



## Two-step recruitment process optimizes retention in FLEX clinical trial

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### ABSTRACT

**Introduction:** The Flexible Lifestyle Empowering Change Study (FLEX) is a multi-site randomized controlled trial to test the efficacy of an adaptive behavioral intervention to promote self-management and improve glycemic control for adolescents with type 1 diabetes mellitus. A two-step recruitment process was used to optimize study retention by facilitating informed decision-making regarding participation.

**Methods:** Those who expressed interest at first contact were given more detailed study information followed by telephone calls to the adolescents and their parents to answer questions and explore potential barriers to participation before making a decision regarding study enrollment.

**Results:** Of 694 eligible adolescents who were invited to participate, 397 (57.2%) expressed interest when initially contacted (Step 1). Upon completion of the follow-up telephone calls (Step 2), 276 (39.8%) still agreed to participate; and 258 (37.2%) enrolled and completed a baseline visit with a parent/guardian. Completion rates for measurement visits remained high throughout the study, with an end-of-study retention rate of 93.4%; and only 12 (4.7%) families withdrew from the study.

**Conclusion:** The two-step recruitment process encourages potential participants to thoughtfully evaluate their willingness to participate, as well as their ability to make a commitment to the full completion of study requirements. When demonstrating the efficacy of a randomized controlled trial, it may be preferable to accept lower recruitment rates in order to optimize retention rates. The additional time and effort required to implement this two-step process is worthwhile. With a high retention rate, we can be more confident that the outcomes of the randomized controlled trial actually reflect the impact of the intervention.

### 1. Introduction

Recruitment and retention are challenging aspects of clinical trial management and these rates vary widely from one study to another [1–3]. Stein et al. conducted focus groups and key informant interviews with investigators, coordinators, and other stakeholders in clinical and translational research (n = 32 individuals) and found that only 41% of the respondents successfully met recruitment goals. For studies that were closed, only 24% actually met their targeted recruitment goals

[4]. Additionally, in a survey of pediatric clinical trials conducted by the Child Health Outcomes Committee of the Clinical and Translational Science Awards, over 42% of the projects closed without meeting recruitment targets [4].

Marcellus conducted a review of retention rates for research studies involving children and adolescents. She found reported retention rates from 30 to 95% [5]. Although there is no absolute standard for acceptable attrition rates, bias in study results can be expected when attrition rates exceed 20% [6]. Eccleston et al.'s review of trials involving

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**Table 1**  
Measurements obtained at visits.

	Baseline	3 month	6 month	12 month	18 month
Fasting blood sample, followed by breakfast	X		X		X
Non-fasting blood sample		X		X	
Ht., wt., waist, B/P	X		X		X
Surveys & interviews	X	X	X	X	X
Continuous glucose monitor (CGM) for 7 days	X		X		X
Two 24-h diet & physical activity recalls	X		X		
Length of visit	2 h	30 min.	2 h	30 min.	2 h
Incentives - adolescent	\$120	\$50	\$200	\$50	\$250
	\$75 – CGM		\$75 – CGM		
	\$25 – recalls		\$25 – recalls		
Incentives - parent	\$20	\$20	\$20	\$20	\$20

psychological therapies in pediatric chronic illness included 13 focused on adolescents with type 1 diabetes. Rates of study completion ranged from 55% to 100% with an overall average completion rate of 82% [7].

Studies examining strategies for retaining participants usually focus on strategies implemented *after* participants agreed to enroll in the study [8–12]. Few studies exist on how to assist potential participants to make informed decisions about participating in a study *before* they enroll in the study [13].

Goldberg & Kiernan describe a novel two-step recruitment approach to improve retention rates in a randomized controlled trial of overweight and obese men and women aimed at modifying behaviors to lose weight. Specifically, individuals who were eligible to participate after a phone and mail screening were then invited to attend an interactive group-based orientation session prior to the baseline visit and randomization. These 1-h sessions were led by the principal investigator, incorporating motivational interviewing techniques. Demands of joining a randomized controlled trial, making eating and activity changes, and weight-loss expectations were addressed. Participants were encouraged to consider all pros and cons of joining the intervention and to recognize that they would be making two commitments – one to themselves and one to ensure the trial's scientific quality. Of the 72 potential participants who attended an orientation session, 51 participants (71%) completed the baseline visit and were randomized. Retention was high, with a 96% completion rate for 18-month visits [13]. This approach inspired the present study team to develop a modified, less time-intensive two-step recruitment process for the behavioral intervention described in this paper.

