increased sharply in recent decades. Further, mortality rates for children with T1D are 3 times that of their healthy peers. Health care for T1D costs $14.9 billion dollars annually in the United States.

The Diabetes Control and Complications Trial (DCCT) and Epidemiology of Diabetes Interventions and Complications studies established associations between lower hemoglobin A1c over time and reduced risk for developing complications of T1D. Children who do not achieve adequate glycemic control face devastating complications, seriously affect their quality and duration of life as well as family dynamics and finances. Short-term effects of poor self-management include hypoglycemia or hyperglycemia, while long-term complications directly related to fluctuating and higher overall blood glucose levels include nephropathy, retinopathy, neuropathy, and heart disease. A growing body of evidence supports the feasibility of attaining near normal blood glucose levels without significantly increasing the risk of severe hypoglycemia for children with T1D. Unfortunately, despite the development of insulin analogs and advanced technologies for glucose monitoring and insulin delivery, less than 25% of US children with T1D meet recommended A1c goals. This paradox illustrates the complexity of incorporating diabetes self-management successfully into daily living.

Children with T1D and their families often struggle to keep up with the substantial demands of diabetes self-management. Optimal chronic illness self-management requires developing knowledge of the condition and treatment; managing medications; monitoring the disease and its symptoms; addressing the effects of illness on physical, emotional, and social role function; reducing health risks; and collaborating with health professionals. Keeping blood sugar in near-normal ranges requires tracking the carbohydrates consumed, performing multiple daily blood glucose measurements, and executing complex calculations to accurately determine insulin doses. Diabetes self-management demands often compete with other life priorities, leading to family conflict and poor disease outcomes. Further, parental fear of
hypoglycemia has been shown to be associated with poorer blood glucose control, possibly mediated through parental stress.\textsuperscript{22,23} Multiple barriers in areas such as motivation, family interactions, and understanding and organizing diabetes self-management impede self-management and correlate with poor self-management and diabetes control.\textsuperscript{24,25}

While inadequate glycemic control ultimately impacts quality of life (QOL) over a lifetime,\textsuperscript{7} many children with diabetes and their parents have impaired QOL because of the demands the disease places on their daily lives (eg, needing to check and respond to blood sugar frequently). Although most recent studies indicate that self-management ability and glycemic control are both positively associated with diabetes-specific QOL,\textsuperscript{26-33} many children have adequate control but impaired QOL.\textsuperscript{31} Children with diabetes and their parents need to be responsive to the disease 24 hours a day, often missing school, leisure activities, or work for minor childhood maladies.\textsuperscript{34-38} QOL is also affected through the uncertainty and worry created by fluctuations in blood sugar. Specifically, many parents and children live in fear of hypoglycemic episodes, which can cause seizures or even be fatal.\textsuperscript{39-41} The worry created by this disease makes it difficult for parents to find or feel comfortable using childcare. In turn, they forgo social activities and neglect their own needs and the needs of family and friends.\textsuperscript{35,36,42,43}

Despite decades of research developing efficacious interventions to improve diabetes self-management, a host of challenges continues to diminish the effectiveness of these interventions in practice.\textsuperscript{44} Meta-analyses of behavioral interventions to improve self-management, glycemic control, or QOL have shown small to moderate effects.\textsuperscript{45-49} For example, motivational interviewing can significantly reduce A1c (by 0.5-1.5 mg%) and improve QOL.\textsuperscript{50,51} The American Diabetes Association (ADA) self-management curriculum can also improve A1c by a similar amount.\textsuperscript{52,53} The largest effects are achieved by multimodal interventions that incorporate behavioral and educational strategies as well as family therapy or social support.\textsuperscript{45,46} Efficacy can also vary by specific patient or family characteristics, such as the child’s age, time since diagnosis, glycemic control, and level of family involvement, so targeting interventions may hold promise.\textsuperscript{46,54} Thus, creating a system to select the most promising resources for a given child and family is crucial to improving outcomes and using health care resources effectively.
Additionally, these interventions are often developed and evaluated within the ideal conditions of clinical trials, resulting in resources that are difficult to implement and sustain in real-world settings. Specifically, lack of health care system infrastructure (eg, payment systems and incentives) and resources (eg, trained personnel and time constraints), and inadequate buy-in from families limit the feasibility, effectiveness, and sustainability of such interventions. Further, some existing strategies, especially those with multiple components, are resource intensive, with their delivery averaging 9 sessions over 7 months. For example, in one trial, behavioral family systems therapy, a well-designed psychological intervention for adolescents, was delivered as 12 sessions over a 6-month period. Only 27% of eligible families agreed to enroll, despite $200 incentives. Thus, among families for whom adherence is already problematic, completing lengthy, intensive interventions may not be feasible, especially when not coordinated with routine diabetes visits. To overcome these challenges, interventions must be family centered; that is, they must address families’ perceived needs and preferences and be delivered in a way that makes the interventions appealing and accessible, yet still feasible and sustainable for health care systems.

Efficacious self-management resources are routinely available in multidisciplinary pediatric diabetes clinics, but currently no systematic method exists to help families and clinicians select among these resources. As a first step in achieving family-centeredness for self-management interventions, in a prior study we sought to understand families’ needs by adapting a validated tool for assessing self-management barriers in pediatric asthma to create PRISM (Problem Recognition in Illness Self-management). PRISM is a validated, 28-item, 10-minute tool for identifying diabetes self-management barriers among children with diabetes and their parents during routine clinic visits. PRISM was developed with input from families and is available free at https://www.hipxchange.org/PRISM. Based on data from PRISM, at least 6 different self-management barriers exist. These include (1) understanding and organizing care, (2) the regimen’s pain and side effects, (3) denial of the disease and its consequences, (4) health care team, (5) family, and (6) peer interactions (Figure 1). In prior work, we examined how PRISM scores related to outcomes such as glycemic control and QOL. We performed regression analyses on data obtained from children and parents. For parents of adolescents,
PRISM scores for 5 of the 6 barriers were significantly associated with the adolescent’s A1c.24 Similarly, parents’ PRISM scores for each of the 6 barriers were significantly related to the adolescent’s QOL. Results for the adolescents themselves and the parents of younger children were similar. Based on regression models predicting A1c or QOL, a response of 3 or more on any one of the items indicative of a PRISM barrier is associated with inadequately controlled diabetes and with low QOL.

Results from PRISM are immediately actionable because an efficacious strategy is available to address each of these self-management barriers (Table 1).47,50-53,55,63-80 To select evidence-based interventions for use in this trial, we considered both the number of families affected by the barriers and the magnitude of the association between the barrier score and meaningful outcomes such as A1c and QOL. Using PRISM score cut points from our prior studies, 80% of families can be expected to identify at least 1 of 4 barriers: (1) understanding and organizing care, (2) regimen pain and bother, (3) denial, and (4) family interactions. In addition, our prior work suggests that these 4 barriers have the greatest impacts on A1c and QOL.
Efficacious interventions are available for each of these 4 common and highly impactful barriers. Specifically, barriers related to understanding and organizing care can be addressed through an ADA-based diabetes education curriculum. Family interaction barriers can be addressed with an intervention based on behavioral family systems therapy. Motivation, which encompasses the readiness to self-manage, including feelings and views about the costs and benefits of self-management,\(^{81,82}\) includes 2 of the PRISM-identified barriers: the regimen’s pain and side effects, as well as denial of the disease and its consequences. Thus, motivational interviewing can address both of these barriers.\(^{50,51}\) By aligning available, efficacious strategies to the families’ individual needs, our study leverages the decades-long evidence base of strategies to enhance self-management for children with diabetes while improving the strategies’ efficiency and potential for success.

