Optimizing Recruitment of Black Adolescents into Behavioral Research: A Multi-Center Study

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Abstract

Objectives Adolescents of color are underrepresented in behavioral health research. Study aims were to quantify the amount and types of outreach effort needed to recruit young Black adolescents with type 1 diabetes and their primary caregiver into a clinical trial evaluating a parenting intervention and to determine if degree of recruitment difficulty was related to demographic, diabetes-related, or family characteristics. **Methods** Data were drawn from a multi-center clinical trial. Participants ($N = 155$) were recruited from seven pediatric diabetes clinics. Contact log data were used to quantify both number/type of contacts prior to study enrollment as well as length of time to enrollment. Families were coded as having expedited recruitment (ER) or prolonged recruitment (PR). Baseline study data were used to compare ER and PR families on sociodemographic factors, adolescent diabetes management and health status and family characteristics such as household organization and family conflict. **Results** Mean length of time to recruit was 6.6 months and mean number of recruitment contacts was 10.3. Thirty-nine percent of the sample were characterized as PR. These families required even higher levels of effort (mean of 9.9 months to recruit and 15.4 contacts). There were no significant between-group differences on any baseline variable for ER and PR families, with the exception of family income. **Conclusions** Researchers need to make persistent efforts in order to successfully enroll adolescents of color and their caregivers into clinical trials. Social determinants of health such as family resources may differentiate families with prolonged recruitment within such samples.

Key words: adolescents; diabetes; race/ethnicity; research design and methodology.

Introduction

Increasing participation of underserved populations in clinical trials has been repeatedly identified as a critical goal both by health researchers and US funding agencies such as the National Institutes of Health (Chen et al., 2014). Increasing the inclusion of Black, Indigenous and/or People of Color (BIPOC) in clinical trials improves their scientific robustness by increasing the degree to which they represent the US population, and is also critical to achieving health equity. Barriers to the enrollment of BIPOC have been identified in a number of studies and include both pragmatic barriers (e.g., inability to miss work for enrollment visits, lack of transportation to study site) and interpersonal barriers (e.g., lack of trust in researchers, discomfort with being a “guinea-pig”; Winter et al., 2018). Recruitment of BIPOC youth for participation in clinical trials is hampered by similar barriers (Raphael et al., 2017). However, an additional factor affecting clinical trials focused upon BIPOC youth and families is the required participation by the youth’s caregiver. Moreover, those studies that require a caregiver to actively participate in the study intervention appear to have even lower success rates than those where the intervention is solely youth-focused (Cui et al., 2015).

As noted above, barriers to the recruitment of BIPOC to clinical trials have been extensively reported and a variety of strategies to address such barriers have been proposed. These include developing trusting relationships with potential participants and the community as a whole, promoting cultural competency among recruitment staff, using convenient venues for recruitment and data collection (e.g., home or community sites such as schools), providing flexible scheduling of study visits to accommodate family schedules, monitoring recruitment efforts on a regular basis, using a variety of recruitment strategies (e.g., phone, contacts during clinical care appointments, outreach at community events) and offering compensation for participation (Grape et al., 2018; Hartlieb et al., 2015; Nicholson et al., 2011). However, few if any studies have reported on the level of effort, such as the number of contacts and length of time, needed to effectively recruit BIPOC in general or BIPOC adolescents in particular. For example, Cui et al. (2019) reported on experiences when recruiting low income and BIPOC children and adolescents for obesity prevention and intervention trials. Three of four recruitment centers reported that use of participant tracking databases and/or repeated contacts with potential recruits were among their top three most successful recruitment strategies. However, detailed information regarding how many contacts were needed was not reported. In one of the only studies to quantify the amount and type of contact required to recruit BIPOC youth and their families, Goldman et al. (2018)

reported on their experiences in clinical trials targeting low income, predominantly BIPOC youth with asthma. However, while the study investigated factors related to the level of difficulty experienced when contacting families, the number of contacts needed to enroll those families who were most challenging to recruit was not reported. Overall, more information is needed to inform the efforts of researchers conducting clinical trials with BIPOC adolescents.

