

Impact of family-centered tailoring of pediatric diabetes self-management resources

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Abstract

Background: The American Diabetes Association recommends a family-centered approach that addresses each family's specific type 1 diabetes self-management barriers.

Objective: To assess an intervention that tailored delivery of self-management resources to families' specific self-management barriers.

Subjects: At two sites, 214 children 8-16 years old with type 1 diabetes and their parent(s) were randomized to receive tailored self-management resources (intervention, $n = 106$) or usual care ($n = 108$).

Methods: Our intervention (1) identified families' self-management barriers with a validated survey, (2) tailored self-management resources to identified barriers, and (3) delivered the resources as four group sessions coordinated with diabetes visits. Mixed effects models with repeated measures were fit to A1c as well as parent and child QOL during the intervention and 1 year thereafter.

Results: Participants were 44% youth (8-12 years) and 56% teens (13-16 years). No intervention effect on A1c or QOL was shown, combining data from sites and age groups. Analyzing results by site and age group, post-intervention A1c for teens at one site declined by 0.06 more per month for intervention teens compared to usual care ($P < 0.05$). In this group, post-intervention A1c declined significantly when baseline A1c was >8.5 (-0.08 , $P < 0.05$), with an even larger decline when baseline A1c was >10 (-0.19 , $P < 0.05$). In addition, for these teens, the significant improvements in A1c resulted from addressing barriers related to motivation to self-manage. Also at this site, mean QOL increased by 0.61 points per month more during the intervention for parents of intervention youth than for usual care youth ($P < 0.05$).

Conclusions: Tailored self-management resources may improve outcomes among specific populations, suggesting the need to consider families' self-management barriers and patient characteristics before implementing self-management resources.

KEYWORDS

type 1 diabetes, patient-centered care, behavioral therapy, self-care, quality of life

1 | INTRODUCTION

Behavioral interventions to improve self-management, glycemic control, or quality of life (QOL) for children with type 1 diabetes have small to moderate positive effects,¹⁻⁵ but a host of challenges diminishes their effectiveness in practice.⁶ As a result, the impact of these interventions on the health and well-being of children with type 1 diabetes does not reach its potential. In fact, less than 20% of the US children with type 1 diabetes between the ages of 6-17 years meet recommended hemoglobin A1c (A1c) goals.⁷ Most behavioral interventions in type 1 diabetes were developed and evaluated within the ideal conditions of clinical trials, often resulting in interventions that are difficult to implement and sustain in real-world clinical settings. Lack of healthcare system infrastructure and resources (eg, payment systems, trained personnel, and time constraints), as well as inadequate buy-in coupled with increased burden for families (eg, extra visits and missed school or work) have limited the feasibility, effectiveness, and sustainability of the interventions.^{1,2,5,6} Among families for whom self-management is already problematic, completing lengthy, intensive interventions may not be feasible or acceptable.^{8,9}

Most approaches to improving self-management behaviors rely on either lifestyle interventions or education, which may be combined with support. Meta-analyses of behavioral interventions to improve self-management, glycemic control, or quality of life have shown small to moderate effects.¹⁻⁵ For example, motivational interviewing can significantly reduce A1c (by 0.5-1.5%) and improve QOL.^{10,11} The largest effects are often achieved by multi-modal interventions that may incorporate behavioral and educational strategies as well as family therapy or social support.^{1,2} However, these approaches are often resource intensive.¹ For example, in one trial, Behavioral Family Systems Therapy for Diabetes was delivered as 12 sessions over a 6-month period.¹² Among families for whom adherence is already challenging, it may not be feasible to complete lengthy, intensive interventions, especially when not coordinated with routine diabetes visits.^{8,9}

To be most effective and sustainable, diabetes care should be "patient-centered."¹³ Patient-centered care addresses and is delivered in a manner that meets patients' and families' needs and preferences.¹⁴ For children with type 1 diabetes and their parents, these needs revolve around barriers to self-management that are associated with worse glycemic control and quality of life.^{15,16} Common self-management challenges faced by individual families such as difficult family interactions, lack of motivation, and limited ability to understand or organize diabetes care can be efficiently identified with the Problem Recognition in Illness Self-Management (PRISM) survey tool. The challenges identified by PRISM can then guide the selection among efficacious self-management resources that are routinely available within multidisciplinary pediatric diabetes clinics, such as diabetes education or psychological support.¹⁻³ This study evaluates the hypothesis that delivering self-management resources in a family-centered manner, using PRISM to guide resource selection, will result in better glycemic control and quality of life for children and their parents.