## 2. Description of study

Type 1 diabetes is a challenging disease that requires constant vigilance to achieve optimal glycemic goals. Daily management includes a continuous insulin infusion or multiple insulin injections, continuous glucose monitoring or at least four finger sticks per day, and frequent treatment adjustments based on food intake, exercise, illnesses and other stressors [14]. The American Diabetes Association's recommendation of HbA1c < 7.5% [15,16] is not achieved by most adolescents despite the development of behavioral interventions aimed at improving HbA1c [17–22].

The Flexible Lifestyle Empowering Change Study (FLEX) is a multi-site randomized controlled trial to test the efficacy of an adaptive behavioral intervention to promote self-management and improve the achievement of glycemic goals for adolescents with type 1 diabetes. The FLEX intervention uses both motivational interviewing to create a motivational framework [23] and problem-solving skills training to teach practical problem-solving tailored to the context and needs of adolescents and their parents [18].

### 2.1. Study participants: Inclusion and exclusion criteria

Study participants were adolescents 13–16 years of age with type 1

diabetes for at least one year, with most recent clinical HbA1c levels between 8.0% and 13.0% (i.e., not meeting glycemic goal of < 7.5%). At least one parent/guardian who was involved in the adolescent's diabetes management needed to be willing to participate. Adolescents were excluded from participating if they were pregnant; had not been seen for diabetes care within the past year; or had a pre-existing chronic disease that precluded their participation in the intervention, such as an uncontrolled psychiatric condition, drug abuse, cancer, or severe developmental delay. Adolescents were *not* excluded for well-controlled depression or other conditions such as asthma or attention-deficit/hyperactivity disorder.

### 2.2. Design and procedures

Participants were randomly assigned to one of two groups: intervention or usual care. Adolescents and parents/guardians who were randomized to the intervention group met with certified diabetes educators on a regular basis over a period of 18 months. These educators acted as “coaches”, using motivational interviewing and problem-solving skills training as the basis for the intervention sessions. The primary aim of the study was to improve HbA1c. The frequency and length of the sessions were determined by adaptive rules that were based on the changes in HbA1c values over the course of the study [24].

Participants and parents/guardians completed standardized baseline and follow-up measurement visits at 3, 6, 12, and 18 months after the baseline visit. See Table 1 for a summary of measurements obtained at baseline and each of the follow-up visits.

Written consent and assent were obtained at the first in-person baseline measurement visit. IRB approval was acquired at each participating site; and the study was registered with <https://clinicaltrials.gov/>. A more complete description of the study design, measurement visits, intervention condition, adaptive rules for change in HbA1c, and “coach” training has been published elsewhere [24].

## 3. Two-step recruitment process

To optimize participant retention in the FLEX study, our goal was to guide both adolescents and their parents in their decision-making process to help them evaluate, not only their desire to participate in a study, but also their ability to meet study requirements throughout the study. Therefore, this novel two-step recruitment process, as well as its success in achieving high levels of retention rates throughout the study, is described.

Given our end-of-study sample size requirement of 200, we established an enrollment goal of 250. This goal allowed for a potential retention rate of 80%. Preliminary medical record queries at two major tertiary pediatric centers in the Mountain West and Midwest were used to identify patients who met the study criteria, yielding a pool of approximately 900 potentially eligible patients.