Among children with type 1 diabetes (T1D), adolescence is a high-risk period when illness management typically declines, as does glycemic control (Burdick et al., 2004; Drotar et al., 2013; Tamborlane et al., 2008). BIPOC adolescents with T1D are at even higher risk for suboptimal diabetes-related health outcomes than White youth (Redondo et al., 2018; Semenkovich et al., 2019; Willi et al., 2015). Despite this, clinical trials focusing on the development of effective behavioral interventions to promote optimal illness management among BIPOC adolescents with T1D are lacking (Butler et al., 2018; Morone, 2019). The few that have been done were predominantly pilot trials with relatively small samples (Ellis et al., 2019). Moreover, adolescents require significant support and assistance from caregivers to effectively manage their diabetes (Jaser, 2011). Due to the need for family support, clinical trials evaluating illness management interventions among adolescents with T1D have often used family-based intervention approaches that require caregiver participation (Hilliard et al., 2016). However, as noted earlier, recruitment of caregivers of BIPOC adolescents to studies that require active caregiver participation in the intervention components may be particularly challenging.

The aim of this study was to quantify the amount and types of outreach effort needed to recruit and enroll young Black adolescents with T1D and their primary caregiver into a clinical trial aimed at improving illness management and glycemic control via a parenting intervention. A secondary aim was to determine if degree of difficulty in recruiting families was related to demographic, diabetes-related, or family characteristics at the time of study enrollment.

Materials and Methods

Procedures

Data for this study were drawn from a multicenter clinical trial investigating the effectiveness of an eHealth intervention to promote optimal glycemic control in young Black adolescents. The trial was registered in clinicaltrials.gov (registration number NCT03168867). The eHealth intervention was delivered at the time of regularly scheduled diabetes clinic visits and provided parenting advice to the adolescent’s primary caregiver regarding ways to support

adolescent diabetes management. The intervention was offered during a 12-month window; families could receive up to three intervention sessions if they attended all regularly scheduled clinic visits, as standards of care for children with T1D recommend that they are seen for monitoring every 3–4 months ([American Diabetes Association, 2020](#)). A tablet computer was provided by the researchers on which the family completed the intervention while waiting to be seen by their healthcare provider in the clinic.

Intervention content has been described in detail elsewhere ([Ellis et al., 2017](#)). However, in brief, the intervention was based on Motivational Interviewing principles ([Miller & Rollnick, 2002](#)) and encouraged caregivers to use a recommended set of parenting strategies to promote optimal youth diabetes management. It was delivered using Computer Intervention Authoring Software, a flexible, Internet-based interactive software optimized for the delivery of motivational content and which used a life-like, animated narrator that spoke, moved, pointed, and displayed emotional responses as appropriate. The narrator also guided the caregiver through optional goal setting activities related to their parenting behavior. To ensure the cultural relevance and appropriateness of the intervention for Black caregivers, the early intervention development process included review of intervention language by Black pediatric researchers, intervention beta-testing with Black caregivers of adolescents with T1D, and incorporation of videoclips in which psychoeducational content was delivered by a Black endocrinologist and a Black caregiver ([Carcone et al., 2014](#)). Each session lasted ~15 min.

Participants ($N = 155$) were recruited from three pediatric diabetes clinics located in the greater metropolitan Detroit area ($N = 93$) and four located in Chicago ($N = 62$). All clinics were staffed by pediatric endocrinologists and followed American Diabetes Association guidelines for the care of children with diabetes ([American Diabetes Association, 2020](#)). In order to be eligible for the clinical trial, participants had to be 10 through fourteen years of age (due to the intervention's focus on diabetes-related parenting skills, which might have been less relevant for caregivers of older adolescents who are more independent in their diabetes management), be diagnosed with T1D for at least 6 months (to reduce the likelihood that families might still be adjusting to a new diagnosis), self-identify as Black/African American and be residing with a caregiver who was willing to participate in the study. Children with psychiatric diagnoses were not excluded, with the exception of those with moderate or severe cognitive impairment, suicidal ideation or psychosis. Families were also excluded if they were not English speaking, lived too far from the study clinical care site to allow for home-based data collection,

could not complete study measures in English, or if the child had a medical diagnosis leading to atypical diabetes management (e.g., cystic fibrosis). The research was approved by the IRB of the first author's university using a single IRB agreement covering all participating institutions. All participants provided informed consent and/or assent to participate. Baseline data used in this study were obtained at the time of the study enrollment visit, immediately following consent procedures. To accommodate the needs of BIPOC youth and caregivers for flexibility in light of busy schedules and competing life demands, all consent and data collection procedures were conducted in the home at a time convenient to the family, including evening and weekends ([Cui et al., 2019](#)). Families were reimbursed \$50 for each data collection visit.