2 | METHODS

2.1 | Study overview

The design and methods of this trial have been published in detail elsewhere.¹⁷ In brief, a randomized parallel arm clinical trial was conducted at two clinical sites, with a 12-month intervention period and 1 year of follow-up in the post-intervention period. The trial compared the effectiveness of family-centered tailoring of diabetes self-management resources (intervention) to that of usual care. Primary outcomes were glycemic control and QOL for children and their parents. The family-centered intervention included: (1) identifying the family's self-management barriers using a validated survey tool, Problem Recognition in Illness Self-Management (PRISM);^{15,18} (2) use of PRISM results to tailor self-management resources to the family's self-identified needs; and (3) delivery of the tailored resources in group sessions coordinated with routine diabetes clinic visits.

2.2 | Participants

Children aged 8-16 years were recruited from two large multidisciplinary diabetes clinics serving diverse urban and rural populations. Other eligibility criteria were (1) type 1 diabetes for at least 1 year, (2) English fluency, and (3) ability to provide consent/assent. Exclusion criteria were (1) parent survey response indicating that the child had a cognitive or mental health issue that might limit potential to benefit from group-based activities, (2) known hemoglobinopathy or medical condition that might affect A1c accuracy, (3) current participation in a diabetes intervention study or the pilot for this trial, (4) inability to continue care with the same clinician during the study, (5) inability of the consenting parent/guardian to accompany their child to all visits during the study, (6) study appointments unavailable within 4 months of enrollment date, and (7) no self-management barrier identified with PRISM. To improve generalizability, baseline A1c values were not used to determine eligibility.

Teens ages 13-16 years and their parents completed PRISM to identify their self-management barriers. For youth (ages 8-12 years), only the parent completed PRISM. PRISM assessed the three self-management barriers addressed in the study: (1) understanding and organizing care, (2) motivation, and (3) family interactions.^{15,18} Families for whom PRISM identified at least one self-management barrier were block randomized (by site and age group) to intervention or usual care on a 1:1 ratio using a computer program. Diabetes providers were not notified of the family's enrollment and had no access to the PRISM scores.

2.3 | Intervention and usual care (control)

The study intervention consisted of using results from the PRISM surveys to determine the type of self-management resource assigned to address one of three specific barriers (Motivation, Understanding and Organizing Care, and Family Interactions) identified by each family. Families who identified only one self-management barrier were scheduled for the next available group session that addressed that specific barrier. Families who

identified multiple barriers were scheduled for the next available group session that addressed one of their barriers. If the teen and parent indicated different barriers, the teen's responses received priority. Trained professional facilitators delivered the resource content on the day of the child's routine diabetes clinic visit, either immediately before or after the clinic visit. Over a 9-month period, each intervention arm family received usual care and was offered four 75-minute self-management resource sessions. Sessions were delivered in an interactive, small-group format (two to six parent-child dyads). Participants stayed within the same small group throughout the intervention. Families received reminder calls 3 weeks and 1 week before each clinic appointment/coordinated group session.

All facilitators received standard materials 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. The full group session content and all materials have been published in a free toolkit (available at <https://www.hipxchange.org/T1DSMART>).¹⁹ In brief, barriers related to *understanding and organizing care* included 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 "Tips and Tools" groups that addressed this barrier, using content derived from the American Diabetes Association's education curriculum.²⁰ *Motivation* barriers encompassed 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.²¹ Certified members of the Motivational Interviewing Network of Trainees facilitated the "Your Diabetes, Your Choices" groups that addressed this barrier, using content based on the tenets of motivational interviewing.^{10,11,22} Barriers related to *family interactions* reflected the challenges of balancing child autonomy with the role of family support and supervision. Pediatric health psychologists facilitated the "Family Teamwork" groups that addressed this barrier using content that followed a Behavioral Family Systems Therapy approach.^{12,23,24} Session fidelity was assessed by trained personnel from audio recordings of 58 of 123 group sessions using content checklists (for the Tips and Tools and Family Teamwork groups) or the Motivational Interviewing Treatment Integrity Coding Manual (MITI4, for the Your Diabetes, Your Choices groups).²⁵ These assessments were reported as percentage of items completed.