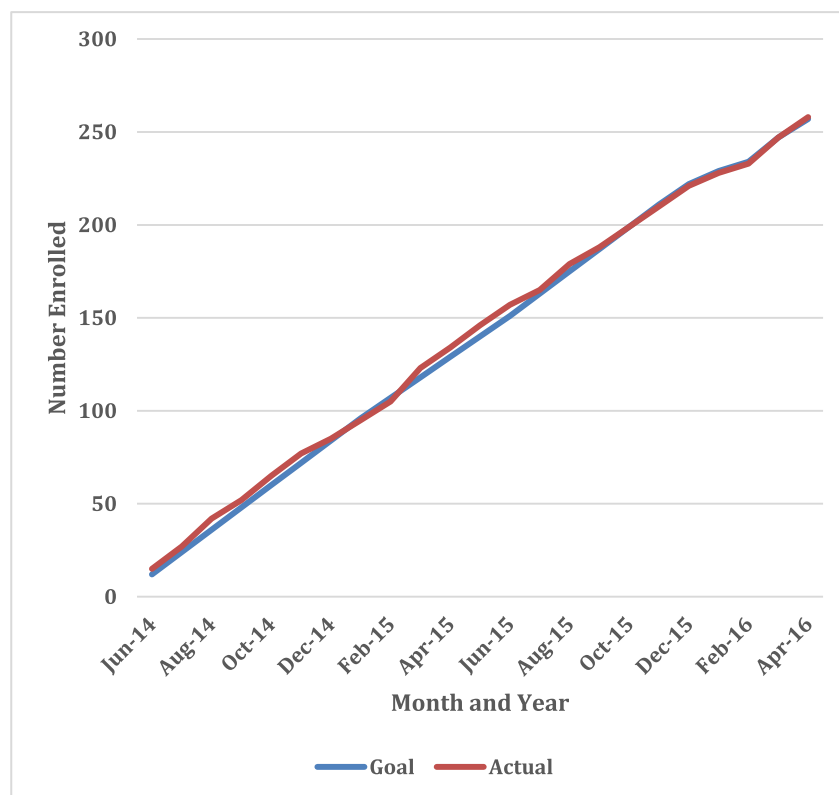


Fig. 1. Enrollment goals and actual enrollment by month and year.

### 3.1. Step one

#### 3.1.1. Identify potential patients to invite to participate

Because the intervention arm of this study involved regularly-scheduled meetings with one of three study “coaches,” the goal was to steadily recruit participants throughout the recruitment period to maintain a relatively even workload for the coaches. Recruitment was limited so that each coach had approximately 4 baseline visits per month for a period of 21 months to reach our recruitment target of 250. About 35-40 adolescents were invited to participate per month. These potential participants were randomly selected from the initial eligibility query. See Fig. 1 for enrollment goals and actual enrollment by month.

After potential participants were identified, each medical record was reviewed to confirm eligibility based on exclusion criteria and any new HbA1c results since the initial query. Letters were then mailed to the parents/guardians of each eligible adolescent introducing FLEX and inviting the adolescent and parent to participate in the study. FLEX brochures and information sheets outlining study goals and requirements for participation were included. Letters also included information about the FLEX study website.

Study posters and handouts were made available in the diabetes clinics of both study sites. In some cases, adolescents and parents initiated the first contact with study personnel or they were referred to the study by a diabetes provider during a clinic visit. Researchers followed the same recruitment process for these patients, beginning with a medical record review for confirmation of eligibility and handing out study materials that were normally included in the introductory mailings.

#### 3.1.2. Follow-up on invitation letters

Research staff members followed up by telephoning potential participants 1–2 weeks after the invitation letters had been mailed or by meeting adolescents and parents in the diabetes clinic in conjunction with their clinical visits. The main goal of this follow-up contact was to

answer any questions adolescents and parents/guardians might have and to provide additional information as needed. Potential participants were then asked if they would be interested in participating. Those who declined were thanked for their time and no further recruitment efforts were attempted.

### 3.2. Step two

#### 3.2.1. Additional study information to those interested in participating

Those who expressed interest in participating were given packets of additional information, either in-person or via mail or email. These packets included information regarding the purpose of the study and potential benefits to participation, measurement visit requirements and location options, time commitments, an explanation of randomization into one of two groups, description of coaching sessions for those who are randomized to the intervention arm, importance of following through with study requirements, and a summary of compensation for adolescents and parents upon completion of measurement visit requirements. Also included in the information packet was a list of questions for adolescents and parents to consider before deciding whether or not to participate. These questions encouraged adolescents and parents to think about how they might feel about participating in a research study and about being randomly assigned to either one of the two groups. They also prompted potential participants to consider possible barriers to participation, such as sports, school activities, or job responsibilities.

#### 3.2.2. Follow-up phone call with parent and adolescent

An appointment for a study staff member to complete a follow-up telephone call was then scheduled with both the adolescent and the parent. They were encouraged to write down their concerns or questions and have a discussion about their thoughts and feelings with one another prior to this scheduled telephone call with the researcher.