This Wisconsin-based clinical trial, called Project ACE (Achieving control, Connecting resources, Empowering families), tests the hypothesis that family-centered tailoring of diabetes self-management resources to meet families’ specific self-management barriers will result in better glycemic control and child and parent QOL than usual care. The causal model underlying this hypothesis is based on evidence that both glycemic control and A1c in children with T1D are influenced by self-management barriers and that these barriers may be mitigated through family-centered tailoring of existing diabetes self-management resources.\(^{24,55}\) Our findings have the potential to help health care organizations effectively use PRISM in clinical settings to identify their patients’ self-management barriers and then use the results to tailor the

<table>
<thead>
<tr>
<th>Barrier</th>
<th>Sample PRISM Item</th>
<th>Tailored resource</th>
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<tbody>
<tr>
<td>Understanding and Organizing  Care</td>
<td>When there are changes to my regimen, I sometimes get confused.</td>
<td>Age-Appropriate ADA-Based Diabetes Education</td>
</tr>
<tr>
<td>Motivation</td>
<td>My regimen has side effects that I really don't like.</td>
<td>Motivational Interviewing</td>
</tr>
<tr>
<td>Pain and Side Effects of Regimen</td>
<td>Nothing bad would happen to me if I didn't follow my regimen.</td>
<td></td>
</tr>
<tr>
<td>Denial of Disease and Consequences</td>
<td>My family gives me a lot of support to help me follow my regimen.</td>
<td>Diabetes Family Teamwork- Based on Behavioral Family Systems Therapy</td>
</tr>
<tr>
<td>Family Interactions</td>
<td>My doctors are friendly and easy to talk to.</td>
<td>Partnering with My Healthcare Team</td>
</tr>
<tr>
<td>Healthcare Team Interactions</td>
<td>I don't want my friends to know about my illness.</td>
<td>Peer Support Group</td>
</tr>
<tr>
<td>Peer Interactions</td>
<td></td>
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</tr>
</tbody>
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evidence-based resources offered to the child’s or family’s identified needs and preferences. Results can also be used to educate health care providers, guide resource use and policies for chronic disease care, and support future interventions to improve self-management in pediatric chronic disease.

Thus, our specific aims were to assess the effect of family-centered tailoring of diabetes self-management resources on outcomes that matter to the children and parents: glycemic control (A1c), QOL, and fear of hypoglycemia.

C. Participation Of Patients And Other Stakeholders In The Design And Conduct Of Research And Dissemination Of Findings

C.1. Types and Number of Stakeholders Involved

Two methods of stakeholder engagement helped ensure that both the study processes and our intervention could be integrated into routine clinic workflows. First, before the study began, interviews with 23 clinicians, clinic leaders, clinic schedulers, and medical assistants as well as with 20 patients’ families elicited potential challenges and solutions related to study procedures and implementation of the intervention (Table 2). Second, stakeholder advisory boards supported sustained engagement throughout the project (Figure 2). A total of 25 parents served on our parent advisory board, with 13 from 1 site and 12 from the other. Twenty-eight children made up the youth and teen advisory boards at the 2 sites (6 youths and 9 teens at site 1; 5 youths and 8 teens at site 2). Our external advisory board consisted of 18 partners, including 8 family partners from the parent and teen advisory boards and 3 advocacy, 5 clinician, and 2 administrative partners.
C.2. Achieving the Desired Balance of Stakeholder Perspectives

Sharing power is necessary to create and sustain a respectful, collaborative, and open environment for our boards. A major potential barrier to successful engagement of family partners is overcoming perceived power and status differentials that often exist in clinician–patient relationships. Parents may feel they cannot express their opinions openly and freely, lest they be judged poorly by health care providers. Clinicians may also feel they cannot provide their honest opinions (eg, regarding problems with self-management) in front of

Table 2. Stakeholders participating in interviews

<table>
<thead>
<tr>
<th>Role</th>
<th>N</th>
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<tbody>
<tr>
<td>Parent/guardian of child with type 1 diabetes</td>
<td>20</td>
</tr>
<tr>
<td>Scheduler</td>
<td>6</td>
</tr>
<tr>
<td>Physician</td>
<td>5</td>
</tr>
<tr>
<td>Nurse</td>
<td>5</td>
</tr>
<tr>
<td>Medical Assistant</td>
<td>3</td>
</tr>
<tr>
<td>Nurse Practitioner</td>
<td>2</td>
</tr>
<tr>
<td>Clinic Manager</td>
<td>1</td>
</tr>
<tr>
<td>Social Worker</td>
<td>1</td>
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</tbody>
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Figure 2. Project ACE stakeholder advisory boards

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patients and family members.\textsuperscript{87} Children’s input is especially affected because they are aware that they have less social power than both parents and clinicians\textsuperscript{88-90} and may feel as if their voices are not being heard.\textsuperscript{91} Through processes of professionally facilitated negotiation and dialogue, perceived power imbalances can be negated.\textsuperscript{87,92} We employed several strategies to equalize the power dynamic. For example, our advisory board processes included specific communication strategies (eg, turn taking and providing constructive feedback) to empower partners. Also, having adequate family partner representation helped prevent members of our external advisory board from feeling marginalized.\textsuperscript{84}

During advisory board meetings, we also employed specific strategies to equalize perceived power. At initiation, facilitators worked with the stakeholders to establish ground rules for equal participation and respectful communication. Name badges included individuals’ first names large and bolded, with everyone referring to partners by their first names. We devised seating arrangements to minimize any perceived status differences. We designed facilitated activities to emphasize the value of multiple perspectives and promote co-learning, giving our partners the opportunity to work together and share perspectives, helping to establish a sense of comfort and mutual respect. This also helped advisory board members and researchers develop a common language that promoted effective communication throughout the process. Finally, as boards would meet multiple times over 3 years, repeated interpersonal contact between members alleviated some perceived status differences. We found these status differences decreased rapidly over the initial 2 meetings.

Another barrier to successful engagement is perceived tokenism by board members.\textsuperscript{84} Ensuring that all members felt valued, regardless of the constituent group, was key to our success. At the start of the process, we emphasized the role of family voices in creating other successful family-centered care programs, such as our family-centered rounding initiative.\textsuperscript{93,94} Partner value was also reinforced through the development of reciprocal relationships, based on trust, mutual respect, and ongoing open communication.\textsuperscript{84} Last, given that limited resources and logistics can negatively affect advisory board engagement,\textsuperscript{84} PCORI’s commitment to supporting the resources needed to foster meaningful engagement greatly helped our success.
To promote a collaborative environment based on transparency, partnership, trust, mutual respect, and the spirit of co-learning, advisory members received training. At the initiation of stakeholder engagement activities, we conducted an orientation for stakeholders. For youths and teens, child life specialists were engaged to deliver this content in a manner appropriate to the children’s development. The training aimed to increase literacy and comprehension regarding research and to improve skills in gathering information and providing feedback. Specific training topics included the role of the partners, understanding research studies, common research and medical terms related to diabetes, effective group communication techniques, principles of effective teamwork, and rules/best practices for constructive criticism. In addition, stakeholders received information about research ethics and confidentiality. At timely junctures, we reinforced and supplemented this orientation with opportunities to practice skills such as reading a results table or critiquing a research summary for lay audiences.

C.3. Methods Used to Identify and Recruit Stakeholder Partners

Through mailings and flyers distributed by clinicians or to our existing lists of families willing to participate in efforts to improve diabetes care, we recruited parents, youths aged 8-12, and teenagers aged 13-17 from each clinical site for separate parent, youth, and teen boards. These boards focused on enhancing recruitment, retention, and data collection as well as reporting findings to lay audiences. To include diverse perspectives, we recruited family partners to the advisory boards based on the following criteria: child age, parent education, race/ethnicity, distance traveled for care, and the child’s glycemic control. We also focused on ensuring participation from “hard-to-reach” families (those not typically included in research) by specifically reaching out to those who might be less likely to engage via trusted clinical partners and from existing registries of clinic patients. In most cases, the parent of a child or teen on our boards also joined the parent board. Families that served on the advisory boards were excluded from study participation.

Our external advisory board blended a subset of family partners with clinicians and administrators from both sites as well as representatives from community diabetes advocacy
groups. This board focused on implementation and dissemination topics. Parents and youths on the external advisory board were drawn from the other parent and teen advisory boards to reinforce the importance and legitimacy of their voices in the research. Children were not included in this external board due to concerns that the benefit of their participation might be outweighed by potential negative consequences, such as discomfort and fatigue.

Of note, the engagement ultimately realized in this research exceeded our plan as submitted in our proposal. Specifically, we increased the number of youth and teen advisory board members to help ensure substantial input from partners similar in age to study participants. We also engaged a larger number of clinical and advocacy partners than anticipated. This occurred primarily due to recognition of their strong interest in the project and the need to support even more engagement at the clinical sites. While we targeted clinical leadership (e.g., division directors), we learned that their busy schedules and diverse interests might not always allow them to engage as intensely as needed or in a timely manner. By adding additional clinicians and not removing anyone from the advisory role, we allowed stakeholders to contribute accordingly as the study progressed.

