First STEPS: Primary Outcomes of a Randomized, Stepped-Care Behavioral Clinical Trial for Parents of Young Children With New-Onset Type 1 Diabetes

Marisa E. Hilliard,[1] Carrie Tully,[2,3] Maureen Monaghan,[2,3] Tom Hildebrandt,[4] Christine H. Wang,[2,3] John R. Barber,[2] Lauren Clary,[2,3] Katherine Gallagher,[1] Wendy Levy,[1] Fran Cogen,[2,3] Celia Henderson,[2,3] Lefkothea Karaviti,[1] and Randi Streisand[2,3]

Diabetes Care 2022;45:2238–2246 | https://doi.org/10.2337/dc21-2704

OBJECTIVE

Despite the emotional challenges of parental adjustment to a child's type 1 diabetes diagnosis and the unique complexities of early childhood, there are few programs designed to meet the needs of parents of young children at new onset. This study evaluated First STEPS (Study of Type 1 in Early childhood and Parenting Support), a stepped-care behavioral intervention designed to support parents' psychosocial functioning and promote children's glycemic outcomes.

RESEARCH DESIGN AND METHODS

Using a two-site randomized clinical trial design, parents (*n* = 157) of children aged 1–6 years completed baseline data within 2 months of diabetes diagnosis and were randomly assigned to intervention (*n* = 115) or usual care (*n* = 42) for 9 months. Intervention steps included: *1*) peer parent coaching, with step-ups to *2*) structured behavioral counseling and *3*) professional consultations with a diabetes educator and psychologist, based on parent mood and child HbA_{1c}. Participants completed follow-ups at 9 and 15 months postrandomization. Primary outcomes were parent depressive symptoms and child HbA_{1c}.

RESULTS

Depressive symptoms improved in both groups, and intervention parents had significantly lower depressive symptoms at the 9- and 15-month follow-ups compared with usual care. HbA_{1c} decreased in both groups, but there were no between-group differences at 9 or 15 months.

CONCLUSIONS

First STEPS improved parents' mood following young children's type 1 diabetes diagnosis. Results indicate likely benefits of parent coach support, supplemented by intervention intensifications, including behavioral intervention and diabetes education. This model has high potential for patient engagement. The absence of a medical intervention component may explain null findings for HbA_{1c}; incorporating targeted behavioral support for intensive diabetes treatment may maximize intervention impact.

The prevalence of type 1 diabetes in young children was 0.28/100,000 in youth under 4 years of age and 1.33/100,000 in youth aged 5–9 years in the most recent

[1]Baylor College of Medicine and Texas Children's Hospital, Houston, TX
[2]Children's National Hospital, Washington, DC
[3]George Washington University School of Medicine and Health Sciences, Washington, DC
[4]Icahn School of Medicine at Mount Sinai, New York, NY

Corresponding author: Marisa E. Hilliard, marisa.hilliard@bcm.edu

Received 30 December 2021 and accepted 11 July 2022

Clinical trial reg. no. NCT02527525, clinicaltrials.gov

This article contains supplementary material online at https://doi.org/10.2337/figshare.20383062.

epidemiological data from 2017 (1). Aspects of early childhood development, such as unpredictable eating and physical activity, common autonomy-seeking behaviors, and limited language skills, make strict adherence to treatment regimens challenging (2). Clinical factors, including high glycemic variability, small insulin requirements, frequent intercurrent illness, and a shortened honeymoon period, further complicate management (2,3). The most recent Type 1 Diabetes Exchange data from 2016–2018 reported the mean HbA_{1c} in children aged <6 years was 8.2 ± 1.2% (4), well above the American Diabetes Association's HbA_{1c} goals of $<7.0\%$ (5). These elevated HbA_{1c} levels and young children's greater likelihood of having diabetic ketoacidosis (DKA) at diagnosis (6) increase the risk for later development of serious diabetes-related complications (7), including cognitive declines (8).

Young children depend entirely on parents to conduct daily management tasks (2). After diagnosis, parents must rapidly learn diabetes education, adapt family routines including mealtimes and school/daycare to include management tasks, and teach diabetes safety skills to other caregivers (9). In the first months postdiagnosis, many parents of young children with type 1 diabetes experience posttraumatic stress–like symptoms (e.g., intrusive thoughts, avoidance, and hypervigilance) (10) and elevated depressive symptoms (11). Data from studies with mothers of children under 13 years of age show this is due in part to the relentless management demands (2) and being in a constant state of vigilance (12) for hypoglycemic episodes. Maternal psychosocial functioning at diagnosis predicts continued concerns years later (13), and ~20% of parents of youth with type 1 diabetes report persistent distress up to 4 years postdiagnosis (10). Parent depressive symptoms are associated with lower monitoring of child diabetes–related tasks (14), and a link between parent depressive symptoms and child HbA_{1c} is evident as early as diagnosis (11).

Given these challenges, parents of young children with type 1 diabetes need targeted support focused on alleviating depressive symptoms and supporting psychosocial functioning, particularly during the critical period following diagnosis, which can set the stage for short- and long-term diabetes management behaviors and glycemic outcomes. However, most of the few existing behavioral interventions target school-aged children or adolescents, with or without their families, at least 6 months postdiagnosis (15). Small intervention studies to enhance parents' diabetes-specific social support via mentors ("parent coaches") and/or behavioral interventionists as a complement to routine clinical care have shown promise (16). Our research team's prior multicomponent behavioral interventions (17,18) found that parents reported increased perceived support, improved coping, decreased family burden, and decreased parenting stress after the intervention, though they stated they would have liked the support sooner after diagnosis (19).

This trial tested a new intervention called First STEPS, which stands for Study of Type 1 in Early childhood and Parenting Support (20). The theoretical foundation is social cognitive theory (SCT), which posits specific psychosocial factors that influence health behaviors (20,21). In line with SCT, intervention components specifically targeted parental self-efficacy, goal-setting, and problem-solving skills related to type 1 diabetes and/or child behavior management, which are often impaired in the context of parent depressive symptoms. We anticipated that targeting these SCT-related social, cognitive, and behavioral factors would benefit parental psychosocial functioning and child glycemic outcomes.