The goal of Step 2 was to facilitate the adolescent and the parent in

making informed decisions regarding whether or not they wished to participate in the study. For this step of the recruitment process, study personnel had two separate conversations, one with the adolescent alone and the other with the parent/guardian alone, because full study participation required a commitment from each. The study staff member began Step 2 by telephoning the parent at the pre-arranged time. The researcher asked if the parent/guardian and the adolescent had a chance to review the study information. If so, the researcher began by inquiring about and answering any questions. Then the researcher asked the parent/guardian to explain in their own words the purpose of the study and what participants would be asked to do. This gave the staff member an opportunity to identify and address any gaps in knowledge, as well as possible misunderstandings. After reviewing study information as needed, the researcher then asked the parent/guardian about any additional questions they might have, as well as any barriers to participation they may have identified. Researchers reviewed the study in detail, explained that participants would be randomly assigned to either the intervention group or the control group with a 50-50 chance of being assigned to either group, and encouraged an open discussion of any concerns or potential barriers to facilitate thoughtful consideration of all aspects of the study requirements before making a commitment to participate in the study. After any barriers or concerns were discussed, the researcher then asked if the parent/guardian was still interested in participating. Those who declined were thanked for their time and no further recruitment efforts were attempted. If the parent/guardian remained interested in participating, the researcher scheduled an appointment for the in-person baseline visit.

The researcher then requested to speak with the adolescent who was asked if they had a chance to review the study information and answered any questions about the study purpose and participation. Staff members followed a format with the adolescent that was similar to that used with the parent discussion; emphasizing that participation was totally voluntary and encouraging adolescents to make their own decisions regarding participation. If the adolescent remained interested in participating, the researcher reviewed the scheduled baseline appointment date to verify their availability. Step 2 conversations with parents usually lasted 10–15 min, while adolescent discussions were 5–10 min.

Typically, recruitment took approximately seven weeks from the initial introductory mailing to the participant's commitment to enroll in the study and schedule the baseline visit. Step 1 took about three weeks (from introductory mailing to completion of follow-up telephone call); Step 2 took about four weeks (from mailing of additional study information packet to scheduling an appointment for the baseline visit).

#### 4. Other strategies to maximize retention

A number of additional strategies were used to maximize retention after enrollment. Scheduling of measurement visits was flexible and occurred Monday through Saturday and visits were combined with diabetes clinic appointments whenever possible. Major measurement visits at baseline, 6, and 18 months were scheduled in the morning because participants were fasting, but minor measurement visits at 3 and 12 months could be scheduled later in the day, including after-school hours. Satellite locations, and occasional home visits, were offered to participants. Free parking was available for all visits and coaching sessions. Participants had the option to complete study questionnaires electronically on the study website or on paper. They were encouraged to complete the questionnaires prior to the measurement visit to reduce the length of the visit. Adolescents were given breakfast or snacks after the fasting blood samples were drawn at the major measurement visits; and bottled water was offered to participants and parents at all visits. Research staff elicited feedback from adolescents and parents about their research experience at each measurement visit. Comments and suggestions were discussed in local staff meetings to identify ways to improve the research experience for participants.

Participants and their parents/guardians were mailed instructions about their upcoming measurement visits 2–3 weeks before each visit. Staff members also contacted participants by telephone, text, or email 1–3 days prior to each visit to remind them of the appointment date and time and to answer any questions they might have. Contact information was confirmed/updated at each measurement visit. A tracking database was used to record all participant communications and to document any relevant family concerns or difficulties with participation.

Upon completion of each measurement visit, adolescents and parents in both arms of the study received monetary incentives as outlined in Table 1. Study team members mailed personalized holiday and birthday cards to participants with hand-written signatures. Birthday cards included a \$10 gift card. Participants were also given small prizes, such as ear buds. No incentives were given for participation in intervention activities; however, efforts were made to be as flexible as possible when scheduling these sessions, as well. In some cases, telehealth options were offered to participants who were unable to come for in-person coaching visits.

## 5. Results

### 5.1. Recruitment

Based on medical record queries, 855 eligible participants were mailed introductory letters; 161 (18.8%) of these were later determined to be ineligible. The primary reason for ineligibility was an HbA1c value that was in the range of 8–13% at the time the introductory letter was mailed, but then moved out of that range before the participant enrolled in the study. Near the end of recruitment, there were 20 participants who were “in process” when the recruitment target was met and enrollment was halted before they were able to enroll in the study.