Families randomized to usual care continued to attend clinic visits with their multi-disciplinary diabetes care teams every 3 months. 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. Clinic appointments reminders were the same as for intervention participants in number and timing.

2.4 | Study outcomes and data collection

Point of care A1c data were obtained from medical records at nine time points (at baseline and then quarterly during the intervention

(3, 6, 9, and 12 months) and during the post-intervention period (15, 18, 21, and 24 months) and standardized to DCCT-equivalent values.¹⁷ QOL data were collected at five time points: at baseline, at 3 months after the first intervention session, and at 3, 6, and 9 months post-intervention. Child QOL was measured by the total scale score for the diabetes-specific PedsQL.²⁶ This measure consists of 33 items on a five-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, with higher scores indicating better QOL. This measure has shown very good internal consistency reliability (Cronbach's alpha 0.87-0.88).²⁶ Parent QOL was measured with the standard linear transformation and averaging of item responses from six subscales of the PedsQL Family Impact Module (Emotional Functioning, Social Functioning, Communication, Worry, Daily Activities, and Family Relationships).²⁷ The Family Impact Module consists of 25 items on a five-point Likert scale. Possible scores range from 0 to 100 with higher scores indicating better QOL. In previous studies, the six subscales have shown good to excellent internal consistency reliability (Cronbach's alpha 0.79-0.97).^{17,27-29}

In addition, enrollment surveys assessed participant characteristics and disease or regimen factors that have known or hypothesized relationships to glycemic control, self-management barriers, or QOL.³⁰⁻³⁹ Participant characteristics included parent/child age (continuous) and gender, race/ethnicity (standard categories, aggregated as white, non-Hispanic vs all other), the child's health status, child's comorbid conditions, and parent's education (12th grade or less, high school graduate, some college, bachelor's degree, graduate, or professional degree). Disease and regimen factors included years since diagnosis and device use (eg, insulin pumps, continuous glucose monitors, or combinations of these functions).

2.5 | Analyses

Primary analyses compared outcomes between intervention and usual care arms as defined by the intention-to-treat principle. Trajectories were fit for A1c, and for QOL for children and parents, using mixed effects models with within-person correlation from repeated measures captured by individual random intercepts and slopes. The effect of intervention in these models is captured by the coefficients of intervention by time trend interaction, which represents the difference in the trajectory of the outcome per month between the two study arms. In overall analyses, fixed effects were included in the models to represent randomization strata (eg, clinic site and age group), and their interactions with time trend were tested. A limited set of additional variables were included in the model to correct for imbalance between usual care and intervention arms. Addition of covariates (eg, baseline demographics, healthcare utilization, and comorbidities) to improve precision did not substantively change study findings; therefore, we present results without additional covariate adjustment. This study was powered to detect minimally clinically significant intervention effects on glycemic control and QOL, with a two-tailed alpha = 0.05. Detailed power calculations are published elsewhere.¹⁷ The same

models were fit within each of the four randomization strata as planned a priori and within baseline A1c ($\leq 8.5\%$, $>8.5\text{--}10\%$ or $<10\%$). Significant results in the A1c trend analyses were confirmed with cross-sectional analyses, for which we report mean A1c values. Furthermore, pattern mixture models, used to evaluate any influence of missing data, did neither result in any substantive changes in the effects seen nor alter the statistical significance of any model parameters. Lastly, to further explain any significant site and age group differences in treatment effect, a post hoc analysis of the impact of each of the three types of tailored intervention content (eg, Tips and Tools; Your Diabetes, Your Choices; or Family Teamwork) was undertaken when intervention and usual care arms had at least 10 participants.

