Published in final edited form as:

Contemp Clin Trials. 2017 July ; 58: 58–65. doi:10.1016/j.cct.2017.04.007.

Design and Baseline Data from a PCORI-funded Randomized Controlled Trial of Family-Centered Tailoring of Diabetes Self-Management Resources

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Abstract

This article describes the methodology, recruitment, participant characteristics, and sustained, intensive stakeholder engagement for Project ACE (Achieving control, Connecting resources, Empowering families). Project ACE is a randomized controlled trial of children and youth ages 8–16 with type 1 diabetes evaluating the impact of tailored self-management resources on hemoglobin A1c (A1c) and quality of life (QOL). Despite strong evidence that controlling A1c reduces long-term complications, <25% of US youth with type 1 diabetes meet A1c targets. Many

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Declaration of conflicting interests

The authors declare that there is no conflict of interest.

Trial Registration Number: NCT02024750

Trial Registrar: Clinicaltrials.gov, <https://clinicaltrials.gov/ct2/show/NCT02024750>

interventions are efficacious in improving A1c and QOL for these youth, whose families often struggle with the substantial demands of the treatment regimen. However, most such interventions are ineffective in the real world due to lack of uptake by families and limited healthcare system resources. Project ACE is a multi-site trial designed to improve diabetes outcomes by tailoring existing, evidence-based interventions to meet families' needs and preferences. We hypothesize that this family-centered approach will result in better A1c and QOL than usual care. Project ACE has recruited and randomized 214 eligible 8–16 year old youth and their parents. The 9-month intervention consisted of 4 group sessions tailored to families' self-management barriers as identified by a validated instrument. Outcomes including A1c and QOL for parents and youth will be assessed for 1 year after the intervention. Stakeholder engagement was used to enhance this trial's recruitment, retention and integration into routine clinical care. Findings will inform implementation and dissemination of family-centered approaches to address self-management barriers.

Keywords

type 1 diabetes; patient-centered care; pediatrics; behavior therapy; self-care

Introduction

The Diabetes Control and Complications Trial (DCCT) and Epidemiology of Diabetes Interventions and Complications studies established associations between lower hemoglobin A1c (A1c) over time and reduced risk for developing complications of type 1 diabetes (T1D).^{1,2} A growing body of evidence supports the feasibility of attaining near normal blood glucose levels without significantly increasing the risk of severe hypoglycemia for youth with T1D.^{3–5} Unfortunately, despite the development of insulin analogs and advanced technologies for glucose monitoring and insulin delivery, less than 25% of US youth with T1D meet recommended A1c goals.^{6–8} This paradox illustrates the complexity of incorporating diabetes self-management successfully into daily living.

Youth with T1D often struggle to keep up with the substantial demands of diabetes self-management.^{9–13} 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.¹⁴ For youth with T1D, 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.^{12,15} 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.^{16,17}

Despite decades of research developing efficacious interventions to improve diabetes self-management, a host of challenges diminishes the effectiveness of these interventions in

practice.¹⁸ Many behavioral interventions for youth with T1D and their parents have demonstrated short-term improvements^{19–23} but are not widely used. Lack of healthcare system infrastructure (e.g., payment systems and incentives) and resources (e.g., trained personnel and time constraints), and inadequate buy-in from families limit the feasibility, effectiveness, and sustainability of such interventions. To overcome these challenges, interventions must be “patient-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 healthcare systems.^{24–26} Patient-centeredness is endorsed by the American Diabetes Association as a standard component of diabetes care.⁷

This article describes a Patient Centered Outcomes Research Institute (PCORI)-funded multi-site clinical trial, Project ACE (Achieving control, Connecting resources, Empowering families). The study 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 youth and parent quality of life (QOL) than usual care. We describe the methodology, recruitment, participant characteristics, and sustained, intensive stakeholder engagement that has guided the research, with attention to the future implications of these factors.

Methods

Study Design

Project ACE is a randomized parallel-group clinical trial consisting of a 9-month intervention period and 1 year of follow-up. This research compares the effectiveness of family-centered tailoring of diabetes self-management resources (intervention) to that of usual care, with regard to glycemic control and QOL among youth with T1D and their parents at two clinical sites. The family-centered intervention package includes: 1) identifying the family’s self-management barriers using a validated survey tool, the Problem Recognition in Illness Self-Management (PRISM),^{16,27} 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.