Recruitment Protocol

All recruitment efforts for the study were conducted by research staff and not by clinicians in the diabetes clinics where adolescents were seen for care. One research team was located in Detroit and the other was located in Chicago. All study staff were trained by study investigators to approach families in a warm, respectful, and culturally sensitive manner throughout the recruitment process.

Data regarding potentially eligible adolescents (based on age, ethnicity, and medical diagnosis) were obtained from the electronic medical records of the participating medical facilities, along with address and phone contact information. Families were first sent an introductory letter describing the study and allowing them to opt-out of any contact by the research team or to call the research team to find out more about the study. After the opt-out period had passed, study staff made phone calls to the adolescent's primary caregiver to provide more information regarding the study, screen interested families for additional eligibility criteria (i.e., adolescent mental health/cognitive exclusions) and schedule a study enrollment visit). Recruitment phone calls were placed at various times of day (morning, afternoon, and evening) and on weekends to optimize the likelihood of contacting the family. In cases where voicemail messages were unreturned, study staff continued to make attempts to contact families by phone until they reached the caregiver and were able to assess interest in study participation. For families where the caregiver could not be reached by phone, recruitment procedures also included clinic drop-ins at the time of scheduled medical visits to make in-person contact. Once determined to be study eligible and interested in participating, each family received a reminder phone call and/or text in the week prior to their enrollment visit. Each type of study contact (introductory letter, phone call, text, and clinic drop-in) was recorded in a log reflecting the contacts

made to each family, the time of day at which the contact was made, and the outcome of the contact (e.g., no answer, left message, caregiver requested a recontact at a later time, disconnected number, family agreed to consent visit, family declined to participate, etc). Contact log data were used to quantify both the number and type of contacts prior to completion of the study enrollment visit as well as the length of time from the first study contact (first recruitment letter sent to the home) to the study enrollment visit. The research team met on a weekly basis to discuss recruitment efforts, review the contact logs and to ensure that families who had not yet been reached were contacted at different times of days, on different days of the week and by different staff members calling from different phone numbers. The study recruitment window lasted ~30 months.

Based on review of medical records, 473 potentially eligible participants were sent a recruitment letter introducing the study. Twenty-three families could not be contacted at any point during the study recruitment window. Eighty-nine families refused study participation either after receiving the letter (by calling and opting out of further contact) or when contacted by phone by study staff. Examples of reasons for study refusals included being too busy, not being interested in receiving a behavioral intervention or participating in research (parent or youth), and planning to change medical provider and therefore not intending to be seen for care at the study clinical care site in the future. 120 families were contacted and found to be ineligible during phone screening based on meeting those study exclusion criteria that could not be determined reliably from the initial medical record review (e.g., comorbid mental health problem or cognitive limitation, not self-identifying as Black, youth not currently residing in the home with the identified caregiver, or residing too far from the study site to allow for home-based data collection). Of the 241 remaining families, 84 never enrolled before the study recruitment window closed and 2 consented but did not complete the baseline data collection. For the present analyses, we included only the 155 families who were study eligible, consented to participate and completed baseline data collection.

Expedited Recruitment Versus Prolonged Recruitment

Following the approach used by [Goldman et al. \(2018\)](#), we characterized families as easier to reach or hardest to reach. However, we adapted these terms and used “expedited recruitment (ER)” or “prolonged recruitment (PR)” in their place to locate responsibility for efforts to optimize enrollment in the clinical trial within the research team. Three criteria were used to identify ER versus PR families. Families who at any point during the recruitment process (a) had a

disconnected/incorrect contact phone number, (b) had a returned recruitment letter due to an incorrect address, or (c) no-showed for their scheduled study enrollment visit were coded as PR. The remaining families were coded as ER. There was no significant difference in percentage of participants who were coded as PR versus ER at the Chicago recruitment site (PR = 37%, ER = 63%) as compared with the Detroit recruitment site (PR = 40%, ER = 60%).