3 | RESULTS

3.1 | Recruitment and retention

Our published protocol provides details of recruitment and participant flow, including a CONSORT diagram.¹⁷ A total of 214 families were recruited and randomized, 108 to usual care, and 106 to the intervention. More youth were enrolled at Site 1 than at Site 2 (52 vs 42, $P < 0.05$); and significantly fewer teens enrolled at Site 1 than at Site 2 (48 vs 71, $P < 0.05$). Significantly more families at Site 2 were excluded based on study criteria than at Site 1 (84% vs 65%, $P < 0.01$), but reasons for exclusion were similar at the two sites. Three families withdrew during the study, two in the intervention arm and one in usual care. No families were lost to follow-up, defined as not contributing study data after the baseline enrollment.

As reported in detail elsewhere, the clinical sites and participant genders and age groups were equally represented in the study.¹⁷ The mean A1c at recruitment was 9.1%, and less than 15% of A1c values met the American Diabetes Association's target of $<7.5\%$. Parents who enrolled tended to be white, non-Hispanic mothers with varying levels of education. The most commonly identified self-management barrier was motivation. Randomization achieved balance on all but two characteristics. Compared to the usual care arm, the intervention arm had significantly fewer mothers enrolled and more participants using insulin pumps. Of note, the study arms were balanced at baseline with regard to each of the three study outcome measures.

Between the study sites, participant demographics and diabetes-related characteristics did not differ significantly, with three exceptions. Site 2 had significantly fewer non-Hispanic, white participants (76% vs 93%, $P < 0.01$) and fewer participants using pumps (44% vs 59%, $P < 0.05$), than Site 1. Although the mean baseline A1c was not significantly different between the sites, Site 2 had significantly more participants with A1c $<7.5\%$ than Site 1 (20% vs 7%, $P < 0.01$). This site-based difference was driven largely by teens, as Site 2 had significantly more teens (ages 13–16) with A1c $<7.5\%$, than Site 1 (23% vs 4%, $P < 0.01$). Examining A1c by site, within age groups, and by study arm, we find that among teens receiving usual care, Site 2 had

significantly more participants with A1c $<7.5\%$ than Site 1 (29% vs 4%, $P < 0.05$), whereas intervention arms from the two sites were similar (Table 1).

3.2 | Group session fidelity and attendance

Overall, the group sessions had high fidelity (mean 93%), with nearly half of sessions examined having a fidelity score of 100%. Fidelity did not differ significantly by site (92% vs 94%, $P = 0.28$), but differed by age group, with higher fidelity in the teen groups than in youth (95% vs 89%, $P < 0.01$).

The vast majority of families (82%) attended at least half of the group sessions (69% attended three of the four and 47% attended all four sessions). Attendance did not differ significantly by site. Among youth participants, only four families (two at each site) did not attend even a single intervention session. Among teen participants, eight families did not attend any intervention session, and all eight of these were at Site 2. These eight teens were similar to other intervention teens at this site ($n = 28$) in their baseline A1c, use of insulin pumps, time needed to travel to the diabetes clinic, and gender of parent who consented and agreed to attend the intervention group session, as well as the barriers they experienced. However, parental educational attainment was significantly lower among these eight non-attenders than for other intervention teens at this site.

3.3 | Impact of the intervention on A1c

Combining data from sites and age groups, we found no significant overall intervention effect on A1c trajectory, neither during the intervention (0.01, 95% CI -0.02 to 0.03) nor post-intervention (-0.01 , 95% CI -0.03 to 0.01) periods. However, intervention arm teens (ages 13–16 years) at Site 1 had a significantly better A1c trajectory post-intervention (mean A1c declined by 0.02 per month) than teens receiving usual care (mean A1c rose by 0.04 per month; Figure 1). Taken together, for intervention arm teens at Site 1, mean A1c trajectory was 0.06 lower per month than teens receiving usual care at that site (-0.06 , 95% CI -0.11 to -0.01). As a consequence of the difference in trajectories, we found in cross-sectional analyses that A1c for teens at Site 1 at the conclusion of the post-intervention period was significantly lower for intervention participants than for those receiving usual care (9.68% vs 10.76%, $P < 0.05$). In cross-sectional analyses, A1c for usual care teens at this site rose by 0.5 (from 10.26 to 10.76) during this period, while intervention teens' A1c declined by 0.13 (from 9.81 to 9.68).