Recruitment and Eligibility Criteria

Youth aged 8–16 years were recruited from 2 large multidisciplinary diabetes clinics serving both urban and rural populations. The sites were chosen 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.²⁸ Children younger than 8 years were excluded because the content and group format of the intervention’s tailored self-management resources are not appropriate to their developmental stage. Individuals > 17 years old were excluded due to their likelihood of leaving the participating clinic for college or employment during the study.

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 same clinician and clinic during the study, 5) inability of the consenting parent to accompany their child to all visits during the study, 6) study appointments unavailable within four months of enrollment, and 7) no PRISM-identified barrier. To improve generalizability to the population broadly, we did not exclude youth based on A1c values.

Randomization and Group Session Assignment

Youth meeting the eligibility criteria and their parents were consented. Assent was obtained for youth 14 years and younger. Each parent and youth aged 13–16 years completed PRISM, a validated, 28-item, 10-minute tool for identifying self-management barriers among youth with diabetes and their parents, developed with input from families (available free at <https://www.hipxchange.org/PRISM>).^{16,27} PRISM identifies the 3 self-management barriers that were addressed in the study: 1) understanding and organizing care, 2) motivation, and 3) family interactions. Families for whom PRISM identified at least 1 self-management barrier were randomized by a computer program to intervention or usual care on a 1:1 ratio. If a child and their parent indicated different barriers, the child responses prevailed. Families who identified multiple barriers were scheduled for the next available group session that addressed 1 of their barriers. Randomization was stratified and implemented in variably-sized blocks to balance intervention versus usual care assignment by site and age group (8–12 years or 13–16 years). Upon completion of a participant's baseline measures, recruitment staff who were masked to subject allocation through the recruitment process would contact a research team member who consulted the randomization list and announced the participant's group assignment. Diabetes clinic providers and care team members were also not made aware of the family's enrollment and had no access to the families' PRISM scores.

Study Intervention

The study intervention consisted of using results from the child and parent's PRISM surveys to tailor the type of self-management resource to families' specific needs, and then delivering that group-based resource on the day of the child's routine diabetes clinic visit, either immediately before or after the clinic visit. Table 1 contains details about the intervention and its delivery using a standard reporting format.²⁹ Over a 9-month period, 4 group-based 75-minute self-management resource sessions were delivered. The group format was preferred by stakeholders and 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.

For each of the 3 barrier types, content experts delivered evidence-based self-management resources, beginning at the family's next clinic visit. Descriptions of the content for each of the 3 self-management resources are presented in Table 2. The full content and all materials for the group sessions will be published in a free toolkit at the project's conclusion.³⁰ 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 American Diabetes Association's education curriculum.³¹ *Motivation barriers* encompass challenges with readiness to self-manage, including beliefs about the costs and benefits of self-management, the importance of self-management, as well as positive and negative aspects of the self-management regimen.^{20,32} 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.³³ Barriers related to *family interactions* reflect the challenges of balancing youth 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.^{21,34,35}

The group session content was delivered according to protocol for each group type. Our study featured stringent protocol monitoring in response to treatment fidelity issues common among similar intervention studies.^{36–38} Fidelity was assessed from audio-recorded group sessions by trained personnel. 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

Individuals randomized to usual care continued to attend clinic visits with their diabetes clinician every 3 months. These visits are typically about 30–60 minutes in length and conducted by either nurse practitioners or pediatric endocrinologists. Visits typically include review and discussion of recent A1c and blood glucose data, a physical exam, adjustment of the insulin regimen, discussion of management challenges, and planning for diabetes management for upcoming events such as camp or school changes. Multidisciplinary teams of certified diabetes educators, dietitians, 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. Reminders about upcoming clinic appointments did not differ from those of intervention participants in number and timing.

Outcomes and Other Measures

The primary objective of the study is a between-group comparison of the youth's A1c as well as QOL for both parent and youth, over time (Table 3). We collected A1c data from routine diabetes clinic visits at 9 time points (quarterly during the trial and post-trial year) while QOL data was collected 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. Youth QOL was measured by the total scale score for the diabetes-specific PedsQL, and supplemented by published items assessing school, work, and play activities.^{39,40} Parent QOL was measured

by 6 relevant subscales from the PedsQL Family Impact Module (Emotional Functioning, Social Functioning, Communication, Worry, Daily Activities, and Family Relationships).⁴¹

Secondary outcomes included intervention effects on: percentage of patients meeting A1c target, PRISM barrier scores,^{16,27} and three other survey-based measures, including worry about hypoglycemia (15-item worry subscale of the Hypoglycemia Fear Scale^{42,43}), diabetes management self-efficacy beliefs (12 items adapted for adolescents from the Confidence in Diabetes Self-Care scale⁴⁴), and self-management behaviors (14 items of the Self Care Inventory⁴⁵). All survey measures have been previously validated and found to have acceptable psychometric properties.