C.4. Methods, Modes, and Intensity of Engagement

We deductively analyzed data from the stakeholder interviews conducted prior to the start of the study using 2 frameworks for implementing new ways of delivering health care.97,98 During the study, all of our advisory boards met in person 9 times throughout the study (approximately 3 times annually) for 2 hours and received $100 for their participation in each board meeting. For each meeting, a detailed agenda was prepared. Meetings typically began with a shared meal and an initial “icebreaker” activity. Early on in the meeting, facilitators shared how the group’s advice from the previous meeting was implemented and the outcomes of the implementation. Next, 2 or 3 activities were completed that focused on solving research challenges or providing input on next steps. The sessions ended by bringing a summary of the subgroups’ ideas back to the whole group and closing activities that could include reflections on the meeting and soliciting suggestions for the timing of the next meeting. Sample agendas are
available in our free toolkits at https://www.hipxchange.org/SustainingEngagement and https://www.hipxchange.org/TOPPER.

Additional details about stakeholder engagement processes and best practices from this research can be found in our toolkits. Specifically, materials in the Sustaining Engagement of Blended Stakeholder Boards Toolkit were originally created for a 2-part workshop series and outline how to meaningfully engage a blended stakeholder board (eg, a board that includes advisors with different roles in health care delivery) across the research trajectory. TOPPER (Toolkit for Patient Partner Engagement in Research) provides details on how to orient patients as research stakeholders. Last, HARPS (Hard-to-Reach Patient Stakeholders: An Engagement Guide) provides a roadmap to engage hard-to-reach patient stakeholders, such as children or racial and ethnic minorities. We have also disseminated our insights nationally to researchers, policymakers, community organizations, and patient stakeholder groups through multiple seminars and interactive workshops.

C.5. Perceived or Measured Impact of Engagement

Relevance of the research question. Before this study was proposed, the research question arose from a conversation with a teen with T1D, who noted, “I go and go and go to my [diabetes] clinic visits and they tell me the same thing every time and none of it ever helps me.” This encounter spurred the principal investigator to explore what could be done to tailor the content of these visits to be more aligned with the needs of children and their families, thereby addressing a research question relevant to the care of people with T1D.

Study design, processes, and outcomes. Both before and during the study, stakeholders provided further extensive input on the study’s design, processes, and outcomes. For example, prior to the start of the study, stakeholder engagement with local advocacy organizations such as Juvenile Diabetes Research Foundation (JDRF) and clinic leadership shaped the survey tools, study processes, and conduct through the course of a pilot test of the intervention. After we received funding, through both the interviews and ongoing engagement on our advisory boards, stakeholders continued to generate solutions to study challenges related to design, procedures, and outcomes.
Regarding study processes, stakeholders indicated that holding the group sessions in rooms that are unfamiliar to participating families might prevent them from attending sessions or cause them to arrive late. To address this, we coordinated with the clinics’ welcome desk to direct participants to the correct rooms. Stakeholders also expressed concern about keeping participants engaged over the course of the study and suggested frequently updating the families’ preferred contact method for study reminders. Additionally, stakeholders determined the timing and content of the study’s reminder calls and emails, improving retention and data completeness.

Regarding the integration of study procedures into the clinic workflow, stakeholders identified and resolved 2 important issues. First, they pointed out that the iPads used to collect survey data during appointments might distract families from their visit with a health care provider. The suggested solution was to add a note to close the iPad’s cover whenever a provider was present. Second, stakeholders pointed out the potential difficulty of scheduling a clinic appointment coordinated with a group intervention session. To address this, the research team worked with the clinic schedulers and leadership to reserve appointments either before or after study activities for participating families. Last, the inclusion of fear of hypoglycemia as a study outcome was the direct result of stakeholder engagement, as was the decision to assess this only for parents. Specifically, while parent stakeholders reported that fear of hypoglycemia was a concern for them, our youth and teen advisors suggested that this was less of a concern for them. Other outcomes such as glycemic control (A1c) and aspects of QOL such as communication were specifically relevant for youths and teens.104,105

Study rigor and quality. Stakeholder engagement affected study rigor and quality and thus was invaluable to the success of our study. For example, stakeholders helped us limit the number of usual care (control) participants who withdrew or did not complete study activities by advising us about how to describe the importance of a control group and the randomization process to assign participants to study arms. Specifically, our stakeholders advised us to explain that randomization is completed by a computer and that research and clinic staff have no control over the assignment. This information resulted in high retention rates among usual care participants, improving both the representativeness of this arm and also the likelihood of
having an adequate sample on which to power our analyses. Stakeholder input also improved our ability to recruit diverse participants. Specifically, families at our site located near a large metropolitan area advised us that providing the intervention as group sessions over the lunch hour (which had worked well at a site in a smaller metropolitan area) would be a “deal breaker” for their participation due in part to transportation issues. In addition, having a group session at lunch meant that parents whose work allows only half- or full-day absences would need to miss an entire day of work for their family to participate in the study. In response, we scheduled the group sessions at the site located near the large metropolitan area to be either in the morning or in the afternoon.

**Participant recruitment.** To increase recruitment and reduce the burden of missed school, stakeholders helped design a résumé entry for children participating in the intervention to add to college and scholarship applications. They also suggested that some exercises completed in part of the intervention group sessions could be collated for teachers to consider for academic credit.

**Adoption of research evidence into practice.** Stakeholders gave input on our dissemination materials, selecting 3 study processes that would be of value to disseminate: (1) group session scheduling system, (2) PRISM survey tool and administration, and (3) best practices for engaging teenagers with chronic diseases as partners in research efforts. They further provided advice about how to share study results that were negative or positive. They also reviewed and provided input about aspects of the toolkit produced from this study, such as ways to make the figure describing the study process easier for lay audiences to understand.
D. METHODS

D.1. Study Overview

Project ACE was a randomized trial that aimed to compare the effectiveness of family-centered tailoring of diabetes self-management resources (intervention) with that of usual care, regarding glycemic control and QOL among children with T1D and their parents at 2 clinical sites. We selected study sites based on (1) feasibility considerations (eg, existing collaborations and adequate sample size to power the study) and (2) representativeness of the population (eg, socioeconomic diversity offered by including an urban center and a center that serves many rural families). The family-centered intervention package included (1) identifying the family’s self-management barriers using a validated survey tool, PRISM; (2) use of PRISM results to tailor self-management resources to the family’s self-identified needs; and (3) delivery of the tailored self-management resources in group sessions coordinated with routine diabetes clinic visits. The tailored group sessions were delivered in coordination with routine quarterly T1D clinic visits over a 9-month period. We followed outcomes for 1 year after the intervention period had been completed.

D.2. Study Design

Project ACE was a randomized parallel-group clinical trial, with a 12-month intervention period and 1 year of follow-up (selected specifically to examine outcomes over a longer period than many such trials of behavioral interventions do). We chose this study design to strengthen inferences about causality while balancing the need to design an intervention that can be implemented in clinical settings. Specifically, we chose the randomized design because it balances confounding variables between the study arms, which strengthens the case that differences in outcomes between the study arms are caused by differences in the interventions assigned to each. We chose to compare family-centered tailoring of self-management resources against usual care because this comparison answers the relevant, practical questions of our family partners and stakeholders: “How do intervention arm outcomes compare with outcomes from usual care?”
D.3. Participants

We recruited children aged 8-16 for Project ACE. We excluded children younger than 8 years old because the content and group format of the intervention’s tailored self-management resources are not appropriate to their developmental stage. We excluded children aged ≥17 due to their likelihood of leaving the participating clinic during the study period for college or employment.

Other eligibility criteria were (1) T1D diagnosis for at least 1 year, (2) fluency in English, and (3) ability to provide informed consent/assent. Exclusion criteria were (1) cognitive or mental health issues precluding potential benefit from group-based activities, (2) known hemoglobinopathy or medical condition that might affect A1C measurement accuracy, (3) participation in a current diabetes intervention study or the pilot study for this trial, (4) inability to continue care with the same clinician and clinic during the study, (5) inability of the consenting parent to accompany his or her child to all visits during the study, (6) study appointments unavailable within 4 months of enrollment date, and (7) no identified self-management barrier as determined by scoring PRISM at recruitment after consent was obtained. To improve generalizability to the population broadly, we did not exclude participants based on A1C values. Children who met the eligibility criteria and their parents were consented. We obtained assent from children aged 14 and younger.