To further understand why results differed by intervention site, we examined whether the intervention's impact differed by glycemic control at baseline, which was known to differ at the two sites. Among Site 1 teens with A1c $>8.5\%$ at baseline, those receiving the intervention had a significantly better A1c trajectory during the post-intervention period, compared to usual care participants (-0.08 , 95% CI -0.15 to -0.004). Among Site 1 teens with A1c $>10\%$ at baseline,

TABLE 1 Baseline participant characteristics by site, age, and study arm^a

	Site 1 (n = 101)				Site 2 (n = 113)			
	Youth (n = 53)		Teen (n = 48)		Youth (n = 42)		Teen (n = 71)	
	Usual care (n = 27)	Intervention (n = 26)	Usual care (n = 25)	Intervention (n = 23)	Usual care (n = 21)	Intervention (n = 21)	Usual care (n = 35)	Intervention (n = 36)
Child characteristics								
Girl	56% (15)	46% (12)	68% (17)	43% (10)	48% (10)	52% (11)	49% (17)	36% (13)
Non-Hispanic, White	96% (26)	92% (23)	92% (23)	91% (21)	67% (14)	76% (16)	83% (29)	75% (27)
In good to excellent health	96% (26)	88% (23)	96% (24)	96% (22)	95% (20)	100% (21)	94% (33)	81% (29)
Diabetes duration, years (mean [sd])	3.9 (2.3)	4.1 (2.4)	7.0 (3.9)	6.6 (3.7)	5.3 (3.1)	4.6 (2.7)	5.7 (3.9)	5.7 (3.1)
Insulin pump use	48% (13)	65% (17)	56% (14)	70% (16)	19% (4)	57% (12)	49% (17)	47% (17)
A1c, % (mean [sd])	8.8 (1.2)	8.5 (0.8)	9.7 (1.5)	9.1 (1.6)	9.9 (1.8)	8.4 (1.3)	8.8 (1.9)	9.4 (1.8)
A1c, mmol/mol (mean [sd])	73 (13)	70 (9)	83 (17)	77 (18)	85 (20)	69 (14)	73 (21)	79 (20)
A1c < 7.5%	12% (3)	8% (2)	4% (1)	5% (1)	5% (1)	29% (6)	29% (10)	17% (6)
QOL (mean [sd])	67.9 (9.6)	61.7 (13.6)	66.7 (13.6)	67.7 (13.6)	63.5 (12.3)	73.5 (12.1)	65.5 (11.2)	65.7 (13.7)
Parent characteristics								
Age, years (mean [sd])	40.9 (5.2)	37.8 (5.1)	43.0 (5.2)	42.9 (5.1)	39.0 (6.0)	39.9 (7.5)	43.9 (5.9)	44.8 (6.2)
Mother	89% (24)	88% (23)	88% (22)	87% (20)	86% (18)	76% (16)	94% (33)	69% (25)
Non-Hispanic, White	96% (26)	96% (25)	96% (24)	96% (22)	76% (16)	75% (15)	94% (32)	78% (28)
Education								
High school graduate or less	7% (2)	19% (5)	4% (1)	17% (4)	24% (5)	33% (7)	20% (7)	22% (8)
Some college	33% (9)	42% (11)	48% (12)	30% (7)	43% (9)	29% (6)	37% (13)	25% (9)
Bachelor's degree or more	59% (16)	38% (10)	48% (12)	52% (12)	33% (7)	38% (8)	43% (15)	53% (19)
QOL (mean [sd])	62.5 (15.0)	56.2 (14.1)	60.7 (17.6)	62.1 (13.1)	52.0 (16.5)	66.8 (16.2)	63.7 (15.7)	63.6 (15.7)
Self-management barriers								
Barrier count (mean[sd])	1.6 (0.5)	1.7 (0.5)	2.8 (0.4)	2.5 (0.6)	1.9 (0.4)	1.7 (0.5)	2.7 (0.5)	2.7 (0.6)
Motivation	96% (26)	100% (26)	100% (25)	100% (23)	100% (21)	95% (20)	100% (35)	100% (36)
Understanding/organizing care	63% (17)	65% (17)	76% (19)	65% (15)	86% (18)	71% (15)	86% (30)	86% (31)
Family interactions	—	—	100% (25)	87% (20)	—	—	89% (31)	83% (30)