Measures

Sociodemographic and Medical Variables

A self-report questionnaire was used to obtain information from the adolescent’s primary caregiver on demographic variables, including number of parents/caregivers in the home, caregiver age, annual family income from all sources, and caregiver education. Caregivers were provided with a list of ten income categories and chose the one that reflected their annual family income. For each category, the midpoint was used in the analyses to represent the income range. Caregiver education and family income served as measures of socioeconomic status (SES), as both are commonly used for this purpose ([Kachmar et al., 2019](#)). Primary caregivers who reported that they were married or living with a partner were coded as two-parent families; all others were considered single-parent families. The adolescent’s medical chart was reviewed to obtain information such as duration of diabetes.

Diabetes-Related Family Conflict

The revised Diabetes Family Conflict Scale (DFCS; [Hood et al., 2007](#)) was used to evaluate family conflict associated with adolescent diabetes management. The DFCS is a 19-item questionnaire; conflict is rated on a 3-point scale (1 = never argue, 2 = sometimes argue, and 3 = always argue), with higher scores indicative of greater conflict. The measure has previously been used in multi-ethnic samples of adolescents with T1D with high reliability ([Semenkovich et al., 2019](#)). The parent-report version of the DFCS was used in this study.

Family Organization

The Confusion, Hubbub and Order scale (CHAOS; [Matheny et al., 1995](#)) is a parent-report measure of environmental confusion and disorganization in the family, including items on noisiness, routines and orderliness. Primary caregivers responded to six items on a 1–4 scale 1 (*very much like my house*) to 4 (*very unlike my house*). Higher scores indicate higher levels of organization. It has previously been validated for use in diverse samples, including Black families ([Dumas et al., 2005](#)).

Diabetes Management

The Diabetes Management Scale (DMS; Schilling et al., 2002) is a self-report questionnaire. It is designed to measure a broad range of diabetes management behaviors, such as insulin management, dietary management, blood glucose monitoring, and symptom response. Each item asks “What percent of the time do you (take your insulin)?” The response scale is 0–100%. A total score is obtained by calculating the mean response to all items to reflect overall management behavior; higher scores indicate higher levels of diabetes management. The measure has previously been shown to be reliably in samples that included predominantly Black adolescents with T1D (Naar-King et al, 2006). The caregiver-report version of the DMS was used in this study in order to capture the effects of primary caregiver’s perceptions of the adolescent’s diabetes management on study enrollment (e.g., caregivers who perceived their adolescent was not managing their diabetes well might be easier to recruit).

Glycemic Control

Hemoglobin A1c (HbA1c), a retrospective measure of average blood glucose during the past 2–3 months, was used to evaluate glycemic control. Values were obtained during data collection visits using the Accubase test kit, which is FDA approved. High-performance liquid chromatography is used to analyze the blood sample.

Statistical Analyses

Analyses were conducted using SPSS version 26.0. A small amount of data (one CHAOS questionnaire, three HbA1c values, representing <1.0% of the total), were missing. These data were imputed using the missing values analysis module in SPSS. Independent t-tests were used to compare the number of contact attempts (letter, phone, and texts) and length of time needed to recruit for the ER and PR groups. The rate of contacts per month was also calculated to determine if differences in length of time to recruit accounted for any differences in number of contacts between ER/PR families. Bivariate analyses (t- and chi-square tests) were also used to test for differences between ER and PR groups on demographic variables (caregiver age and education, number of caregivers in the home, and family income) clinical variables related to diabetes (length of diagnosis with diabetes, adolescent illness management, and glycemic control), and family characteristics (diabetes-related family conflict and level of organization within the home). A secondary analysis was also conducted using multiple regression to predict time to recruitment from the same demographic, clinical and family variables and including all participants in the sample regardless of their recruitment

Table 1. Demographic Characteristics of Youth and Primary Caregivers (N = 155)

Variable	Mean $\pm$ SD or N (%)
Child age (years)	13.4 $\pm$ 1.7
Child gender	
Male	67 (43)
Female	88 (57)
Child ethnicity	
African American	142 (92)
Other	13 (8)
Duration of diabetes (years)	5.8 $\pm$ 3.8
HbA1c	
%	11.5 $\pm$ 2.7
mmol/mol	102 $\pm$ 29.2
Insulin regimen	
Basal bolus therapy-injection	103 (67)
Basal bolus therapy-pump	42 (27)
Other	10 (6)
Recruitment site	
Detroit	93 (60)
Chicago	62 (40)
Caregiver age (years)	42.2 $\pm$ 8.6
Caregiver gender	
Female	139 (90)
Male	16 (10)
Caregiver ethnicity	
Black	145 (94)
Other	10 (6)
Caregiver education (years)	13.4 $\pm$ 2.3
Number of caregivers in the home	
Two	77 (50)
One	78 (50)
Yearly family income in US dollars	35,342 $\pm$ 26,516

(ER/PR) status. In this regression equation, the dependent variable (time to recruitment in days) was entered as a continuous variable.