While multicomponent behavioral interventions have helped support parents and improved psychosocial functioning, participants may receive components that are not needed unless an intervention is tailored. Stepped care (SC) trial designs include interventions that add new components and increase in dose or intensity based on participants' response to lower levels (or "steps") of the intervention (22). This approach has been used with people with other conditions, such as disordered eating, substance use, and depression (23–25). One key consideration of SC designs is they allow participants to receive the least intense intervention prior to increasing intensity based on demonstrated need. Thus, First STEPS used an SC design to provide needed intervention intensifications to participants as indicated by their responses to each intervention step, as measured by the trial's primary outcomes.

The primary aim of this trial was to determine the longitudinal impact of the First STEPS intervention for parents of young children soon after diagnosis of type 1 diabetes on parents' psychosocial functioning and children's glycemic outcomes. Specifically, we hypothesized that parents in the intervention arm would have significantly lower depressive symptoms and their children would have significantly lower HbA_{1c} than the usual care (UC) control arm at 9 months (primary) and 15 months (maintenance) postrandomization.

RESEARCH DESIGN AND METHODS

Study Design

This was a two-site two-arm randomized controlled trial comparing the intervention (SC) to UC. The primary outcomes were the parents' depressive symptoms and child's glycemic outcomes (HbA_{1c}) at 9 months postrandomization. Maintenance at 15 months postrandomization was also evaluated. The institutional review boards at pediatric hospitals affiliated with two academic medical centers in Washington, DC and Houston, TX approved the protocol (20). The protocol was registered on ClinicalTrials.gov (NCT02527525). Recruitment took place between 2016 and 2019.

Procedures and Participants

Recruitment occurred through review of newly diagnosed young children in the electronic medical records at the two study sites. Participants were parents/legal guardians of children aged 1–6 years, diagnosed with type 1 diabetes for $\leq$8 weeks. Eligibility criteria included parent aged $\geq$21 years and English fluency. Exclusion criteria included a parent with a serious mental illness or intellectual disability that would impede informed consent and full study participation or child with a life-threatening medical illness or significant intellectual or developmental disability (e.g., autism) that may substantially increase diabetes management challenges. There were no exclusions based on children's insulin regimen or HbA_{1c} at diagnosis. Parents self-identified as the primary caregiver in charge of diabetes management. Secondary caregivers (e.g., another parent or another adult in home) were invited to enroll to complete

questionnaires only (no intervention participation) if interested.

As outlined in the Consolidated Standards of Reporting Trials (CONSORT) flowchart (Supplementary Fig. 1), the study teams at the two sites approached 364 potential participants while their children were inpatient for type 1 diabetes diagnosis and/or through a recruitment letter mailed to their homes, then followed up by telephone within 1 week of discharge to determine eligibility. Study staff reached 298 families, of whom 217 met eligibility criteria and verbally consented to participate. Study staff sent participants a personalized link to a Research Electronic Data Capture (REDCap) (26) survey to provide electronic documentation of consent and complete baseline questionnaires by 8 weeks postdiagnosis; this was completed by 170 participants. Participants then completed an orientation session with study staff in which they reviewed the study timeline and activities, shared their diagnosis story, watched a video about type 1 diabetes, and were randomly assigned to one of the intervention arms. Orientation sessions occurred at a scheduled diabetes appointment when possible (mean 64.9 ± 36.4 days postdiagnosis). In total, 158 families completed the orientation session and were randomly assigned at a 3:1 ratio to SC (n = 116) or UC (n = 42), based on preallocated random blocks balanced for child race/ethnicity, site, and marital status, created using a computer generator by the study biostatistician. Following randomization, the principal investigator withdrew 1 participant due to change in study eligibility, resulting in a final sample of 157 participants. Table 1 provides full sample characteristics.

Participants received financial incentives for completing all study assessments, with an increasing rate to encourage retention: baseline, $50; 3-month brief check-in, $10; 6-month brief check-in, $10; 9-month, $75; and 15-month, $100. The incentives were initially provided via gift cards at major retailers, and later, the sites began using reloadable debit cards (ClinCard). Participants also received small tokens of appreciation for participation (27).

Study Arms

Intervention

The First STEPS intervention condition used an SC design with three intervention steps, each increasing in intensity, illustrated in Fig. 1 (20,28). In addition to receiving usual diabetes care, all participants in this arm received step 1, in which they had contact with a parent coach, who was a parent with a child with type 1 diabetes who was trained by the research team to provide peer support for 9 months (28). Parent coaches shared their experiences parenting a child with type 1 diabetes, provided emotional support, and answered participants' questions about their experiences adjusting to diabetes management routines, communicating with the diabetes care team and other caregivers about the child's management, and about their use of diabetes management devices. They also shared relevant resources. Parent coaches were trained to contact their participants weekly in the first three months of the intervention, then monthly until the end of the study, and to respond to all participant-initiated communications.

Participants received step 1 parent coaching throughout the 9-month intervention period. They then had two opportunities to advance to also receive higher intervention steps at the time of two diabetes care appointments, which occurred approximately every 3 to 4 months. Study staff met with participants at each appointment to administer a depressive symptoms screener and document the child's HbA_{1c} value collected at the medical appointment. If either the parent's depressive symptoms score met the clinical cutoff of 16 or the child's HbA_{1c} was $\geq$8.0%, the parent moved to the next intervention step. At the appointment $\sim$3 months postrandomization, participants who met either or both criteria advanced to step 2 and continued to be in touch with their parent coach. Those who did not meet criteria remained in step 1; all participants initially randomized to the SC intervention continued with their parent coach for the full 9 months of the intervention, regardless of step movement. At the next diabetes care appointment $\sim$6 months postrandomization, the same process was used to determine whether participants would move up a step (step 1 to step 2 or step 2 to step 3), in addition to ongoing contacts with their parent coach. The content of steps 2 and 3 followed intervention protocols, whether the participant moved up based on parent depressive symptoms, child HbA_{1c}, or both.

Step 2 included five telephone sessions with a master's level study interventionist (four individual sessions and one group session) within 3 months. The sessions provided psychoeducation about child development and parent psychosocial functioning and taught skills for managing depressive symptoms, parenting young children, problem-solving, self-care, and gratitude. They also reviewed glycemic targets for young children and applied the problem-solving skill to address barriers the parent had faced in relation to achieving HbA_{1c} goals in their young child, such as challenges at mealtimes, overnight, and around physical activity. The interventionists talked with the participants about their experiences and tailored the examples and applications of the step 2 intervention topics accordingly.