Recruitment for this study occurred in 3 ways: (1) in-person recruitment by research team members at the participating diabetes specialty clinics, (2) email or regular mail recruitment sent to clinic patients, and (3) flyers/notices at the diabetes clinics or on their websites.

For in-person recruitment, a member of the health care team approached a potentially eligible child and parent/guardian at his or her visit to ask about interest in learning about our study. If the answer was yes, the health care team member notified the research assistant, who explained the study to the child and parent/guardian. Following the explanation, all interested parents were asked 21 screening questions to determine basic eligibility. The screening occurred either in paper form or electronically via an online survey platform (Qualtrics).
For recruitment from our registry of research participants, we sent information about the study along with an invitation to complete the basic eligibility screen either electronically or via postal mail (for those in our registry who previously provided consent to be contacted regarding research opportunities). The letter contained the study information sheet and a link to Qualtrics to complete the screening questions to determine basic eligibility. Those without internet access completed a paper copy of the basic eligibility screener and returned it in a postage-paid envelope, provided in our mailer.

In addition, we posted a recruitment flyer at the clinic sites and on clinic websites. The flyer provided contact phone numbers through which parents requested study information via email or regular mail. The research coordinator received permission from the clinic administrator or web host to post the flyer.

With all recruitment methods, if a family remained eligible after the screener, research staff provided the parent/guardian as well as the child with the appropriate age-based consent/assent, either at the clinic visit or in person at a mutually agreed upon time. We followed standard consent processes as recommended by our institutional review board (IRB). While our IRB did not allow us to systematically collect reasons for declining to participate, we commonly encountered a few reasons, such as (1) believing that there was not enough time at the appointment to complete the enrollment process, (2) needing flexibility to have diabetes appointments at other, nonstudy clinics, (3) avoiding additional time at the clinic for study processes, and (4) needing to ask other caretakers or parents who were not at the clinic visit before agreeing to participate.

At the time of study enrollment, participants completed survey-based measures on iPads using Qualtrics or on paper, if the participant preferred. To determine eligibility, parents as well as children aged 13-16 completed PRISM to identify the family’s self-management barriers. Families for whom PRISM identified at least one self-management barrier were randomized by a computer program to intervention or usual care on a 1:1 ratio. If an adolescent and his or her parent indicated different barriers, the adolescent’s responses received priority. We did this because our preliminary data suggested that adolescents are
D.4. Intervention and Usual Care (Control)

The study intervention consisted of using results from the child’s and parent’s PRISM surveys to tailor the type of self-management resource to address 1 of any 4 specific barriers (regimen pain and bother, denial, understanding and organizing care, and family interactions) identified by each family, and then delivering that resource in a small-group setting on the day of the child’s routine diabetes clinic visit, either immediately before or after the clinic visit. We facilitated the scheduling of these coordinated visits by working with participating clinics to hold the appointments before and after the study’s group sessions for booking by study patients only (details in the intervention toolkit). Table 3 contains details about the intervention and its delivery using a standard reporting format. Over a 9-month period, each participating family in the intervention group received usual care and was to receive four 75-minute self-management resource sessions, delivered in a small-group format and with the content focused to address a single identified self-management barrier. The first group session was delivered at the first clinic visit after enrollment. The group format was preferred by stakeholders and had facilitated retention of families in the trial’s pilot study. In addition, the format maximized the number of families that could be served by a single professional facilitator and utilized the group dynamic to enhance content delivery.
During the 4 group sessions, facilitators delivered content for 1 of the 3 evidence-based self-management resources, tailored to address one of the participating families’ identified self-management barriers, beginning at each family’s next clinic visit. Descriptions of the content for each of the 3 self-management resources are presented in Table 4. The full content and all materials for the group sessions have been published in a free toolkit (available at https://www.hipxchange.org/T1DSMART). In brief, barriers related to understanding and organizing care include challenges with the family’s understanding of diabetes or diabetes self-management and the ability to incorporate self-management skills into daily living. Registered nurses and certified diabetes educators facilitated the groups addressing this barrier, using the “Tips and Tools” content, which is derived from the ADA’s education curriculum.52 Motivation barriers (regimen pain and bother or denial) encompass challenges with readiness to self-manage, including beliefs about the costs and benefits of self-management, the importance of self-management, and positive and negative aspects of the self-management regimen.50,51 Certified members of the Motivational Interviewing Network of Trainees facilitated the groups addressing this barrier, using the “Your Diabetes, Your Choices” content, based on the tenets of motivational interviewing.116 Barriers related to family interactions reflect the challenges of balancing child autonomy with the role of family support and supervision. Pediatric health
psychologists facilitated groups addressing this barrier using the “Family Teamwork” content, following a behavioral family systems therapy approach.\textsuperscript{55,64,117}

<table>
<thead>
<tr>
<th>Table 4. Summary of group session content by session type</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Tips and Tools</strong></td>
</tr>
<tr>
<td><strong>PRISM barrier addressed</strong></td>
</tr>
<tr>
<td>Understanding and Organizing Care</td>
</tr>
<tr>
<td><strong>Session content</strong></td>
</tr>
<tr>
<td>• Recognize and respond to high and low blood sugars</td>
</tr>
<tr>
<td>• Understand how and when blood sugar is affected by various types of insulin or by exercise</td>
</tr>
<tr>
<td>• Use tools like blood sugar logs, carb counting, and the plate method of healthy eating to inform management decisions</td>
</tr>
<tr>
<td>• Gain awareness of positive outcomes of optimal diabetes management now and for future transitions like driving, college, or dating</td>
</tr>
</tbody>
</table>

The group session content was delivered according to a standard protocol. Our study featured stringent protocol monitoring to address treatment fidelity problems common among similar intervention studies.\textsuperscript{45,118,119} We assessed fidelity for 58 of 123 group sessions using either checklists for session content (for the “Tips and Tools” and “Family Teamwork” groups) or the Motivational Interviewing Treatment Integrity Coding Manual (for the “Your Diabetes, Your Choices” groups)\textsuperscript{120} from audio-recorded group sessions by trained personnel. We transformed these assessments to a scale of 0 to 100 (higher scores signify higher fidelity). Both content experts and facilitators provided feedback about fidelity and contributed to plans for implementing any needed changes to improve group session delivery. Families received reminder calls 3 weeks and 1 week prior to each upcoming clinic appointment/coordinated group session.

**Usual care (controls).** As with intervention participants, individuals randomized to usual care continued to attend clinic visits with their diabetes clinician every 3 months. These visits were typically about 30 to 60 minutes in length and conducted by either nurse practitioners or
pediatric endocrinologists. Based on published literature as well as stakeholder input, these usual care visits typically included review and discussion of recent A1c and blood glucose data, a physical examination, adjustment of the insulin regimen, discussion of management habits and challenges, advice about diet and physical activity or sports participation, and planning diabetes management for upcoming events such as camp or school changes. Multidisciplinary teams of certified diabetes educators, dieticians, and social workers were available to assist families at both study sites. Referral to certified diabetes educators, nutritionists, and mental health professionals continued per usual for both usual care and intervention participants, with referrals typically initiated based on individual provider judgment. To monitor participant use of these additional services, our surveys included an item asking families to report visits to these providers. Reminders about upcoming clinic appointments were the same as those of intervention participants in number and timing.

D.5. Study Outcomes

The primary objective of the study was a between-group comparison of the child’s A1c as well as QOL for both parent and child, over time. We chose these 3 primary outcomes due to relevance to patients and clinicians as well as the availability of reliable and valid assessments that are feasible and responsive to change over time.

To assess A1c, both participating clinics used DCA Vantage® analyzer (Siemens Healthcare Global) point-of-care devices. To convert point-of-care A1c values to DCCT-equivalent values for analyses, we created a separate regression equation for each point-of-care machine used in participating clinics. Data for these equations arose from determining point-of-care A1c values from each clinic machine for 87 deidentified banked samples with known A1c results from our central laboratory. The National Glycohemoglobin Standardization Program has certified this laboratory’s ion exchange chromatography/spectrometry method and reagents as having documented traceability to the DCCT reference method.