Results

Sample demographics are shown in Table 1. Mean adolescent age was 13.7 years (SD = 1.7) and mean caregiver age was 42.2 years (SD = 8.6). Mean length of diagnosis with T1D was 5.8 years (SD = 3.8). Median yearly family income was \$25,000, corresponding to ~95% of the US 2020 poverty line for a family of four ($M = \$35,342$, $SD = \$26,516$, range = \$5,000–\$105,000). Mean HbA1c was 11.5% (SD = 2.7%), suggesting that the sample’s glycemic control was outside of the recommended range, as guidelines are for HbA1c to be maintained at or below 7.0% in adolescents (American Diabetes Association, 2020). The glycemic control demonstrated in the present sample is also consistent with known disparities in health outcomes for Black adolescents with T1D (Redondo et al., 2018; Semenkovich et al., 2019). For example, the mean HbA1c of Black youth in the T1D Exchange was reported to be 9.6% (Willi et al., 2015) and was reported to be 12.5% in a study focusing on health

Table II. Comparison of Families with Expedited Recruitment (ER) Versus Prolonged Recruitment (PR) on Number of Contacts and Length of Time to Recruit

Variable	ER (N = 95)			PR (N = 60)			<i>t</i>	<i>p</i>	Cohen's <i>d</i>
	<i>M</i>	<i>SD</i>	Range	<i>M</i>	<i>SD</i>	Range			
Letters	1.1	0.4	1.0–4.0	1.3	0.5	1.0–3.0	–1.59	.114	–0.45
Phone calls	5.5	8.0	0.0–50.0	11.8	11.29	1.0–52.0	–4.17	.000	–0.67
Text messages	0.4	0.9	0.0–4.0	1.1	2.4	0.0–12.0	–2.79	.001	–0.42
Clinic drop-ins	0.0	0.1	0.0–1.0	0.4	0.7	0.0–3.0	–5.14	.000	–0.91
Total contacts	7.0	8.2	1.0–52.0	15.4	12.3	2.0–54.0	–5.06	.000	–0.84
Time to recruitment (months)	4.6	4.5	0.7–24.8	9.9	2.12	1.0–25.4	6.01	.000	–1.41
Contacts/month	2.0	1.7	0.3–11.7	1.8	1.0	0.4–5.0	0.09	.366	0.14

Table III. Comparison of Families with Expedited Recruitment (ER) Versus Prolonged Recruitment (PR) on Demographic, Clinical and Family Variables

Variable	ER (N = 95)			PR (N = 60)			<i>t</i>	<i>p</i>	Cohen's <i>d</i>
	<i>M</i>	<i>SD</i>	Range	<i>M</i>	<i>SD</i>	Range			
Caregiver age	42.5	8.2	29.2–75.1	41.7	9.3	25.8–66.3	0.61	.546	0.09
Caregiver education (years)	13.6	2.4	6.0–22.0	13.1	2.0	8.0–20.0	–1.56	.121	0.22
Annual family income (USD)	39,593	27,969	5,000–105,000	28,611	22,665	5,000–105,000	2.56	.012	0.42
Length of diabetes diagnosis (years)	5.5	3.9	0.7–14.1	6.4	3.6	0.0–3.0	–1.30	.195	–0.24
DMS	74.4	14.2	33.0–100.0	73.4	14.3	2.0–54.0	0.44	.663	0.07
HbA1c (%)	11.2	2.8	6.7–18.2	11.8	2.5	5.3–17.2	–1.28	.204	–0.22
DFCS	31.6	7.8	19.0–54.0	33.1	7.9	19.0–53.0	–1.14	.258	–0.19
CHAOS	3.0	0.5	1.8–4.0	2.9	0.5	1.8–4.0	0.52	.603	0.20

outcomes in Black youth with diabetes conducted in two large urban areas (Chalew et al., 2000).