In addition, at enrollment and twice during the study period, surveys assessed covariates such as participant characteristics and disease or regimen factors that have known or hypothesized relationships to glycemic control, self-management barriers, or QOL^{46–55}. 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). The surveyed comorbid conditions were selected 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 (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 software 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 at 1 week before the due date if still not completed. Participants could also request paper surveys to be mailed to them in lieu of electronic surveys. Participants with incomplete surveys were given an iPad or paper survey at their next clinic or study visit.

A1c Laboratory Methods

Both clinics used DCA Vantage® analyzer (Siemens Healthcare Global) point-of-care devices to measure A1c. 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.⁵⁶ Data for these equations arose from determining point-of-care A1c values from each clinic machine for 87 de-identified 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.⁵⁷

Statistical Methods

This study was powered to evaluate effects on glycemic control and QOL, with a 2-tailed $\alpha=0.05$. We wished to estimate the sample size for detecting minimal clinically important differences of 0.5% in A1c and 3 points in QOL with 80% power across 5 observation times. Our approach was based 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 re-analysis of available outcome data for similar age and diabetes duration.⁵⁸ These approaches yielded sample size estimates around 100 patients per group.

All analyses will compare 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 will be mixed effects models with repeated measures that capture the time trend via linear, polynomial or spline terms. Trajectories will be fit for youth's A1c and for QOL for youth and parents. Outcomes will be modeled as continuous, with normally distributed residuals, and within-individual random intercepts and slopes to capture within-individual correlation. Models assuming equal variance of these components in both group will be compared with those allowing unequal variances via likelihood ratio tests, and the addition of a random effect for intervention group will be similarly tested. Distributional assumptions will be checked, and transformations and/or robust alternatives will be applied when needed. The primary hypothesis is that trajectories differ between the intervention and usual care arms. This will be tested via interaction effects between treatment group and time trend. Fixed effects will be included in the models for the stratification variables clinic site and age group, and their interactions with time trend tested. A limited set of additional variables will be included in the model to correct for imbalance between usual care and intervention arms. Potential covariates include baseline demographics, healthcare utilization, comorbidities, and insulin regimen (e.g., pump or injection). The influence of missing data will be evaluated primarily via pattern mixture models,^{59,60} which are specially tailored for mixed effects models with informative missingness.

Stakeholder Engagement

Two methods of stakeholder engagement helped to ensure that both the study processes and our intervention could be integrated into routine clinic workflows. First, semi-structured interviews with clinicians, clinic leadership, clinic schedulers and medical assistants, as well as patients' families elicited potential challenges and solutions related to study procedures and implementation of the intervention (Table 4). These interviews were deductively analyzed using 2 frameworks for implementing new ways of delivering healthcare.^{61,62}

Second, stakeholder advisory boards supported sustained engagement throughout the project (Figure 1). Through mailings and flyers distributed by clinicians, we recruited parents, youth 8–12 years old, and teenagers 13–17 years old from each clinical site for separate parent, youth, and teen boards. Families serving on the advisory boards were excluded from study participation. In addition, an external advisory board blended a subset of family advisors with clinicians and administrators from both sites, as well as representatives from community diabetes advocacy groups. All advisory boards met 3 times annually throughout the study, guiding successful study implementation and eventually interpreting findings and facilitating dissemination. Table 5 contains examples of the solutions our stakeholders generated to some of the study's challenges with recruitment, retention, and integration into the clinic. Advisors receive \$100 for their participation in each 2-hour board meeting. Two toolkits detailing stakeholder engagement processes and best practices from this research are free and publicly available.^{63,64}

Recruitment

Recruitment began in September 2014 and was completed in May 2015. A total of 214 youth were recruited and randomized. Intervention delivery concluded in summer 2016, with data collection anticipated to be complete by summer 2017. Figure 2 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, such as the medical assistant who typically collects vital signs and places patients in exam rooms, 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 (e.g., no appointment with study provider available). 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 because an intervention group and coordinated clinic visit appointment were not available in a timely manner. Ultimately, 108 families were randomized to usual care and 106 to receive the intervention.