^aValues may not add to 100% due to rounding or non-response.

intervention participants experienced an even larger intervention impact on A1c trajectories after the intervention (−0.19, 95% CI −0.32 to −0.05).

Lastly, we found evidence that specific session types were responsible for the age and site-specific intervention impacts on A1c. Among Site 1 teens who experienced barriers around being motivated to self-manage their diabetes, those who received the intervention tailored to this barrier (Your Diabetes, Your Choices; n = 11) had a significantly better post-intervention A1c trajectory (−0.13, *P* < 0.01), than those who received usual care (n = 12). Similarly, among Site 2 youth experiencing barriers around being able to understand and organize their diabetes care, those who received the Tips and Tools content tailored to this barrier (n = 10), had significantly better post-intervention A1c trajectory (−0.07, *P* < 0.05), than those receiving usual care (n = 11).

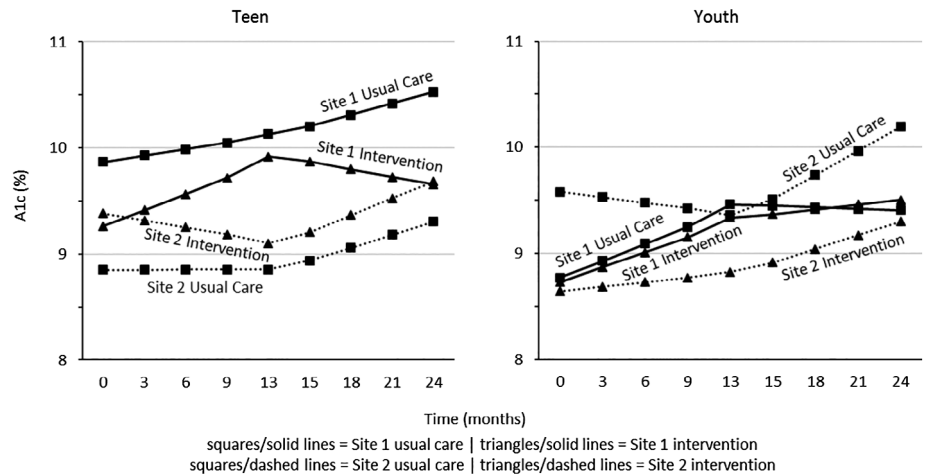
3.4 | Impact of the intervention on QOL for the child with diabetes

Our analyses demonstrated no significant overall intervention effect on QOL trajectories for the child, during the intervention (0.02, 95% CI −0.25 to 0.30) or post-intervention (−0.07, 95% CI −0.52 to 0.37) periods, when combining data from sites and age groups. There was also no significant intervention effect within sites by age groups.

3.5 | Impact of the intervention on QOL for the parent of a child with diabetes

Our analyses demonstrated no significant overall intervention effect on QOL for the parent, during the intervention (−0.04, 95% CI −0.31 to 0.24) or post-intervention (−0.01, 95% CI −0.47 to 0.45) periods,

FIGURE 1 A1c trajectory by study arm and site for teens (13-16 years) and youth (8-12 years)



when combining data from sites and age groups. However, at Site 1, parents of intervention arm youth (ages 8-12 years) had a significantly better QOL trajectory during the intervention (mean parent QOL increased by 0.34 points per month), than youth receiving usual care (mean parent QOL declined by 0.28 points per month; Figure 2). Taken together for parents of youth ages 8-12 years at Site 1, those receiving the intervention had a significantly better QOL trajectory during the intervention period than those receiving usual care (0.61, 95% CI 0.05 to 1.17). Post-hoc subgroup analyses found no significant treatment effects on parent QOL by session type.