Thirty-nine percent of families in the sample ($N = 60$) were characterized as PR. Recruitment contacts and mean length of time to recruit for the ER and PR groups are shown in Table II. Across all families in the study, the mean number of total recruitment contacts was 10.3 per family ($SD = 10.8$, range = 1.0–54.0). Number of phone calls ($t = -4.47$, $p < .001$), text messages ($t = -2.79$, $p < .01$), and clinic drop-ins ($t = -5.15$, $p < .001$) differed significantly between the ER and PR groups. ER families required 7.0 contacts on average ($SD = 8.2$) whereas PR families required 15.4 contacts on average ($SD = 12.3$) ($t = -5.06$, $p < .001$). Almost no ER family received a clinic drop-in visit, while on average 40% of PR families received one. Across all families, the mean length of time to recruit was 6.6 months ($SD = 5.9$, range = 0.7–25.3). ER families took 4.6 months on average to recruit while PR families took 9.9 months ($t = -6.01$, $p < .001$).

Results of the comparisons between ER and PR families on demographic, diabetes-related and family variables are shown in Table III. There were no significant between-group differences of any variable with the exception of family income ($t = 2.56$, $p = .012$). ER families had a mean family income of \$39,107 ($SD = \$28,328$) while PR families had a mean family income of \$26,005 ($SD = \$23,150$). Number of

caregivers in the home (single vs. two) has previously shown to be related to glycemic control and other factors that might affect study recruitment (Frey et al., 2007); number of caregivers has also been shown to be related to family income in samples of youth with T1D (Thompson et al., 2001). In order to rule out that number of parents in the home accounted for the relationship between family income and recruitment status, we also compared the number of single and two caregiver families within the ER and PR groups. However, chi-square analyses indicated no significant differences (ER single-caregiver $N = 46$, two-caregiver $N = 48$; PR single-caregiver $N = 30$, two-caregiver $N = 29$; $X^2 = 0.05$, n.s.) As only the family income variable was significantly different between the ER and PR groups, multivariate analyses were not conducted.

The secondary analyses using multiple regression to predict time to recruitment resulted in similar findings; none of the demographic, diabetes related or family variables, including family income were significantly associated with the dependent variable and the overall equation was not significant ($F [8, 139] = 0.506$, n.s., $R^2 = .03$).

Discussion

The aims of this study were to describe the amount and types of outreach contacts needed to recruit young

Black adolescents and their primary caregiver into a clinical trial and to determine whether families who had a PR period differed in consistent ways from those who did not. Although factors related to lower recruitment rates of BIPOC children and adolescents into clinical trials have been described (Flores et al., 2017), data regarding the specific types and amount of contact needed for success are limited. Such information is critical for researchers working with BIPOC adolescents so they may plan appropriately for sufficient study staffing. Goldman et al. (2018) also note that researchers may fear that repeated contacts will be perceived as bothersome or intrusive by families who are the target of recruitment efforts; these types of concerns can be effectively addressed when studies demonstrate that repeated efforts to contact families in fact result in successful enrollment rather than negative interactions with potential participants.

Findings from this study highlight the importance of persistence in reaching out to Black families to make contact, as the mean length of the recruitment period prior to study enrollment was 6 and a half months, and ten contact attempts of varying types were required per family on average. Families with a PR period, who comprised ~40% of the sample, required almost 10 months to recruit on average and up to 54 total contacts prior to enrollment. Families were contacted on average approximately twice a month; however, these data did not allow a more fine-grained analysis of contact frequency at different points in time relative to the date of enrollment. Differences between ER and PR families regarding the number of contacts needed to enroll were primarily explained by the differences in length of time to enroll in the study, as the rate of contacts per month was not significantly different. However, with regard to types of contacts, almost no ER family required a drop-in visit by research staff during scheduled diabetes clinic appointments, while almost 40% of PR families did so. Although this difference is not surprising given that we partially defined the PR category based on encountering a disconnected phone number at any point during recruitment, it still highlights in-person contacts as an effective approach for those who were difficult to contact. Drop-in clinic visits allowed study staff to provide personalized information regarding the study, address any reservations on the part of families, and ultimately increase the rate of successful enrollment. Anecdotally, recruitment staff did not report experiencing negative interpersonal reactions from families during these recruitment visits. Such visits also allowed staff to better determine if lack of ability to contact the family by phone reflected family disinterest in participating, since they were able to present detailed information about the study and obtain feedback. If participants then verbalized lack of interest in