Table 6 provides the demographics and diabetes-related characteristics for participating families. Randomization achieved balance on all but 2 characteristics. Compared to the usual care group, the intervention group has significantly fewer mothers completing the survey at enrollment and more youth using insulin pumps.

Discussion

Project ACE aims to evaluate effects on A1c and QOL that may result from addressing common barriers to self-management for youth with T1D and their families in a family-centered manner. The study is novel in its approach of delivering an intervention tailored to families' specific self-management needs, as assessed by a validated tool. The trial has leveraged intensive stakeholder engagement to achieve high rates of recruitment and to recruit families representative of groups who traditionally experience disparities in diabetes control.⁶⁵ Analyses of baseline participant characteristics suggest the target population was well-represented, which should support the generalizability of study findings.

Randomization has balanced the intervention and usual care groups across nearly all baseline characteristics. Lastly, attention to intervention fidelity and documentation of study processes will allow others to replicate our findings and understand the contextual differences important to future dissemination.

In our study, stakeholders have played a key role in designing the intervention and in adapting study processes to support successful recruitment and intervention delivery within the clinical setting.⁶⁶ Through this process of stakeholder engagement via our advisory boards and in-person interviews, we gained buy-in and approval from families and healthcare team members whose support was critical to the project's success. As a result, we have experienced high rates of recruitment, even among populations that may typically be thought of as hard to reach for research participation. This is crucially important because minority families and those with less educational achievement struggle more with self-

management and thus are in need of interventions that can assist them toward better glycemic control and QOL.⁶⁵ Our stakeholders provided input that helped our study appeal to these hard-to-reach families, and they spoke in favor of in-person recruitment in clinics rather than relying on flyers or mailed invitations.^{66,67} As a result, minority families were enrolled in numbers proportionate to our sites' population demographics and as good as or better than similar recently published trials.^{22,23,68,69} Parents with a high school education or less were also well represented in our sample. In addition, the vast majority of participant exclusions did not arise from characteristics of the participants themselves, but from study logistics such as not having space available in a group whose first session occurred at the same time as the child's next clinic visit and also would address the family's specific self-management barrier. Thus, findings should generalize well to the target population.

To further increase the generalizability of our study findings, we also chose to include youth regardless of baseline A1c value. In other similar trials, youth with A1c values that are at goal or >13% are often excluded.^{21,23,70–72} Among our study participants, 17% met the ADA-recommended target of A1c <7.5 at baseline, which is comparable to the T1D exchange registry cohort.⁸ While effects on A1c may be harder to demonstrate statistically when youth begin the study with near target A1c values, our intervention also addresses QOL for these youth and their parents. Although fewer studies address QOL and the QOL measures used differ, baseline diabetes-specific QOL among youth in our study is comparable to that in another similar trial⁷² and slightly lower than that of the T1D population.⁷³ Baseline parent scores from the Family Impact Module were also similar to those of parents with chronically ill children.^{41,74,75} Further, since our study models the trajectory of A1c values over time, we may be able to detect attenuation of the expected rise in A1c values through adolescence for those who entered the trial with controlled A1cs.

Recruitment was also likely enhanced by our decision to use the point of care machines to assess the study outcome, A1c. In general, patients prefer the finger poke needed for point of care A1c testing to the venous blood draw required to have the A1c performed in the hospital or clinic laboratory. However, in the field of T1D research, the standard practice is to obtain A1c values either by sending samples directly to the DCCT core lab or to a laboratory whose processes are certified by the National Glycohemoglobin Standardization Program. To produce DCCT-standardized values, we created equations that allowed us to convert a given point of care machine's result to a DCCT-standardized result. While this required some investment of resources to test known blood samples on several point of care machines, the point of care assessment was preferable to the participants, in line with current clinic processes, and eliminated study expenses associated with obtaining DCCT-certified laboratory evaluation. Ultimately, we expect this decision will also yield high levels of participant retention and data completeness because the collection of this study outcome occurs routinely at clinic visits for most youth with T1D.