Step 3 involved two professional consultations, one with a diabetes educator and one with a licensed psychologist with expertise in diabetes. The consultations occurred in person when possible or by telephone or videoconferencing if requested by participants. The diabetes educator provided feedback on the child's diabetes management using data from the child's continuous glucose monitor (CGM) if available; if not, they placed a blinded CGM on the child for 1 week and provided feedback based on those data. Families who preferred not to wear a CGM completed detailed logs of blood glucose values, food, and physical activity for 1 week. The diabetes psychologist reviewed the parent's experiences and concerns related to parenting a young child with diabetes, provided support and strategies related to the parent's challenges with psychosocial functioning, problem-solved challenges around diabetes management and behavior management in their young child, and suggested referrals for mental/behavioral health treatment as indicated.

UC

The UC condition included multidisciplinary medical treatment for type 1 diabetes as usual with no additional intervention (20). At both sites, usual diabetes care following new diagnosis included daily contact with nurses for 1 to 2 weeks after discharge, outpatient medical follow-up visits with a physician or nurse practitioner every 3 to 4 months, and diabetes

Table 1—Sample characteristics

	Overall (*N* = 157)	Site		*P* value
		CNH (*N* = 80)	TCH (*N* = 77)	
Demographics				
Child age, years, at baseline, mean ± SD	4.5 ± 1.6	4.5 ± 1.8	4.5 ± 1.5	0.959
Child sex, female	86 (54.8)	46 (57.5)	40 (51.9)	0.485
Child race/ethnicity				
Non-Hispanic White	93 (60.0)	46 (59.0)	47 (61.0)	0.494
Non-Hispanic Black	23 (14.8)	13 (16.7)	10 (13.0)	
Hispanic	23 (14.8)	9 (11.5)	14 (18.2)	
Asian/Asian American	8 (5.2)	6 (7.7)	2 (2.6)	
Multiracial	8 (5.2)	4 (5.1)	4 (5.2)	
Parent age, years, at baseline, mean ± SD	34.9 ± 7.0	36.7 ± 7.0	33.3 ± 6.6	0.001**
Parent sex, female	144 (91.7)	73 (91.3)	71 (92.2)	0.828
Parent race/ethnicity				
Non-Hispanic White	97 (62.2)	48 (60.8)	49 (63.6)	0.701
Non-Hispanic Black	23 (14.2)	13 (16.5)	10 (13.0)	
Hispanic	19 (12.2)	8 (10.1)	11 (14.3)	
Asian/Asian American	12 (7.7)	8 (10.1)	4 (5.2)	
Multiracial	4 (2.5)	2 (2.5)	2 (2.6)	
American Indian/Alaskan Native	1 (<1)	0 (0)	1 (1.3)	
Number of adults in home, mean ± SD	2.1 ± 0.6	2.0 ± 0.6	2.1 ± 0.7	0.178
Child's health insurance, private	112 (72.3)	60 (75.0)	52 (69.3)	0.431
Highest parental education, graduated college	84 (53.5)	49 (61.3)	35 (45.5)	0.047*
Clinical features				
HbA_{1c} at randomization, mean ± SD	8.42 ± 1.35	8.09 ± 1.14	8.75 ± 1.48	0.003**
DKA at diagnosis	57 (37.0)	23 (29.5)	34 (44.7)	0.050
CGM use				
Baseline	38 (24.2)	17 (21.3)	21 (27.3)	0.378
9 months	96 (61.9)			
15 months	102 (65.8)			
Pump use				
Baseline	4 (2.6)	2 (2.5)	2 (2.6)	1.000
9 months	41 (26.5)			
15 months	39 (25.7)			

Data are *n* (%) unless otherwise indicated. CNH, Children's National Hospital (Washington, DC site); TCH, Texas Children's Hospital (Houston, TX site). *$P < 0.05$; **$P < 0.01$.

education on an as-needed basis. Both teams include social workers (as needed) and diabetes psychologists (by referral), and referrals are also made to community-based mental/behavioral health professionals. However, youth/family contacts with internal and community-based mental/behavioral health professionals were not documented consistently enough to track for the study.

Measures

Participants in both arms completed questionnaire batteries at baseline, 9 months postrandomization (primary outcome: posttreatment), and 15 months postrandomization (maintenance). They also completed the questionnaire to assess depressive symptoms at 3 and 6 months postrandomization (midtreatment), as this score was used to determine movement between steps. Child glycemic outcomes were assessed across the full 15-month study period (including midtreatment at 3 and 6 months postrandomization, as a second index to determine movement between steps). While the questionnaire batteries included multiple measures (20), this report is limited to describing the sample's demographic and clinical characteristics and reporting the trial's primary outcomes: parental depressive symptoms, child HbA_{1c}, and overall study satisfaction.

Sociodemographic Data

At baseline, parents self-reported their age, race/ethnicity (theirs and child's), household income, highest parental education, child's health insurance, and marital status.

Parent Depressive Symptoms

Parents completed the 20-item Center for Epidemiological Studies-Depression Scale (CES-D) (29), a measure of depressive symptoms over the past week. A score of 16 indicates elevated risk for depression (29). Reliability in this sample was good ($\alpha = 0.92$).

Medical Data

Study staff completed electronic medical chart reviews to confirm diagnosis date, presence of DKA at diagnosis, and use of insulin pump or CGM at each time point.

At routine diabetes care appointments, medical assistants at both sites drew blood samples to calculate HbA_{1c} using point-of-care DCA 2000 analyzers (Bayer Inc., Tarrytown, NY). Study staff extracted these values from the electronic medical record at each appointment. If HbA_{1c} values from other sources (e.g., inpatient hospitalization or external laboratory) were entered in the record, staff extracted those values as well.