4 | DISCUSSION

Many behavioral interventions for children with type 1 diabetes demonstrate short-term improvements, yet these interventions are not widely used in clinics or accessed by families.^{1-3,6,11,20,40} We sought to understand whether tailoring interventions to families' needs and preferences could overcome these challenges and improve outcomes

among children with type 1 diabetes and their parents. Although no significant intervention effect was seen when combining data across study sites and age groups, examining intervention effects for each site, age group, and type of content generated important information to guide implementation of self-management resources in clinical settings and future research. For example, teens at one site who received the intervention had a significantly better A1c trajectory (0.06 points lower per month), which corresponds to a clinically meaningful improvement in A1c of 0.72 points over the year following the intervention. Extrapolating from results of the DCCT, sustained A1c improvements of the magnitude seen in our cross-sectional results could reduce relative risk for retinopathy and nephropathy by at least twofold.⁴¹ In addition, at one site, parents of youth ages 8-12 years who received the intervention demonstrated a significantly better QOL trajectory during the intervention (0.61 points per month), corresponding to improvement in parent QOL of 7.3 points per year, which exceeds the minimally important difference of 3.5 points in this population.⁴² Improvements in glycemic control in the post-

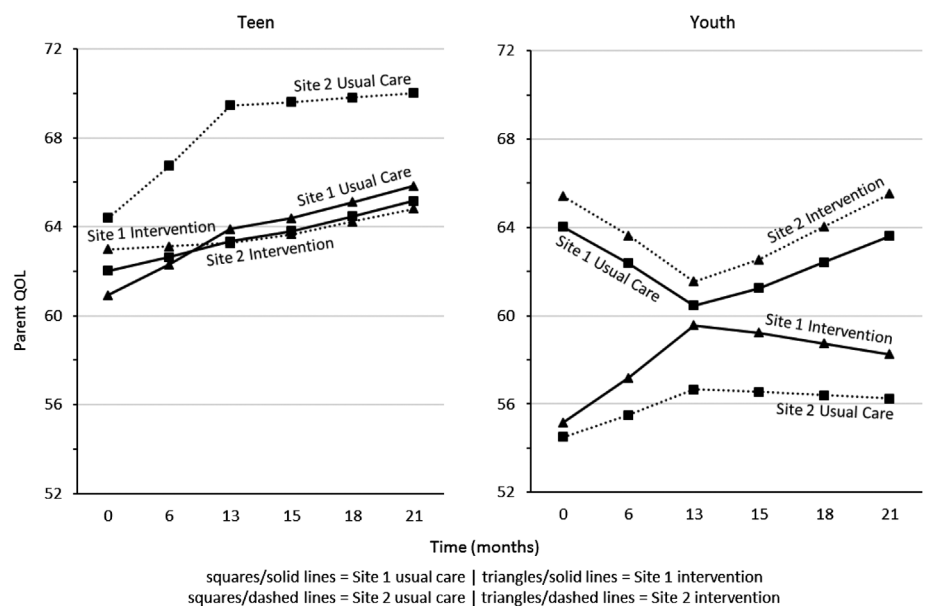


FIGURE 2 QOL trajectory by study arm and site for parents of teens (13-16 years) and youth (8-12 years)

intervention period were greatest for children with higher baseline A1c values. In addition, improvements in A1c were largely due to the resources that addressed barriers related to motivation and to understanding and organizing diabetes care.

Our results suggest that healthcare systems or clinics may want to consider their capacity to deliver resources and also the characteristics of their patient population prior to implementing self-management resources. For organizations with capacity to offer only one resource, the Your Diabetes, Your Choices content that addresses motivation to self-manage is promising because it addresses the most common self-management barrier among children 8-16 years of age with type 1 diabetes. In addition, to generate the most impact on glycemic control with limited resources, organizations could focus on offering tailored resources to youth and teens with elevated A1c values. However, given our findings that youth and teens benefit best from different resources, delivering the Your Diabetes, Your Choices content as well as the Tips and Tools content may best address needs for teens and for youth. Lastly, when family interactions are the source of teen's challenges with diabetes self-management, a more intensive resource akin to the efficacious Behavioral Family Systems Therapy approach may be needed,^{12,23} as we were unable to demonstrate impact when delivering content from this resource only every 3-4 months.