Our study evaluated multiple patient- or participant-reported outcomes. We assessed child and parent QOL using recommended validated measures. We measured child QOL using the total scale score for the diabetes-specific Pediatric Quality of Life Inventory (PedsQL).
measure consists of 33 items on a 5-point Likert scale. Items are reverse scored and transformed to a 0- to 100-point scale. The total score is the average over the number of items answered. Possible scores range from 0 to 100, with higher scores indicating better QOL. This measure has shown very good internal consistency reliability (Cronbach α = 0.87-0.88). A minimally important difference for the PedsQL is considered to be 5.27 units based on self-reported data from adolescents. We measured parent QOL using the standard linear transformation and averaging item responses from 6 subscales of the PedsQL Family Impact Module (Emotional Functioning, Social Functioning, Communication, Worry, Daily Activities, and Family Relationships). The Family Impact Module consists of 25 items on a 5-point Likert scale. Items are reverse scored and transformed to a 0- to 100-point scale. The total score is the average over the number of items answered. Possible scores range from 0 to 100, with higher scores indicating better QOL. In previous studies, these subscales have shown good to excellent internal consistency reliability (Cronbach α = 0.79-0.97). Regarding the Family Impact Module, to our knowledge, there are no published reports of minimally important differences. However, using a recommended distribution-based statistical method that relies on the standard deviation of the measure, we calculated a minimally important difference of 3.53 for the Family Impact Module from our data.

In addition, we assessed fear of hypoglycemia, our secondary outcome, through parent surveys of the 15-item worry subscale of the Hypoglycemia Fear Scale (HFS-P). Each item was rated on a 5-point Likert scale, from 1 = “never” to 5 = “always.” The items are then summed for a total score. Possible scores range from 15 to 75, with higher scores indicating greater fear. The internal consistency reliability of the Worry subscale of the HFS-P has been shown to be very good to excellent (Cronbach α = 0.89-0.91). We included this secondary outcome in the study based on stakeholder input about how fear or worry about hypoglycemia affects ability to achieve optimal glycemic control.

D.6. Study Setting

We recruited children aged 8-16 years from 2 large multidisciplinary diabetes clinics affiliated with academic medical centers in Wisconsin that serve both urban and rural
populations. We chose the sites to meet the need for size and diversity of the study population, enhance the generalizability of our findings to the pediatric T1D population, and meet Chambless criteria by evaluating effectiveness across real-world clinical settings.\textsuperscript{133}

D.7. Timeframe for the Study

The intervention period for participating children and parents was 12 months, with the tailored group sessions beginning at the first regularly scheduled clinic visit after enrollment and delivered over 9 months. This allowed delivery of the intervention to be coordinated with the provision of routine T1D care. After the intervention period, we followed participants for an additional 12 months, allowing the impact of the intervention to be examined over the long term as families integrate the new skills and behaviors into their self-management routines. Section D.8 contains details of the follow-up schedule for study outcome measures.

D.8. Data Collection and Sources

Table 5 shows an overview of the study data collection. From medical records, we obtained A1c data that are routinely collected at diabetes clinic visits for 9 time points during the study (quarterly during the trial and post-trial year). We collected QOL data at 5 time points: at baseline; at 3 months after the first intervention session; and at 3, 6, and 9 months after the intervention ended.

<table>
<thead>
<tr>
<th>Data element</th>
<th>Baseline (0 mo)</th>
<th>Session A (3 mo)</th>
<th>Session B (6 mo)</th>
<th>Session C (9 mo)</th>
<th>Session D (12 mo)</th>
<th>Post-intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>A1c</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>QOL</td>
<td></td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Parent</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Child</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PRISM barrier scores</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other survey-based measures</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Covariates</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Family characteristics</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Disease and regimen factors</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
In addition, at enrollment and twice during the study period, we used surveys to assess covariates such as participant characteristics and disease or regimen factors that have known or hypothesized relationships to glycemic control, self-management barriers, or QOL.\textsuperscript{30,32,107-114} Participant characteristics included parent/child ages (continuous) and genders, race/ethnicity (white, non-Hispanic vs all other), as well as child health status and comorbid conditions and parent education (standard categories). We selected surveyed comorbid conditions based on their frequency in populations in general pediatrics or in children with T1D. Disease and regimen factors included years since diagnosis and device use (eg, insulin pumps, continuous glucose monitors, or combinations of these functions).

At the time of study enrollment, participants completed survey-based measures on iPads using Qualtrics or on paper, if the participant preferred. Subsequent study surveys were emailed to participants for completion online 3 weeks in advance of the due date and again 1 week before the due date if still not completed. We chose the time intervals for these survey requests based on input from stakeholders. Participants could also request paper surveys to be mailed to them in lieu of electronic surveys. We monitored data completion, and participants with incomplete surveys were given an iPad or paper survey to complete at their next clinic or study visit. Participants also received reminder calls 3 weeks and 1 week before their clinic appointments and intervention group sessions during the intervention period. To further optimize retention, we rechecked contact information at each in-person encounter with participating families.

As an additional effort to retain and collect data from all participants, once the intervention period was complete, we sent out a final reminder regarding incomplete A1c values or surveys to 15 participating families for whom we had no postintervention data. This yielded postintervention data for 6 participants. Last, after finding that self-report of A1c values was highly reliable among our participants, we also added a survey item requesting self-report of any A1c value obtained outside the study’s clinical sites, in an attempt to gain A1c data from participating families who may have moved or changed clinics during our study period. This yielded 4 additional A1c values.
A total of 3 families withdrew during the study (see Figure 3). Two of these families were in the intervention group, while one was in usual care. One family provided no rationale for withdrawing, one family moved to another state and therefore would not be returning to the clinic, and one family was generally overwhelmed by life events. No families were lost to follow-up, defined as not contributing study data after the baseline enrollment.

D.9. Analytical and Statistical Approaches

All analyses compared outcomes between intervention and usual care arms as defined by the intention-to-treat principle. Following inspection of cross-sectional descriptive statistics, bivariate correlations, and graphs of individual trends over time, the primary analytic technique was mixed effects models with repeated measures that capture the time trend via linear, polynomial, or spline terms. We fit trajectories for child’s A1c and for QOL for child and parent as well as for fear of hypoglycemia. We modeled outcomes as continuous, with normally distributed residuals and within-individual random intercepts and slopes to capture within-individual correlation. We compared models assuming equal variance of these components in both arms with those allowing unequal variances via likelihood ratio tests. We checked distributional assumptions, and applied transformations and/or robust alternatives when needed.

The primary hypothesis was that outcome trajectories differ between the intervention and usual care arms. We tested this via interaction effects between treatment group and time trend, as initially proposed. We included fixed effects in the models to represent randomization strata (eg, clinic site and age group), and tested their interactions with time trend. We included a limited set of additional variables in the model to correct for imbalance between the usual care and intervention arms. Finally, we evaluated additional covariates (eg, baseline demographics, health care utilization, and comorbidities) for potential to improve precision, as originally proposed. Ultimately, addition of these covariates did not substantively change study findings. We therefore present results without additional covariate adjustment. In addition, we include an investigation of the heterogeneity of treatment effects as planned in the proposal, with a focus on age group- and site-based differences determined a priori based on the study
strata, the existing literature about efficacious interventions, and models of trends in study outcomes performed prior to unblinding our data.\textsuperscript{50,51,54,55,63,134} Last, we evaluated the influence of missing data primarily via pattern mixture models,\textsuperscript{135,136} which are specially tailored for mixed effects models with informative missingness. Briefly, individuals with greater numbers of observations have more influence on estimated trends. If such individuals also have different underlying slopes or levels of the outcome, bias enters into the estimators. Pattern mixture models use patterns of missingness, such as the number of missing observations for a person, to capture the underlying trends. Separate mixed models can then be fit within strata of individuals with the same number of observations. Finally, the stratified estimators are averaged together, giving each stratum a weight that represents the number of individuals in the stratum, thus making the estimator represent the entire sample.

This study was powered to evaluate effects on glycemic control and QOL, with a 2-tailed alpha = 0.05. We estimated the sample size for detecting minimally clinically important differences of 0.5\% in A\textsubscript{1c} and 3 points in QOL with 80\% power across 5 observation times, based on previously noted data for QOL measures. We based our approach to estimating the needed sample size on either detecting a mean difference across time points with a within-individual correlation of 0.5 or detecting a difference in linear trends reaching the specified difference at follow-up, with the expected variance in trends estimated from reanalysis of available outcome data for similar age and diabetes duration.\textsuperscript{137} We set the difference between arms to go from 0 at baseline to 0.5\% or 3 points linearly across the 5 study time points. These approaches yielded sample size estimates of about 100 patients per group.