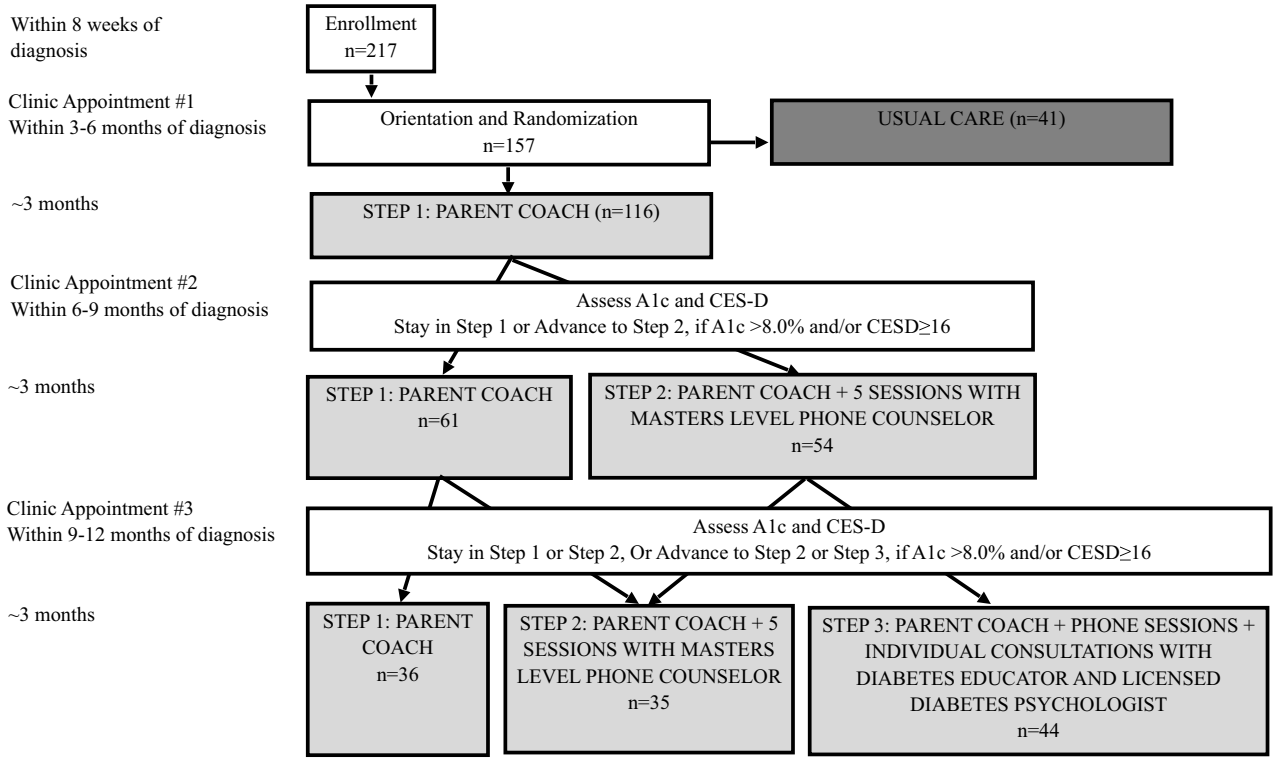

Figure 1—SC progression.

Satisfaction

At the 9-month follow-up, all participants in both arms completed a satisfaction survey. As an indicator of overall satisfaction, they were asked to rate the degree to which they agreed with the statement, "Overall, I am glad that I participated in this project." Response options were on a 5-point scale, from "strongly agree" to "strongly disagree."

Fidelity Monitoring Procedures

For step 1, parent coaches completed monthly surveys, in which they indicated, for each participant they were currently assigned, the frequency and method of communication over the prior month and topics and resources reviewed and shared. Parent coaches completed monthly surveys and participated in supervision phone calls monthly with licensed mental health study staff with their first participant. After their first participant had concluded the study and parent coaches were working with subsequent participants, parent coaches had quarterly phone calls with study staff and continued to complete monthly surveys. For step 2, the interventionist documented whether each session was completed and the content covered. Step 2 interventionists audio recorded sessions for fidelity monitoring and participated in supervision with a licensed psychologist between each session, focusing on participant safety and intervention delivery per the study manual. For step 3, the diabetes educator and psychologist completed separate forms documenting sessions completed and topics discussed. The study coordinator documented whether the child was already using a personal CGM and, if not, whether the blinded CGM was placed or if the family declined placement.

Sample Size and Power

The original sample size goal was N = 200, ≥0.80 power to detect a desired effect size of d = 0.40 with five repeated measures. Power was recalculated due to the tight eligibility criteria, and with N = 150, we used an equivalent model as the original power analysis with the same input parameters, and estimated 0.82 power to detect a d = 0.50. Recruitment ended with our sample of n = 157, providing enough power to detect moderate effect sizes.

Statistical Analysis

The analysis used an intent-to-treat model, in which all randomly assigned participants were included in analyses. Sociodemographic differences between treatment conditions at baseline were analyzed using independent t tests or χ^2 tests of independence. Latent growth curve models (30) were planned with randomization (SC vs. UC) and sequential step achieved (step 1, 2, or 3) entered as time-varying covariates. The time index of the model was centered on 9-month outcome (t_0 = 9-month assessment), yielding interpretation of intervention effect at 9 months as primary treatment outcome. Planned covariates included DKA at diagnosis, parental race/ethnicity, and health insurance (private vs. public), based on prior literature linking these factors with glycemic outcomes (6,7,17). Study site was also included.

Models were first fit with simple linear constraints on latent slope with correlated slope and intercept covariance, adding treatment and planned covariates to the model after establishing the best model of change over the 15-month assessment window. Cohen *d* estimates of effect size were calculated from means and SDs.

RESULTS

Sample Characteristics

The study sample included 157 parents of young children with type 1 diabetes. Table 1 details parent and child characteristics at baseline (collected within 2 months of diagnosis; mean 29.0 ± 15.4 days). Mean youth age was 4.5 ± 1.7 years. Mean HbA_{1c} at randomization (orientation session) was 8.4 ± 1.4%, and 37% of children presented in DKA at diagnosis. There were significant differences between sites at baseline in parent age, highest parental education, and baseline A1C; the *P* value for percent with DKA at diagnosis was 0.0501 (Table 1). Over 97% (*n* = 153) of the sample completed the 15-month postrandomization follow-up. The CONSORT table (Supplementary Fig. 1) provides details about sample retention in each arm at the 9- and 15-month follow-ups.