Our process of coordinating the group-based sessions with routine diabetes clinic visits and matching the session content to families' needs was designed to promote intervention session completion among participants. A group-based approach leverages many families' desire to exchange ideas and learn from others with type 1 diabetes as a way to boost acceptance.^{43,44} In addition, delivering resources in groups allows a single facilitator to serve several families simultaneously. However, this approach does require considerable engagement from clinic leadership and staff. Our 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 to ensure that families can and actually do access self-management help.

Our inability to demonstrate overall effectiveness when combining data across study sites and age groups may be due to various factors in our design and implementation within the real-world clinical settings as well as differences between site participants. For example, to increase the generalizability, we included youth and teens regardless of baseline A1c value. In other trials, children with A1c values that are at goal or >13% were often excluded. Therefore, in our study, significant effects on A1c may have been harder to demonstrate statistically. In addition, the interventions in our trial were implemented with the goal to meet families' preferences to enhance uptake, so the content was fit into four 90-minute group sessions delivered in coordination with routine clinic visits. As a result, our participants received intervention content only once every 3-4 months, rather than weekly or every other week in efficacy trials. Thus, the intensity of our intervention delivery was likely reduced in comparison to the original efficacious interventions.

Differences in the intervention's impact by study site and age group led us to investigate potential site or age-based differences in intervention fidelity, attendance at group sessions, or participant characteristics. Training of group session facilitators was the same for both sites and the fidelity of intervention delivery did not differ between sites. However, fidelity was greater for group sessions delivered to teens, compared to youth. This may explain why the largest intervention impact on glycemic control was seen among teens. Probably most importantly, Site 2 had significantly more participants with baseline A1c <7.5% than Site 1. Furthermore, the proportion of usual care teens at Site 2 with a baseline A1c in the target range was significantly greater than at Site 1, whereas the proportion in target range in the intervention arm were similar. These teens, who were already maintaining an A1c in the target range, may have been less likely to experience the rise in A1c that commonly occurs among adolescents and was seen among Site 1's usual care teens. Lastly, intervention impact was greater among teens with higher baseline A1c values. Thus, site-based differences in A1c at baseline may explain why similar A1c trajectories for teens at Site 2 did not reach significance, as they did for Site 1.

Although this trial has many strengths, there are some notable limitations. Our trial was conducted at two clinical sites, which could limit the generalizability of findings. In addition, we excluded families who 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, participating families' characteristics were similar to those of the US population of children with type 1 diabetes. In addition, although we did not inform providers of their patients' participation, it is possible that families discussed it with them, which could result in intensification of the usual care provided, limiting our ability to detect impact for our intervention. Our results with regard to A1c trajectories suggest that additional work could be done to potentially improve the impact of the approach for youth. For example, developing a survey to identify self-management barriers from the perspective of the youth, rather than the parent may improve impact. Alternatively, the intervention content and materials may need adaptation to better meet the needs of youth, as intervention fidelity was lower for youth. Future work could also investigate whether any intervention effect is due solely to the increased contact time for intervention group families. Lastly, increasing the intensity of the intervention could improve its impact, especially if this can be achieved through telehealth platforms that limit burden from travel to the clinic.

In conclusion, our findings suggest that family-centered tailoring of type 1 diabetes self-management resources may benefit specific youth and teens, especially those with A1c values >8.5% and those with barriers related to either understanding and organizing their self-management or their motivation to self-manage. In addition, our process for creating buy-in and coordinating self-management help with routine clinic visits resulted in high rates of uptake for the intervention. Disseminating the information gained from this study could support healthcare organizations in effectively and efficiently make use of existing but limited healthcare system resources to support self-

management. For example, access to this family-centered approach could be broadened by adapting the intervention for use via videoconferencing or other similar technologies.

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