D.10. Changes to the Original Study Protocol

The final study protocol was approved by the University of Wisconsin–Madison’s IRB and submitted to ClinicalTrials.gov (see Appendix). Of note, there were no substantive changes regarding study sites, recruitment methods, eligibility criteria, sample size, or outcome measures from the originally proposed study.

To improve the quality of our study, prior to any recruitment, we added 3 additional exclusion criteria to the study protocol. To ensure the integrity of our primary outcome
measure, we excluded participants with known hemoglobinopathy or other medical conditions that might affect A1c measurement accuracy. We also excluded participants who were enrolled in any other diabetes study at the time of enrollment. Finally, we excluded participants with known cognitive or mental health issues that would preclude potential benefit from group-based activities, such as our study intervention.

We also adjusted the timing and frequency of data collection to make optimal use of study resources. For example, instead of collecting QOL and fear of hypoglycemia via survey at 12 months as originally proposed, we collected these data at 15 months—that is, 3 months after the end of the intervention—so the assessment would capture the full effect of the intervention. In addition, we moved the final survey data collection from 24 months to 21 months, allowing participants up to 3 months to complete this final data element either at home or during a clinic visit. Finally, we had the opportunity to collect 2 additional A1c values (one at 15 months and one at 21 months) at minimal cost.

E. RESULTS

E.1. Recruitment and Retention

A total of 214 families were recruited and randomized between September 2014 and May 2015. Intervention delivery concluded in summer 2016; data collection was completed by August 2017. Figure 3 provides a standard CONSORT diagram depicting the flow of participants through recruitment and randomization. During the recruitment period, 994 families presented to participating clinics. A member of the diabetes care team asked families if a member of the research team could briefly tell them about a research study. Among the 877 families who were briefed by the research team about the study, 143 (16%) were ineligible based on inclusion/exclusion criteria and 276 (31%) were excluded due to factors related to study logistics. The most common logistical exclusion was seeing a diabetes provider who did not have any available timely clinic appointments coordinated with intervention delivery. This occurred primarily because the number of eligible families often exceeded the available provider appointments. This was particularly true among providers who had very limited clinical
time devoted to diabetes care, perhaps as little as one morning or afternoon per week. Among 363 potentially eligible families, 267 (74%) consented to participate. Of those, 21 families were ineligible because no barrier was identified by PRISM. Another 32 were excluded prior to randomization because there were no available clinic appointments coordinated with group sessions that addressed one of their self-management barriers. Ultimately, 214 families were randomly assigned, 108 to receive usual care and 106 to receive the intervention.

Table 6 provides demographics and diabetes-related characteristics for participating families. Randomization achieved balance on all but 2 characteristics. Compared with the usual care group, the intervention group had significantly fewer mothers completing the survey at enrollment and more participants using insulin pumps. Of note, the 2 study arms were balanced at baseline regarding each of the 4 study outcome measures. Further, the frequency with which participants experienced the study’s self-management barriers varied. The most commonly reported barrier was denial of diabetes and its consequences (> 85%), while the least commonly reported barrier was regimen pain and bother (< 50%) among adolescents. We found no differences by site in the frequency with which participants experienced each of the study’s self-management barriers (data not shown).
Figure 3. Project ACE CONSORT diagram

117 Families not briefed about study

12 Families without a parent present

95 Families declined to be screened for eligibility

131 Families not meeting eligibility criteria
276 Families excluded due to factors related to study logistics

96 Families declined to participate

21 Families excluded because have no barrier to address
32 Families excluded because of lack of available clinic visit or group intervention session

994 Families presented in clinic

865 Families briefed about study

770 Families screened for eligibility

363 Potentially eligible families

267 Families provided consent

214 Families randomized

106 Randomized to intervention

2 Withdrew

104 Completed intervention

108 Randomized to usual care

1 Withdrew

107 Completed usual care
Overall, intervention sessions had high fidelity (mean score 93), with nearly half of sessions examined having a fidelity score of 100. Attendance at intervention group sessions was high, with 69% of families attending at least 3 of the 4 sessions (Table 7). Among youth participants, only 4 families (2 at each site) did not attend even 1 intervention session. Among teen participants, 8 families did not attend a single intervention session, and all 8 of these were at site 2. Similarly, our trial participants completed A1c assessments and study surveys at high rates, and the rates of completion did not differ significantly between intervention and usual care participants (Table 8 and Figure 4). Last, we found no differences between intervention

Table 6. Participant characteristics (%, n)\(^a\)

<table>
<thead>
<tr>
<th>Child characteristics</th>
<th>Overall (N=214)</th>
<th>Usual care (N=108)</th>
<th>Intervention (N=106)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Youth, 8-12 years old</td>
<td>44.4% (95)</td>
<td>44.4% (48)</td>
<td>44.3% (47)</td>
</tr>
<tr>
<td>Teen, 13-16 years old</td>
<td>55.6% (119)</td>
<td>55.6% (60)</td>
<td>55.7% (59)</td>
</tr>
<tr>
<td>Girl</td>
<td>49.1% (105)</td>
<td>54.6% (59)</td>
<td>43.4% (46)</td>
</tr>
<tr>
<td>Non-Hispanic, White</td>
<td>83.6% (179)</td>
<td>85.2% (92)</td>
<td>82.1% (87)</td>
</tr>
<tr>
<td>Clinical site</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Site 1</td>
<td>47.2% (101)</td>
<td>48.2% (52)</td>
<td>46.2% (49)</td>
</tr>
<tr>
<td>Site 2</td>
<td>52.8% (113)</td>
<td>51.9% (56)</td>
<td>53.8% (57)</td>
</tr>
<tr>
<td>In good to excellent health</td>
<td>92.5% (198)</td>
<td>95.4% (103)</td>
<td>89.6% (95)</td>
</tr>
<tr>
<td>Diabetes duration, years (mean (sd))</td>
<td>5.4 (3.3)</td>
<td>5.5 (3.5)</td>
<td>5.3 (3.1)</td>
</tr>
<tr>
<td>Insulin pump use</td>
<td>51.4% (110)</td>
<td>44.4% (48)</td>
<td>58.5% (62)</td>
</tr>
<tr>
<td>A1c &lt; 7.5%</td>
<td>14.3% (30)</td>
<td>14.4% (15)</td>
<td>14.4% (15)</td>
</tr>
<tr>
<td>A1c at recruitment (mean (sd))</td>
<td>9.1% (1.6)</td>
<td>9.3% (1.7)</td>
<td>8.9% (1.5)</td>
</tr>
<tr>
<td>A1c at intervention start (mean (sd))</td>
<td>9.1% (1.6)</td>
<td>9.2% (1.7)</td>
<td>9.1% (1.5)</td>
</tr>
<tr>
<td>Quality of life (mean (sd))</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Youth, 8-12 years old</td>
<td>66.4 (12.6)</td>
<td>65.9 (10.9)</td>
<td>67.0 (14.1)</td>
</tr>
<tr>
<td>Teen, 13-16 years old</td>
<td>66.2 (12.8)</td>
<td>66.0 (12.1)</td>
<td>66.5 (13.6)</td>
</tr>
<tr>
<td>Parent characteristics</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age, years (mean (sd))</td>
<td>41.8 (6.2)</td>
<td>42.0 (5.8)</td>
<td>41.7 (6.6)</td>
</tr>
<tr>
<td>Mother</td>
<td>84.6% (181)</td>
<td>89.8% (97)</td>
<td>79.3% (84)</td>
</tr>
<tr>
<td>Non-Hispanic, White</td>
<td>87.9% (188)</td>
<td>90.7% (98)</td>
<td>84.9% (90)</td>
</tr>
<tr>
<td>Education</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>High school graduate or less</td>
<td>18.2% (39)</td>
<td>13.9% (15)</td>
<td>22.6% (24)</td>
</tr>
<tr>
<td>Some college</td>
<td>35.5% (76)</td>
<td>39.8% (43)</td>
<td>31.1% (33)</td>
</tr>
<tr>
<td>Bachelor’s degree or more</td>
<td>46.3% (99)</td>
<td>46.3% (50)</td>
<td>46.2% (49)</td>
</tr>
<tr>
<td>Quality of life (mean (sd))</td>
<td>61.2 (15.8)</td>
<td>60.4 (16.5)</td>
<td>62.1 (15.1)</td>
</tr>
<tr>
<td>Fear of hypoglycemia (mean (sd))</td>
<td>38.8 (9.9)</td>
<td>39.6 (10.3)</td>
<td>38.0 (9.6)</td>
</tr>
</tbody>
</table>

\(^a\)Values may not add to 100% due to rounding or non-response. Bolded values indicate significant differences between trial arms.
and usual care participants’ self-reported use of nutrition, diabetes education, and health psychology services during the intervention period.