participating in the study during the face to face interaction, staff were able to refocus their efforts on those who might wish to enroll. It is also important to note that although persistence in contacting families was a significant component of study success, staff were trained to be respectful of any verbalization from a caregiver or youth that they did not wish to participate and to carefully document this so that additional contacts would not be made to those who refused participation.

Using a variety of types of contact approaches (US mail, phone calls, texts, and in person) also ensured that a range of formats were utilized to communicate with families regarding with study, which has previously been shown to increase successful recruitment of BIPOC youth (Mendelson et al., 2020). Regular review of call logs to ensure that study staff were calling outside of normal business hours and at varying times of day in order to reach caregivers who worked outside the home, did not work a 9:00 to 5:00 schedule, and/or had work schedules that varied from week to week may also have increased recruitment success.

Indicators of SES have previously been shown to predict participation in clinical trials within multi-ethnic samples of children (Robinson et al., 2016) where the separate effects of ethnicity and SES are more difficult to disentangle. Our study suggested that even within a low-income sample of Black families, family income may be related to the degree of difficulty associated with recruiting families, although this finding was not consistent. The lowest income families may have other characteristics associated with recruitment challenges. Income may have been a proxy variable for social determinants of health such as unstable housing resulting in frequent changes of address and home phone numbers, inability to pay utility bills (cellular phones) or other factors related to recruitment. Other variables, including caregiver education, number of caregivers in the home, adolescent diabetes management and health status, and family characteristics such as level of household organization and conflict related to diabetes did not distinguish between families who had ER or PR.

Findings from this study address only the recruitment of BIPOC youth and families; however, ensuring adequate retention in clinical trials is an equally important endeavor, as differential attrition from study arms can jeopardize the internal validity of such studies and high rates of missing data can likewise call study results into question (Little et al., 2012). The limited number of studies reporting on number of contacts suggests that high levels of contact by researchers are also critical to the retention of BIPOC youth and families in clinical trials (Goldman et al., 2018) but additional studies to replicate such findings are warranted. More standardized definition of terms such as

“retention” is also needed to advance the field in this area (Robinson et al, 2016). Differing approaches to operationalization of this term can occur because patterns of missed study visits can vary substantially; for example, families may drop out early and miss all subsequent study follow-up visits or may initially appear to be lost to follow-up but later be located and complete subsequent study visits.

Limitations of the study include the fact that recruitment efforts were also directed toward families who were contacted but deemed study ineligible upon further screening. Likewise, a subset of families neither enrolled in the study nor declined to participate. Efforts directed toward the recruitment of these families were not captured in the current analyses, which focused only on characteristics of those who enrolled. Whether these families differed systematically from those who were enrolled is unknown. In addition, only families with T1D whose adolescents were currently attending a pediatric diabetes clinic were included in this study, as the intervention being tested in the parent clinical trial was delivered in a clinic setting. Although the standards of care for pediatric T1D include regular visits to a tertiary care setting (American Diabetes Association, 2020), findings are not representative of adolescents only receiving care from pediatricians or other primary care physicians or who are disengaged from medical care. Finally, study findings cannot be generalized to adolescents with T1D from other ethnic or racial backgrounds such as Latino/a youth or to Black youth living in rural areas or areas outside of the northern USA.

In summary, researchers need to make persistent yet targeted efforts in order to successfully enroll BIPOC adolescents into clinical trials, including youth with chronic health conditions. Careful documentation of recruitment efforts is also warranted in order to add to the body of knowledge regarding effective recruitment strategies for enrolling BIPOC youth with chronic health conditions in clinical trials. Additional research to develop and evaluate culturally tailored recruitment materials for use in studies with BIPOC families is also warranted. Such efforts are also needed not only to improve the representativeness of samples enrolled in such studies but to ensure that effective behavioral interventions are provided to those high-risk adolescents most in need of services. Increasing participation of BIPOC adolescents in clinical trials is critical to ensuring trial robustness and to improving health equity.

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