Intervention Outcomes

Engagement

Participants reported overall high satisfaction, with 95% of participants in the SC arm and 95% in the UC arm indicating they "agree" or "strongly agree" that they were glad they participated in this project. Of the 115 participants randomly assigned to SC, 36 (31.3%) remained in step 1 for the entirety of the 9-month intervention period (did not meet criteria to advance to step 2 at either opportunity). Of the 115 assigned to SC, 35 (30.4%) advanced to step 2 only, and the remaining 44 (38.3%) advanced to step 2 and then to step 3. Those who advanced to step 2 only either did not meet criteria to move to step 3 or moved to step 2 at the second/final opportunity. Of those who advanced to step 2 (*n* = 79), 15 participants (19.0%) met the CES-D criteria only, 50 (63.3%) met the HbA_{1c} criteria only, and 14 (17.7%) moved due to both parent CES-D and child HbA_{1c}. Of those who advanced to step 3 (*n* = 44), 8 (18.2%) moved due to CES-D only, 30 (68.2%) moved due to HbA_{1c} only, and 6 (13.6%) due to both.

Intervention Fidelity

Of the 115 participants in SC, 99 (86.1%) had at least *monthly* contact with their parent coach across the 9-month intervention period, with 78 (67.8%) having one or more contacts in the final month (month 9 of the intervention). Of the 115, 47 participants met with their parent coaches in-person at least once (41%), with others citing difficulty with timing or distance as barriers for in-person meetings. Parent coaches completed 98% of the monthly surveys and supervision phone calls with the parent coach liaison. Parent coaches reported using phone calls, text messaging, and emails most frequently to contact their participants. Parent coaches reported their most discussed topics were supporting the parent and child's adjustment to diabetes, discussing parents' experiences with daily diabetes management, and discussing eating/nutrition. Of the 79 participants who advanced to step 2, 62 (79%) completed all 5 telephone sessions, and 67 (85%) completed at least 4 of the 5 (80%) sessions. In total, out of the 395 expected step 2 sessions (79 participants × 5 sessions), 347 (88%) were completed. Interventionists had 98% adherence to the core intervention content in the step 2 manual. Of the 44 participants who advanced to step 3, 34 (77%) completed the diabetes educator consultation. Of those, 8 (23.5%) participants completed a blinded CGM trial, 24 (70.6%) used data from their personal CGM, and 2 (5.9%) used glucose logs in lieu of CGM data. Diabetes educators reported that the most reviewed topics were the timing of insulin delivery, diet log, and blood glucose monitoring. Also, in step 3, 40 participants (91%) completed the diabetes psychologist consultation. Diabetes psychologists reported that the most discussed topics were adjustment to diabetes diagnosis for parent and child, getting support from others, and problem-solving parents' diabetes management difficulties.

Depressive Symptoms

There was a significant effect of randomization (SC vs. UC) on depressive symptoms indicating that those randomly assigned to SC reported lower CES-D, indicating fewer depressive symptoms, at 9 months ($\beta = -5.13$; SE = 1.32; $P < 0.001$; Cohen $d = -0.39$ [−0.74, −0.03]) and 15 months ($\beta = -3.68$; SE = 1.73; $P < 0.05$; $d = -0.27$ [−0.63, 0.08]), controlling for individual variability in change over time (i.e., random slopes). Within-group differences indicated that both groups had significant improvement in CES-D scores. Covariate effects were all nonsignificant. Table 2 details the means and SDs for each group; descriptive data for SC participants who ended the intervention in each step are included but not analyzed because CES-D scores were one indicator of movement between steps. Supplementary Figure 2*A* illustrates the CES-D scores at each time point by group. To illustrate the degree of clinically meaningful change in depressive symptoms, Supplementary Table 1 reports the percent of participants in each arm with CES-D scores above the clinical cutoff (15) at each time point; post hoc χ^2 analyses indicated the differences in percentages per group did not reach statistical significance.

Glycemic Outcomes

There was no significant effect of randomization on HbA_{1c} at 9 months or 15 months postbaseline accounting for individual variability in change. Point effect size estimates were $d = -0.21$ (−0.57, 0.14) at 9 months and $d = 0.0$ (−0.35, 0.35) at 15 months for SC versus UC, suggesting a marginal (but not significant) effect at 9 but not 15 months. Within-subject differences suggest that there was global improvement in HbA_{1c} across groups, despite significant individual variability in change over time ($VAR_{slope} = 0.053$; SE = 0.016; $P = 0.001$). Participants with private insurance (vs. public) and DKA at diagnosis had significantly greater reductions in HbA_{1c}, including significantly lower HbA_{1c} at 9 and 15 months (Table 3). Supplementary Figure 2*B* illustrates the HbA_{1c} values at each time point by group.

Predictors

There were several significant covariate effects observed in the models (Table 3), although no covariate effect was robust across end points. Youth with private insurance and those with DKA at diagnosis had greater per-month reductions in HbA_{1c} over the 15-month follow-up. Compared with non-Hispanic White parents, non-

Table 2—Primary outcomes (parent CES-D and child HbA_{1c}) at each time point by study arm

	Baseline	3 months	6 months	9 months	15 months	Within-subject, standardized latent slope estimate (95% CI)
Parent CES-D Scores (possible range: 0–60; clinical elevation: 16)						0.21 (−1.26, 1.68)
SC	16.89 ± 11.76	10.12 ± 9.25	9.27 ± 8.32	8.94 ± 7.84	9.79 ± 9.48	
Step 1		5.91 ± 4.25	5.56 ± 4.59	5.61 ± 6.09	5.49 ± 6.18	
Step 2		10.2 ± 7.65	9.26 ± 7.64	8.71 ± 6.96	10.4 ± 9.30	
Step 3		13.4 ± 11.8	12.2 ± 9.97	12.0 ± 8.77	12.9 ± 10.7	
UC	15.78 ± 11.77	11.23 ± 8.13	11.83 ± 9.47	12.34 ± 10.70	12.46 ± 10.59	
Child HbA_{1c} (%)						−0.01 (−0.63, 0.61)
SC	8.40 ± 1.35	7.90 ± 1.29	8.05 ± 1.40	8.01 ± 1.32	8.06 ± 1.49	
Step 1		6.93 ± 0.70	6.89 ± 0.69	7.00 ± 0.72	7.21 ± 0.93	
Step 2		7.58 ± 0.77	8.08 ± 1.00	8.11 ± 1.16	7.95 ± 0.90	
Step 3		8.91 ± 1.25	8.92 ± 1.47	8.69 ± 1.35	9.04 ± 1.90	
UC	8.45 ± 1.40	8.29 ± 1.96	8.34 ± 1.91	8.14 ± 1.35	8.06 ± 0.96	

Raw mean ± SD reported in each cell. For within-subject change, we report standardized latent slope estimate scaled for the 15-month time point and 95% CI. All statistical analyses presented compare SC vs. UC; no statistical analyses were conducted on comparing steps, because the outcome measures (CES-D and HbA_{1c}) were used to indicate movement between steps.