In general, our study arms are balanced with regard to the primary trial outcomes as well as many other factors. However, youth in our intervention group were significantly more likely to use an insulin pump and less likely to have their mother as the enrolling parent. For very large sample sizes, randomization to study groups ensures that both measured and unmeasured baseline covariates will be balanced in the long run. In studies with small

sample sizes such as ours, imbalances between groups can occur by chance, despite randomization. Randomization in our trial was stratified by study site and age group, and blocked to maintain a 1:1 ratio within strata. For both logistical and statistical reasons, we followed long-standing advice not to stratify on additional baseline variables.⁷⁶ Further, detection of potential imbalances is more likely when many baseline characteristics are collected and tabulated, as is the case in our study. To address potential imbalances, models assessing the intervention's impact will include adjustments for covariates, such as insulin pump use. Prior research has shown that this type of adjustment at the analysis stage achieves very nearly the same purpose as stratified randomization.⁷⁷ Adjustment variables will be judiciously chosen, however, and limited to those identified a priori as influential on outcomes.⁷⁸ Lastly, the statistical significance of potential imbalances at recruitment should be considered only to identify problems in the randomization process^{78,79} and not to choose variables for inclusion in adjusted analyses. A careful review of our randomization procedures did not reveal any problems or explanations beyond chance occurrence of these potential imbalances.

While this trial has many strengths, there are some notable limitations. First, the trial is being conducted at 2 clinical sites, which could limit the generalizability of findings. In addition, we excluded families who did not speak or read English. We also did not recruit families when parents believed their child might be uncomfortable participating in the trial's group-based activities. Despite these factors, the characteristics of our participating families were similar to those of the US population of children with T1D.^{74,80} Future work could expand the evaluation of our intervention in additional settings and with other populations. Second, the trial addresses only 3 of the 5 self-management barriers identified by PRISM. Future work could deliver existing interventions to address other known self-management barriers such as peer or healthcare team interactions.^{16,20,81,82} Third, although we did not inform providers of their patients' participation, it is possible that families discussed this 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. To address this, we are monitoring the number and type of services provided to participants. Lastly, 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, so it is unlikely that this will substantially impact our findings.^{41,74,75,83}

Conclusion

In summary, despite decades of evidence for the efficacy of resources that help youth with T1D and their families achieve optimal blood glucose control and enhance their QOL, the consistent, effective delivery of these resources has been hindered. When completed, Project ACE will provide a base of knowledge on which to implement and disseminate family-centered approaches to address self-management barriers, not only in pediatric diabetes but also for other chronic diseases. To maximize the usefulness of the research, the trial is being implemented with attention to rigorous study design and execution. Further, the input of our highly engaged stakeholders has supported the study's development and evaluation of an intervention that is feasible to implement and disseminate in real-world health care systems.

Acknowledgments

The authors gratefully acknowledge the generosity of the families who participated and all the stakeholders who have supported the study.

Funding

Research reported in this article was funded through a Patient-Centered Outcomes Research Institute (PCORI) Award (#IH-1304–6279). The views in this article are solely the responsibility of the authors and do not necessarily represent the views of the Patient-Centered Outcomes Research Institute (PCORI), its Board of Governors or Methodology Committee.

The project described received additional funding by the Clinical and Translational Science Award (CTSA) program, through the National Institutes of Health National Center for Advancing Translational Sciences (NCATS), grant UL1TR000427. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health

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Figure 1.
Project ACE stakeholder advisory boards

Figure 2.
Project ACE CONSORT diagram

Table 1

Project ACE intervention description

Element	Description
Content delivery	Interactive group sessions and homework assignments to support practice between sessions
Exposure quantity and duration	4 sessions of 75 minutes, before or after routine diabetes visit
Time span	1 session every 3 months for a total of 9 months
Unit of delivery	Groups of 2–6 child/parent dyads
Deliverer	Healthcare professionals including social workers, nurses, psychologists and diabetes educators
Setting	At the healthcare facilities where participants receive their routine diabetes care
Activities to increase compliance or adherence (e.g. incentives)	\$20 gift card remuneration and snack or meal at group session
Supervision	All sessions were audio-recorded and assessed for fidelity. All facilitators received standard materials (guides and handouts) and participated in initial training as well as facilitator meetings to share ideas, address concerns and review fidelity data, either in person or via videoconferencing.