Table 7. Intervention group session attendance by age group and site (%, n)\textsuperscript{a}

<table>
<thead>
<tr>
<th>Sessions attended</th>
<th>Overall (N=106)</th>
<th>Site 1 (N=26)</th>
<th>Site 2 (N=21)</th>
<th>Site 1 (N=23)</th>
<th>Site 2 (N=36)</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>47% (50)</td>
<td>65% (17)</td>
<td>52% (11)</td>
<td>35% (8)</td>
<td>39% (14)</td>
</tr>
<tr>
<td>3</td>
<td>22% (23)</td>
<td>15% (4)</td>
<td>14% (3)</td>
<td>35% (8)</td>
<td>22% (8)</td>
</tr>
<tr>
<td>2</td>
<td>13% (14)</td>
<td>12% (3)</td>
<td>14% (3)</td>
<td>17% (4)</td>
<td>11% (4)</td>
</tr>
<tr>
<td>1</td>
<td>7% (7)</td>
<td>0% (0)</td>
<td>10% (2)</td>
<td>13% (3)</td>
<td>6% (2)</td>
</tr>
<tr>
<td>0</td>
<td>11% (12)</td>
<td>8% (2)</td>
<td>10% (2)</td>
<td>0% (0)</td>
<td>22% (8)</td>
</tr>
</tbody>
</table>

\textsuperscript{a}Intervention group participants only.

Table 8. Proportion of participants completing A1c assessments at each study time point, overall and by intervention status (%, n)

<table>
<thead>
<tr>
<th>Intervention period</th>
<th>Overall (N=214)</th>
<th>Usual care (N=108)</th>
<th>Intervention (N=106)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 month (Baseline)</td>
<td>98% (210)</td>
<td>98% (106)</td>
<td>98% (104)</td>
</tr>
<tr>
<td>3 month</td>
<td>89% (191)</td>
<td>85% (92)</td>
<td>93% (99)</td>
</tr>
<tr>
<td>6 month</td>
<td>88% (188)</td>
<td>85% (92)</td>
<td>91% (96)</td>
</tr>
<tr>
<td>9 month</td>
<td>78% (166)</td>
<td>74% (80)</td>
<td>81% (86)</td>
</tr>
<tr>
<td>12 month</td>
<td>76% (163)</td>
<td>72% (78)</td>
<td>80% (85)</td>
</tr>
<tr>
<td>Post-intervention period</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 month</td>
<td>83% (177)</td>
<td>86% (93)</td>
<td>79% (84)</td>
</tr>
<tr>
<td>6 month</td>
<td>73% (157)</td>
<td>71% (77)</td>
<td>75% (80)</td>
</tr>
<tr>
<td>9 month</td>
<td>75% (160)</td>
<td>73% (79)</td>
<td>76% (81)</td>
</tr>
<tr>
<td>12 month</td>
<td>79% (170)</td>
<td>81% (87)</td>
<td>78% (83)</td>
</tr>
<tr>
<td>Total</td>
<td>82% (1582)</td>
<td>81% (784)</td>
<td>84% (798)</td>
</tr>
</tbody>
</table>

Our analyses demonstrated no significant overall intervention effect on trend in A1c, during the 12-month intervention period or within the year thereafter (Table 9). However, we found evidence of heterogeneity of treatment effect across site and age groups. We found intervention group teenagers (aged 13-16 years) at site 1 to have a significantly better A1c trajectory after the intervention was completed than teenagers who received usual care at that site (−0.059; 95% CI, −0.11 to −0.01).
Table 9. Adjusted regression coefficients (β) and p-values for treatment effect on A1c (N=214)a

<table>
<thead>
<tr>
<th></th>
<th>Intervention period</th>
<th>Post-intervention period</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>β (95%CI)</td>
<td>p-value</td>
</tr>
<tr>
<td>Overall</td>
<td>0.005 (-0.02, 0.03)</td>
<td>0.72</td>
</tr>
<tr>
<td>Youth (8-12 years)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Site 1 (n=53)</td>
<td>-0.006 (-0.05, 0.03)</td>
<td>0.78</td>
</tr>
<tr>
<td>Site 2 (n=42)</td>
<td>0.031 (-0.01, 0.08)</td>
<td>0.17</td>
</tr>
<tr>
<td>Teen (13-17 years)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Site 1 (n=48)</td>
<td>0.031 (-0.03, 0.09)</td>
<td>0.32</td>
</tr>
<tr>
<td>Site 2 (n=71)</td>
<td>-0.022 (-0.07, 0.03)</td>
<td>0.39</td>
</tr>
</tbody>
</table>

aTreatment effect is the mean difference in change in outcome per month between study arms. Adjustments were made for study stratification variables (age and site) and covariates that were imbalanced between study arms at baseline (insulin pump use and parent at enrollment is mother). The model included 1582 A1c observations.


Our analyses demonstrated no significant overall intervention effect on trend in QOL for the child during the 12-month intervention period or within the 9 months thereafter (Table 10). We found no significant heterogeneity in treatment effect across site and age groups.

Table 10. Adjusted regression coefficients (β) and p-values for treatment effect on child quality of life (N=214)a

<table>
<thead>
<tr>
<th></th>
<th>Intervention period</th>
<th>Post-intervention period</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>β (95%CI)</td>
<td>p-value</td>
</tr>
<tr>
<td>Overall</td>
<td>0.023 (-0.25, 0.30)</td>
<td>0.87</td>
</tr>
<tr>
<td>Youth (8-12 years)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Site 1 (n=53)</td>
<td>0.310 (-0.27, 0.89)</td>
<td>0.29</td>
</tr>
<tr>
<td>Site 2 (n=42)</td>
<td>0.060 (-0.55, 0.67)</td>
<td>0.85</td>
</tr>
<tr>
<td>Teen (13-17 years)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Site 1 (n=48)</td>
<td>0.272 (-0.28, 0.83)</td>
<td>0.33</td>
</tr>
<tr>
<td>Site 2 (n=71)</td>
<td>-0.446 (-0.90, 0.01)</td>
<td>0.06</td>
</tr>
</tbody>
</table>

aTreatment effect is the mean difference in change in outcome per month between study arms. Adjustments were made for study stratification variables (age and site) and covariates that were imbalanced between study arms at baseline (insulin pump use and parent at enrollment is mother). The model included 951 child quality of life measures.

Our analyses demonstrated no significant overall intervention effect on QOL for the parent during the 12-month intervention period or within the 9 months thereafter (Table 11). Parents of intervention group children aged 8-12 at one site had a significantly better QOL trajectory during the intervention period than parents of those who received usual care at this site (0.613; 95% CI, 0.05-1.17).

Table 11. Adjusted regression coefficients (β) and p-values for treatment effect on parent quality of life (N=214)*

<table>
<thead>
<tr>
<th></th>
<th>Intervention period</th>
<th>Post-intervention period</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>β (95%CI)</td>
<td>p-value</td>
</tr>
<tr>
<td>Overall</td>
<td>-0.037 (-0.31, 0.24)</td>
<td>0.79</td>
</tr>
<tr>
<td>Youth (8-12 years)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Site 1 (n=53)</td>
<td><strong>0.613 (0.05, 1.17)</strong></td>
<td><strong>0.03</strong></td>
</tr>
<tr>
<td>Site 2 (n=42)</td>
<td>-0.463 (-1.07, 0.14)</td>
<td>0.13</td>
</tr>
<tr>
<td>Teen (13-17 years)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Site 1 (n=48)</td>
<td>0.127 (-0.44, 0.69)</td>
<td>0.66</td>
</tr>
<tr>
<td>Site 2 (n=71)</td>
<td>-0.368 (-0.83, 0.09)</td>
<td>0.12</td>
</tr>
</tbody>
</table>

*Treatment effect is the mean difference in change in outcome per month between study arms. Adjustments were made for study stratification variables (age and site) and covariates that were imbalanced between study arms at baseline (insulin pump use and parent at enrollment is mother). The model included 922 parent quality of life measures.