Hispanic Black parents had children with higher HbA_{1c} at the 9-month end point and had higher CES-D scores at the 15-month follow-up. There were no significant site effects on change in any of the primary outcomes, but HbA_{1c} was ∼0.32 points higher in children at the Texas site than the DC site at the 9-month follow-up, which was not observed at the 15-month follow-up.

CONCLUSIONS

Results of the two-site First STEPS behavioral intervention trial suggest access to trained peer parent coaches soon after a young child's new diagnosis of type 1 diabetes, with the opportunity to receive additional behavioral and educational intervention components from professionals as needed, benefits parents' depressive symptoms. As most previous intervention research has focused on older youth with established diabetes (31), this represents a meaningful advance in the field's knowledge of efficacious strategies to support parents through the substantial emotional, behavioral, and social challenges inherent to the new-onset phase and this uniquely challenging developmental period. Given high rates of parental depressive symptoms soon after diagnosis (32) and for several years (14), this is a clinically important outcome. Moreover, high engagement in the intervention highlights the appeal of this approach for parents and its potential for successful implementation in practice.

While the SC intervention demonstrated benefits for parental depressive symptoms, comparable intervention-specific benefits were not observed for children's HbA_{1c}. Similar to previous parent coaching trials at later points postdiagnosis (12,17,18,33), change in glycemic outcomes was elusive in this newly diagnosed sample. Elevated blood glucose levels at the time of diagnosis, DKA in some children at diagnosis, and variable length honeymoon period in this age group (2,3) may have made this outcome particularly difficult to achieve. Although not statistically significant, CIs suggesting a potential, marginal intervention response in HbA_{1c} suggest there may be minor benefits of step 1 (peer coaching) during the initial months postdiagnosis. However, this improvement does not appear to persist over time. The ∼0.4% decrease in HbA_{1c} over the study's follow-ups (up to 15 months) in both groups demonstrates some natural glycemic improvement, which may require a more intensive intervention to change further.

Table 3—Summary of covariate effects on latent change in CES-D and HbA_{1c} in full sample

	Latent slope		9 months		15 months	
	CES-D	HbA_{1c}	CES-D	HbA_{1c}	CES-D	HbA_{1c}
Site	−0.04 (0.10)	−0.01 (0.02)	0.92 (1.17)	0.32 (0.16)*	−0.25 (0.20)	0.65 (1.43)
Private insurance, comparison: public insurance	−0.97 (0.93)	−0.03 (0.06)*	0.46 (1.46)	−0.58 (0.20)**	−0.80 (0.25)**	−0.69 (1.79)
Parent race, comparison: non-Hispanic White						
Hispanic	−0.13 (0.12)	−0.03 (0.02)	0.90 (1.64)	−0.30 (0.32)	−0.45 (0.39)	0.13 (1.51)
Non-Hispanic Black	0.14 (0.15)	0.003 (0.03)	−0.80 (1.59)	1.23 (0.30)**	1.25 (0.31)***	0.05 (2.24)
All other race/ethnicity groups	−0.08 (0.15)	0.01 (0.02)	−2.82 (1.82)	0.23 (0.23)	0.26 (0.32)	−3.28 (2.22)
DKA at diagnosis	−0.05 (0.08)	−0.03 (0.01)*	1.05 (0.93)	0.17 (0.13)	−0.01 (0.14)	0.78 (1.14)

Models for 9-month and 15-month outcomes centered on the latent intercept at the specific assessment. Consequently, the effects reflect covariate effects on latent mean outcome for each end point. Latent slope effects were equivalent in each model and can be interpreted in latent change in each outcome per month. β (SE) reported in each cell. "All other race/ethnicity groups" category includes Asian/Asian American, multiracial, and American Indian/Alaska Native participants. *$P < 0.05$; **$P < 0.01$; ***$P < 0.001$.

The nearly equivalent number of parents progressing to each of the three intervention levels supports the appropriateness of a SC approach to match the amount, type, and intensity of intervention to parent and child needs. Approximately two-thirds of intervention arm participants required more intensive interventions, and one-third demonstrated the highest level of need, suggesting traditional, uniform intervention protocols may not be adequately individualized for different experiences. We were unable to compare intervention efficacy between steps given the reliance on study outcomes (i.e., parent CES-D scores and child HbA_{1c}) at each check-in to determine whether participants moved between steps. This is a common challenge with SC intervention trials (34) and supports the need for testing tailored care models in adaptive clinical trial designs. Thus, it remains unclear who gains the most benefit from lower versus higher intensity interventions, as there are several factors that may impact children's diabetes-related health in the new-onset period. In this case, we provided similar intensifications to everyone who met criteria to advance to the next intervention step. While the interventionists in all steps engaged participants in discussion about their experiences and incorporated that information into their intervention delivery (e.g., answering parents' specific questions and tailoring examples and skill practice applications relevant to each participant's experiences), they provided the same core intervention content whether participants advanced steps due to parent depressive symptoms or child HbA_{1c}. Although parental depressive symptoms and child HbA_{1c} are correlated (11,13,14), they are not necessarily causally linked. Thus, providing one intervention to everyone may have limited the effect on HbA_{1c} for some participants. An important future research direction may include offering more intensive or different interventions to families whose children's glycemic markers are persistently outside targets or who are likely to have trajectories of poor glycemic outcomes. For example, given evidence that early use of diabetes devices, including insulin pumps or CGM, relates to improved glycemic outcomes (35), combination of behavioral intervention with introduction of advanced devices at diagnosis may produce stronger, longer lasting changes in glycemic outcomes. Given the relatively high proportion of participants who advanced to higher intervention steps due to the child's HbA_{1c} in this study, such changes may have substantial impacts on how participants move through the steps and on the primary outcome of HbA_{1c}.