Table 2

Summary of group session content by session type

Tips and Tools		Your Diabetes, Your Choices		Family Teamwork	
PRISM barrier addressed					
Understanding and Organizing Care		Motivation		Family Interactions	
Session content					
<ul style="list-style-type: none">• Recognize and respond to high and low blood sugars• Understand how and when blood sugar is affected by various types of insulin or by exercise• Use tools like blood sugar logs, carb counting, and the plate method of counting, and the plate method of healthy eating to inform management decisions• Gain awareness of positive outcomes of optimal diabetes management now and for future transitions like driving, college, or dating	<ul style="list-style-type: none">• Enhance youth and parent perceptions of importance of diabetes management• Build youth and parent confidence in their diabetes management• Develop skills to support motivation (e.g., listening, affirming, and recognizing discrepancies between current and desired diabetes control)• Plan how youth and parent will maintain motivation to manage diabetes after the intervention ends and as the youth matures	<ul style="list-style-type: none">• Build knowledge and skills for effective problem-solving• Restructure strong beliefs about diabetes management• Develop skills to support open, direct talk about diabetes management and minimize miscarried helping• Develop a shared understanding about living with diabetes, using a 5-day diabetes simulation exercise for parents			

Table 3

Project ACE data collection elements

Data Element	Baseline	Session A	Session B	Session C	Session D	Post-Intervention				
	(0 mo)	(3 mo)	(6 mo)	(9 mo)	(12 mo)	(3 mo)	(6 mo)	(9 mo)	(12 mo)	
Alc	X	X	X	X	X	X	X	X	X	X
QOL										
Parent	X		X			X	X	X		X
Child	X		X			X	X	X		X
PRISM barrier scores	X		X			X	X	X		X
Other survey-based measures	X		X			X				
Covariates										
Family characteristic	X					X				X
Disease and regimen factors	X		X			X				X

Table 4

Stakeholders participating in interviews

Role	N
Parent/guardian of child with type 1 diabetes	20
Scheduler	6
Physician	5
Nurse	5
Medical Assistant	3
Nurse Practitioner	2
Clinic Manager	1
Social Worker	1

Table 5

Stakeholders' solutions to study challenges

Challenge	Solution
<i>Recruitment</i>	
Disappointment when randomized to control group Missing school for study activities could hinder life plans like employment or college	Explain that randomization is done by computer; research and clinic staff do not control assignment Design resume entry describing study participation and intervention materials teachers can consider for academic credit
<i>Retention</i>	
Participants may get lost if group sessions are not in usual clinic area Keeping youth and parents engaged over time	Coordinate with clinic welcome desk to direct families to group sessions Frequently update preferred contact method for study reminders
<i>Integration into clinic flow</i>	
iPads used to collect study surveys may distract families from provider visit Coordinating clinic appointment with group session is cumbersome and slow	Add a note on the iPad to remind families to close the iPad when provider is present Coordinate with clinic to reserve appointments coordinated with the group sessions for participants

Table 6

Participant characteristics *

	Overall (n=214)	Usual Care (n=108)	Intervention (n=106)
Child characteristics			
Age, years			
8–12	44.4% (95)	44.4% (48)	44.3% (47)
13–16	55.6% (119)	55.6% (60)	55.7% (59)
Girl	49.1% (105)	54.6% (59)	43.4% (46)
Non-Hispanic, White	83.6% (179)	85.2% (92)	82.1% (87)
In good to excellent health	92.5% (198)	95.4% (103)	89.6% (95)
Diabetes duration, years (mean (sd))	5.4 (3.3)	5.5 (3.5)	5.3 (3.1)
Insulin pump use	49.5% (106)	42.6% (46)	56.6% (60)
A1c < 7.5%	16.8% (36)	15.7% (17)	17.9% (19)
A1c at recruitment (mean (sd))	8.9% (1.7)	9.1% (1.8)	8.8% (1.6)
A1c at intervention start (mean (sd))	8.9% (1.7)	9.0% (1.8)	8.9% (1.7)
QOL (mean (sd))			
8–12 year olds	66.4 (12.6)	65.9 (10.9)	67.0 (14.1)
13–16 year olds	66.2 (12.8)	66.0 (12.1)	66.5 (13.6)
Parent characteristics			
Age, years (mean (sd))	41.8 (6.2)	42.0 (5.8)	41.7 (6.6)
Mother	84.6% (181)	89.8% (97)	79.3% (84)
Non-Hispanic, White	87.9% (188)	90.7% (98)	84.9% (90)
Education			
High school graduate or less	18.2% (39)	13.9% (15)	22.6% (24)
Some college	35.5% (76)	39.8% (43)	31.1% (33)
Bachelor's degree or more	46.3% (99)	46.3% (50)	46.2% (49)
QOL (mean (sd))	61.2 (15.8)	60.4 (16.5)	62.1 (15.1)

* Values may not add to 100% due to rounding or non-response. Bolded values indicate significant differences between trial arms.