Our analyses demonstrated no significant overall intervention effect on parental fear of hypoglycemia during the 12-month intervention period or within the 9 months thereafter (Table 12). We found no evidence of heterogeneity of treatment effect across site and age groups.
E.6. Sensitivity Analyses

We checked the models used to arrive at the results in Sections E.3 to E.6 for model fit and outliers via residual plots and by addition of nonlinear age and time trend. We identified no lack of fit. Similarly, addition of covariates did not change the results. Although missing data were relatively infrequent (> 85% of participants provided data on each of the primary outcomes at most of the data collection time points), we undertook an analysis of the influence of missing data on study results. We found that stratification and weighting by missingness patterns did not substantively change the effects seen in our models and did not alter the statistical significance of any model parameters, defined a priori as $p < 0.05$.

<table>
<thead>
<tr>
<th>Table 12. Adjusted regression coefficients ($\beta$) and $p$-values for treatment effect on fear of hypoglycemia (N=214)$^a$</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Overall</strong></td>
</tr>
<tr>
<td>$\beta$ ($95%$CI) $\quad$ p-value $\quad$ $\beta$ ($95%$CI) $\quad$ p-value</td>
</tr>
<tr>
<td>Intervention period $\quad$ Post-intervention period</td>
</tr>
<tr>
<td>0.134 (-0.12, 0.39) $\quad$ 0.30 $\quad$ -0.006 (-0.38, 0.37) $\quad$ 0.98</td>
</tr>
<tr>
<td><strong>Youth (8-12 years)</strong></td>
</tr>
<tr>
<td>Site 1 (n=53) $\quad$ 0.348 (-0.15, 0.85) $\quad$ 0.17 $\quad$ -0.023 (-0.77, 0.72) $\quad$ 0.95</td>
</tr>
<tr>
<td>Site 2 (n=42) $\quad$ 0.081 (-0.47, 0.63) $\quad$ 0.77 $\quad$ 0.288 (-0.60, 1.18) $\quad$ 0.52</td>
</tr>
<tr>
<td><strong>Teen (13-17 years)</strong></td>
</tr>
<tr>
<td>Site 1 (n=48) $\quad$ -0.185 (-0.74, 0.37) $\quad$ 0.51 $\quad$ 0.253 (-0.53, 1.03) $\quad$ 0.52</td>
</tr>
<tr>
<td>Site 2 (n=71) $\quad$ 0.202 (-0.25, 0.66) $\quad$ 0.38 $\quad$ -0.349 (-1.00, 0.30) $\quad$ 0.29</td>
</tr>
</tbody>
</table>

$^a$Treatment effect is the mean difference in change in outcome per month between study arms. Adjustments were made for study stratification variables (age and site) and covariates that were imbalanced between study arms at baseline (insulin pump use and parent at enrollment is mother). The model included 768 fear of hypoglycemia measures.
F. DISCUSSION

F.1. Context for the Study Results

Many behavioral interventions for children with T1D and their parents have demonstrated short-term improvements, but these interventions are not widely used in clinics or accessed by families. The content and delivery of these resources are often not tailored to family needs and preferences. We sought to understand whether tailoring interventions to families’ needs and preferences could improve outcomes among children with T1D and their parents. Within our study population of children aged 8-16 with T1D from 2 clinical centers in Wisconsin, our findings do not support treatment benefit for family-centered tailoring of self-management resources. However, we do see evidence of heterogeneity of the treatment effect between our study sites. Specifically, at one clinical site, teenagers who received the intervention had a significantly better A1c trend after the intervention was completed. At that same site, parents of youths aged 8-12 also demonstrated a significantly better trend in their QOL during the intervention.

An important finding from this work was the success of our approach for coordinating group-based self-management resources with routine diabetes clinic visits. Our process resulted in high rates of attendance at self-management resource sessions among families, with 69% attending 3 of the 4 group sessions. This suggests that the approach could be used with success to deliver self-management resources in clinical settings.

Although the types of interventions implemented in our study were efficacious in the idealized setting of clinical trials, we were unable to demonstrate overall effectiveness as implemented in our study. This lack of overall effectiveness might be due to various factors related to how the intervention was implemented to fit within the real-world clinical setting and the lives of families with T1D. For example, to increase the generalizability of our study findings, we also chose to include youths regardless of baseline A1c value. In other similar trials, youths with A1 values that are at goal or > 13% are often excluded. Thus, significant effects on A1c may be harder to demonstrate statistically. Also, we implemented the content of these efficacious interventions to fit within the four 90-minute group sessions and
delivered these sessions in coordination with routine clinic visits. Thus, rather than receive intervention content frequently (often weekly or every other week) our participants received content only once every 3 to 4 months. Early on, we explored whether “homework” to be completed between the group sessions could reinforce content during these larger intervals. However, we found that completion of the homework was not feasible for families.

F.2. Generalizability of the Findings

We conducted the trial at 2 clinical sites, which could limit the generalizability of findings. In addition, we excluded families that did not speak or read English, and we did not recruit families when parents believed their child might be uncomfortable participating in the trial’s group-based activities. Despite these factors, our participating families’ characteristics were similar to those of the US population of children with T1D.\textsuperscript{127,142}

F.3. Implementation of Study Results

Our study findings suggest that our processes for delivering self-management resources resulted in high levels of uptake and intervention completion among participating families. This process of demonstrating to families that the resource is designed to meet their specific needs (as determined on the brief PRISM survey) and coordinating delivery of the resource with other required visits to the clinic could be used widely to help ensure that families can actually access self-management help. Our project engaged clinic leadership and staff to allow this coordination to occur.

F.4. Subpopulation Considerations

As noted previously, our findings do suggest that specific subpopulations (eg, teenagers and parents of youths at 1 clinical site) may have benefited from family-centered tailoring of self-management resources. However, this effect was evidenced only for A1c and parent QOL and was not evidenced for study participants as a whole.

F.5. Study Limitations

While this trial has many strengths, there are some notable limitations. Limitations related to generalizability were described above. In addition, although we did not inform
providers of their patients’ participation, it is possible that families discussed it with providers. This could result in changes to the care provided. For example, providers might believe those receiving usual care need additional support, resulting in more visits with the clinic. However, we monitored the number and type of services provided to participants as reported by parents on our surveys and found no significant differences between intervention and usual care groups. Nonetheless, contamination of our usual care group could have occurred. To better understand our findings, we could have conducted qualitative interviews after the intervention ended. Also, the trial addressed only 4 of the 6 self-management barriers identified by PRISM. Finally, to reduce survey burden, we administered only 6 of the 8 subdomains of the Family Impact Module of the PedsQL. However, parents’ scores on this tool were similar to those previously reported, making it unlikely that this substantially affected our findings.

F.6. Future Research

The next logical step in this line of research is to understand why our intervention might have succeeded in improving outcomes in some subgroups of participants but not others. For example, it will be important to understand why 8 families of adolescents at site 2 did not attend a single intervention session. It is possible that this nonattendance is in part responsible for our findings of intervention effects for adolescents at one clinical site but not at the other. In addition, to address some of the limitations noted, future work could expand the evaluation of our intervention in additional settings and with other populations. Future work could also deliver existing interventions to address other known self-management barriers, such as peer or health care team interactions.
G. CONCLUSIONS

As evaluated in our trial with children aged 8-16 with T1D from 2 clinical centers in Wisconsin, family-centered tailoring of self-management resources did not improve $A_1c$ or the QOL of the child or parent. However, our findings suggest that family-centered tailoring of T1D self-management resources might have benefited specific subpopulations, such as teenagers and parents of youths at 1 of 2 clinical sites. In addition, our process for creating buy-in and coordinating self-management help with routine clinic visits resulted in high rate of uptake for the intervention. Dissemination of the information gained from this study could support health care organizations in effectively identifying and addressing self-management barriers, in T1D and perhaps even in other pediatric chronic diseases. Further, the success of our intervention delivery process is useful in considering how to most efficiently make use of existing but limited health care system resources to support self-management.

In addition, family-centered tailoring of T1D self-management resources might benefit specific populations. For example, the parents of youths with T1D at one site showed significant improvements in QOL, suggesting benefit of these tailored interventions specifically for parents of children aged 8-12. Also, teenagers might represent a second target group for implementing our intervention, given the improvements in $A_1c$ after they had completed the intervention. In fact, inspired by Project ACE, one of our study sites is implementing a group-based intervention for families living with T1D, in which PRISM is being considered as a key tool for identifying self-management barriers. However, we are mindful that these findings are site and age group specific, so they might not be reproducible.
H. REFERENCES


I. RELATED PUBLICATIONS


J. ACKNOWLEDGMENTS

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