The trial's high recruitment and retention (27) and the racial, ethnic, and socioeconomic diversity of the sample relative to other research in type 1 diabetes enhance generalizability of the findings. While the study was not specifically powered to examine any specific covariate or its potential to interact with the intervention or progression through the steps, there was evidence that the chosen covariates (including indicators of race, ethnicity, financial resources, and geographic region) did explain some variability in individual outcomes in the sample. There is consistent evidence of inequities based on lower socioeconomic status and Black, Latinx, and Indigenous race/ethnicity, specifically as people in these groups have less access to advanced diabetes technologies, higher risk for poor glycemic outcomes, and greater future health care utilization (including emergency visits) (36,37). Future iterations may improve the First STEPS intervention with a more nuanced focus on sources of psychosocial functioning concerns and barriers to achieving target HbA_{1c} related to social determinants of health and systematic contributors to health disparities (e.g., disparate health care access, implicit provider bias, and institutional racism) (38,39). Additionally, inclusion of parents who are not fluent in English would increase the intervention's relevance to a broader population.

There were limitations of this study that should be considered in interpreting the results. The primary outcome of HbA_{1c} was assessed locally, not using a central laboratory. It is possible that HbA_{1c} values from the analyzers at each site may have varied from each other or from other sources (e.g., hospitalizations or community laboratories). However, all clinical sites regularly validate the point of care machines and alternate HbA_{1c} sources were uncommon, making systematic inaccuracies unlikely. We did not measure residual pancreatic β-cell activity, which may have limited the precision of our measurement of glycemic outcomes, given the newly diagnosed sample. Additionally, systematically collecting glucose time in range using CGM data would have strengthened our assessment of glycemic change; due to variable CGM use in this sample over the study period, we did not have consistent enough CGM data to calculate time in range (40). This will be important in future trials as CGMs become even more widely used and can provide more precise data about glycemic change. While the study protocol included several strategies to support intervention fidelity (e.g., intervention manuals, training, and frequent supervision and feedback), the measures of fidelity relied largely on parent coaches' and interventionists' self-report; the investigators reviewed a subset of recorded sessions in each step, but there was not an objective measure of intervention fidelity for every intervention contact. Finally, enrolling and retaining a sample that represents the population is important and challenging. Of the 269 families we reached and confirmed eligibility, 80.7% consented, but 58.7% proceeded to randomization. Because we were not able to track demographic data about people who did not consent and most of the loss to follow-up after consent occurred before baseline data were completed, we cannot speculate about differences between these groups. Additionally, this report includes only data from primary caregivers, only 8% of whom identified as fathers, which limits the results largely to the experiences of mothers and female caregivers. Future analyses examining data from secondary caregivers who also completed surveys may shed more light on the experiences of fathers and other caregivers.

In conclusion, shortly following a new diagnosis of type 1 diabetes in young children, peer coaching with intensifications of professional support as needed appears to be worthwhile, with demonstrated benefits for improving parents' depressive symptoms. Mobilizing parents to provide the first stage of this approach and referring to behavioral specialists, psychologists, and educators for targeted additional intervention makes efficient use of limited clinical resources and has high potential for sustained implementation in practice.

Acknowledgments. The authors thank the families who participated in the study, the parent coaches who participated and delivered the intervention for the study, the medical staff

members at both institutions who supported the research activities in the hospital floors and diabetes clinics, and the research staff and collaborators who contributed to the conduct of the study (listed in the Supplementary Appendix online). The authors also appreciate the contributions and support of the study's consultants (Drs. Margaret Grey [Yale School of Nursing], Carlos Grilo [Yale School of Medicine], and Susan Sullivan-Bolyai [University of Massachusetts Medical School]) and members of the Data Safety and Monitoring Board. Kishan Desai (Baylor College of Medicine and Texas Children's Hospital) assisted with formatting the manuscript.

Funding. This work was funded by National Institute of Diabetes and Digestive and Kidney Diseases grant 1R01 DK102561 (principal investigator R.S.). M.E.H. also received complementary support from National Institute of Diabetes and Digestive and Kidney Diseases grant 1K12 DK097696 (principal investigator B. Anderson).

Duality of Interest. No potential conflicts of interest relevant to this article were reported.

Author Contributions. All authors researched data. M.E.H., C.T., T.H., C.H.W., J.R.B., and R.S. wrote the manuscript. M.M., L.C., K.G., W.L., F.C., C.H., and L.K. reviewed and edited the manuscript and contributed to the discussion. R.S. is the guarantor of this work and, as such, had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

References

1. Lawrence JM, Divers J, Isom S, et al.; SEARCH for Diabetes in Youth Study Group. Trends in prevalence of type 1 and type 2 diabetes in children and adolescents in the US, 2001-2017. JAMA 2021;326:717–727
2. Monaghan M, Bryant BL, Inverso H, Moore HR, Streisand R. Young children with type 1 diabetes: recent advances in behavioral research. Curr Diab Rep 2022;22:247–256
3. Monaghan M, Herbert LJ, Wang J, Holmes C, Cogen FR, Streisand R. Mealtime behavior and diabetes-specific parent functioning in young children with type 1 diabetes. Health Psychol 2015;34:794–801
4. Foster NC, Beck RW, Miller KM, et al. State of type 1 diabetes management and outcomes from the T1D Exchange in 2016-2018. Diabetes Technol Ther 2019;21:66–72
5. American Diabetes Association. 13. Children and adolescents: *Standards of Medical Care in Diabetes—2021*. Diabetes Care 2021;44(Suppl. 1):S180–S199
6. Jensen ET, Stafford JM, Saydah S, et al. Increase in prevalence of diabetic ketoacidosis at diagnosis among youth with type 1 diabetes: the SEARCH for Diabetes in Youth Study. Diabetes Care 2021;44:1573–1578
7. Duca LM, Reboussin BA, Pihoker C, et al. Diabetic ketoacidosis at diagnosis of type 1 diabetes and glycemic control over time: the SEARCH for Diabetes in Youth Study. Pediatr Diabetes 2019;20:172–179
8. Cameron FJ, Northam EA, Ryan CM. The effect of type 1 diabetes on the developing brain. Lancet Child Adolesc Health 2019;3:427–436
9. Smaldone A, Ritholz MD. Perceptions of parenting children with type 1 diabetes diagnosed in early childhood. J Pediatr Health Care 2011; 25:87–95
10. Rechenberg K, Grey M, Sadler L. Stress and posttraumatic stress in mothers of children with type 1 diabetes. J Fam Nurs 2017;23:201–225
11. Noser AE, Dai H, Marker AM, et al. Parental depression and diabetes-specific distress after the onset of type 1 diabetes in children. Health Psychol 2019;38:103–112
12. Sullivan-Bolyai S, Lee MM. Parent mentor perspectives on providing social support to empower parents. Diabetes Educ 2011;37:35–43
13. Streisand R, Mackey ER, Elliot BM, et al. Parental anxiety and depression associated with caring for a child newly diagnosed with type 1 diabetes: opportunities for education and counseling. Patient Educ Couns 2008;73: 333–338
14. Whittemore R, Jaser S, Chao A, Jang M, Grey M. Psychological experience of parents of children with type 1 diabetes: a systematic mixed-studies review. Diabetes Educ 2012;38:562–579
15. Hilliard ME, Powell PW, Anderson BJ. Evidence-based behavioral interventions to promote diabetes management in children, adolescents, and families. Am Psychol 2016;71:590–601
16. Sullivan-Bolyai S, Deatrick J, Gruppuso P, Tamborlane W, Grey M. Constant vigilance: mothers' work parenting young children with type 1 diabetes. J Pediatr Nurs 2003;18:21–29
17. Mackey ER, Herbert L, Monaghan M, Cogen F, Wang J, Streisand R. The feasibility of a pilot intervention for parents of young children newly diagnosed with type 1 diabetes. Clin Pract Pediatr Psychol 2016;4:35–50
18. Tully C, Mackey E, Aronow L, et al. Parenting intervention to improve nutrition and physical activity for preschoolers with type 1 diabetes: a feasibility study. J Pediatr Health Care 2018;32: 548–556
19. Monaghan M, Hilliard ME, Cogen FR, Streisand R. Supporting parents of very young children with type 1 diabetes: results from a pilot study. Patient Educ Couns 2011;82:271–274
20. Hilliard ME, Tully C, Monaghan M, Wang J, Streisand R. Design and development of a stepped-care behavioral intervention to support parents of young children newly diagnosed with type 1 diabetes. Contemp Clin Trials 2017;62:1–10
21. Tully C, Clary L, Monaghan M, Levy W, Hilliard ME, Streisand R. Implementation and preliminary feasibility of an individualized, supportive approach to behavioral care for parents of young children newly diagnosed with type 1 diabetes. Cognit Behav Pract 2021;28:293–308
22. Richards DA. Stepped care: a method to deliver increased access to psychological therapies. Can J Psychiatry 2012;57:210–215
23. Firth N, Barkham M, Kellett S. The clinical effectiveness of stepped care systems for depression in working age adults: a systematic review. J Affect Disord 2015;170:119–130
24. Jaehne A, Loessl B, Frick K, Berner M, Hulse G, Balmford J. The efficacy of stepped care models involving psychosocial treatment of alcohol use disorders and nicotine dependence: a systematic review of the literature. Curr Drug Abuse Rev 2012;5:41–51
25. Hill JJ, Kuyken W, Richards DA. Developing stepped care treatment for depression (STEPS): study protocol for a pilot randomised controlled trial. Trials 2014;15:452
26. Harris PA, Taylor R, Minor BL, et al.; REDCap Consortium. The REDCap consortium: building an international community of software platform partners. J Biomed Inform 2019;95:103208
27. Shneider C, Hilliard ME, Monaghan M, et al. Recruiting and retaining parents in behavioral intervention trials: strategies to consider. Contemp Clin Trials 2021;108:106502
28. Tully C, Shneider C, Monaghan M, Hilliard ME, Streisand R. Peer coaching interventions for parents of children with type 1 diabetes. Curr Diab Rep 2017;17:39
29. Radloff LS. The CES-D scale: a self-report depression scale for research in the general population. Appl Psychol Meas 1977;1:385–401
30. Bollen KA, Curran PJ. *Latent Curve Models: A Structural Equation Perspective*. New York, John Wiley & Sons, Inc., 2006
31. Murphy HR, Rayman G, Skinner TC. Psycho-educational interventions for children and young people with type 1 diabetes. Diabet Med 2006;23:935–943
32. Radziszewska B, Richardson JL, Dent CW, Flay BR. Parenting style and adolescent depressive symptoms, smoking, and academic achievement: ethnic, gender, and SES differences. J Behav Med 1996;19:289–305
33. Hilliard ME, Monaghan M, Cogen FR, Streisand R. Parent stress and child behaviour among young children with type 1 diabetes. Child Care Health Dev 2011;37:224–232
34. Candlish J, Teare MD, Cohen J, Bywater T. Statistical design and analysis in trials of proportionate interventions: a systematic review. Trials 2019;20:151
35. Patton SR, Noser AE, Youngkin EM, Majidi S, Clements MA. Improved glycemic control in children with recent-onset type 1 diabetes mellitus. Diabetes Technol Ther 2019;21:379–384
36. Miller KM, Beck RW, Foster NC, Maahs DM. HbA1c levels in type 1 diabetes from early childhood to older adults: a deeper dive into the influence of technology and socioeconomic status on HbA1c in the T1D Exchange Clinic Registry findings. Diabetes Technol Ther 2020;22:645–650
37. Majidi S, Ebekozien O, Noor N, et al. Inequities in health outcomes in children and adults with type 1 diabetes: data from the T1D Exchange Quality Improvement Collaborative. Clin Diabetes 2021;39:278–283
38. Addala A, Hanes S, Naranjo D, Maahs DM, Hood KK. Provider implicit bias impacts pediatric type 1 diabetes technology recommendations in the United States: findings from the Gatekeeper Study. J Diabetes Sci Technol 2021;15:1027–1033
39. Hawkes CP, Lipman TH. Racial disparities in pediatric type 1 diabetes: yet another consequence of structural racism. Pediatrics 2021;148: e2021050333
40. Sinisterra M, Wang CH, Marks BE, et al. Patterns of continuous glucose monitor use in young children throughout the first 18 months following type 1 diabetes diagnosis. Diabetes Technol Ther 2021;23:777–781