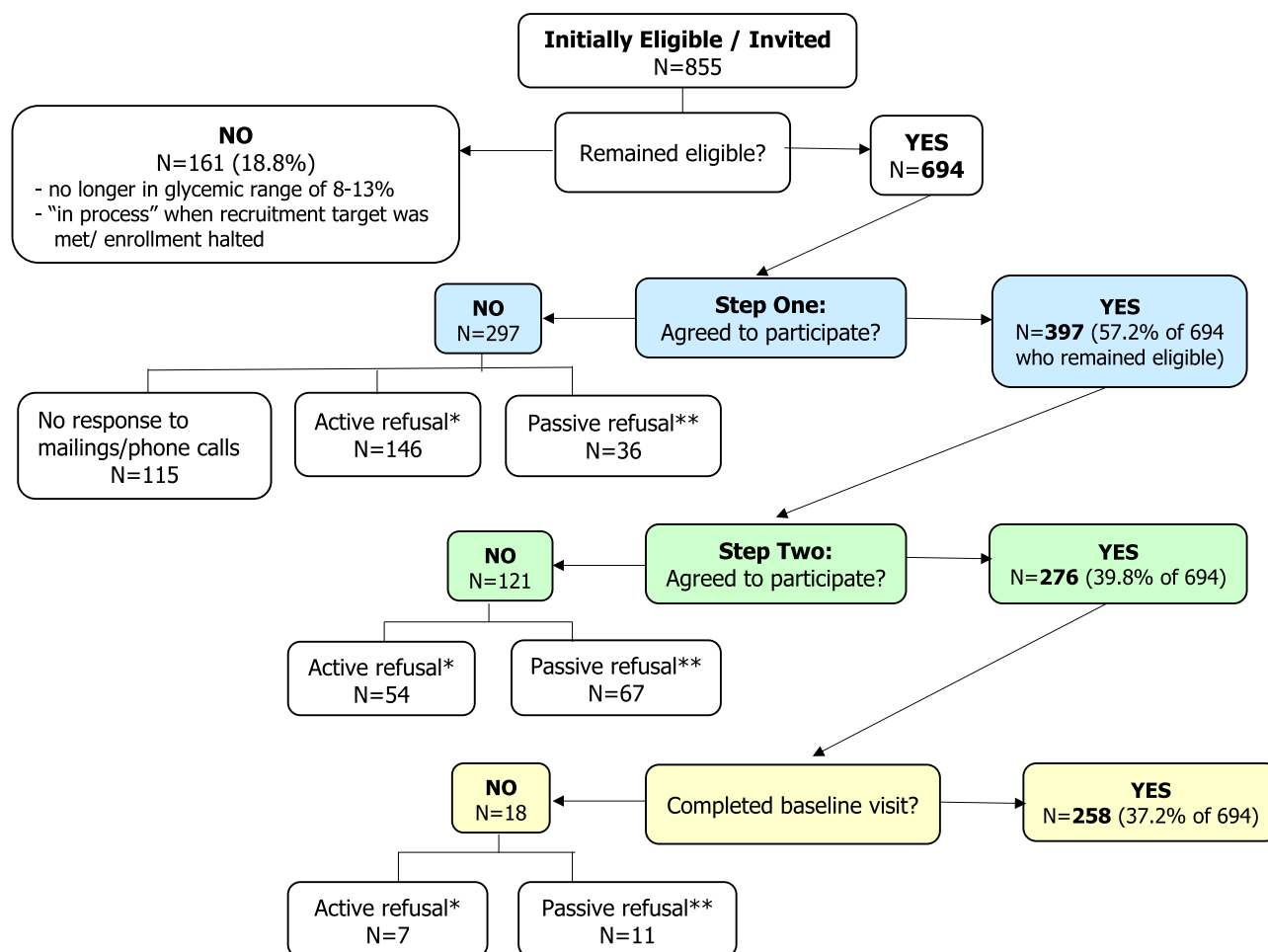
Of the remaining 694 potentially eligible participants who were invited to participate in the study, 115 did not respond to mailings or follow-up phone calls and a total of 182 eligible participants refused during the initial follow-up of study invitations (Step 1 of the recruitment process), resulting in an initial recruitment rate of 57.2%. An additional 139 refused during or after Step 2 of the recruitment process, resulting in a final recruitment rate of 37.2% adolescents who completed a baseline visit with a parent/guardian.

Those who did not enroll in the study were classified as “no response” ( $n = 115$ ) or declined to participate ( $n = 321$ ). See Fig. 2 for a detailed breakdown of recruitment outcomes.

Adolescents classified as no response were those who did not respond to mailings, emails, or phone calls and thus, no verbal contact was made with them. Those who declined to participate were classified as either active or passive refusals. Active refusals were adolescents and parents who verbally declined participation, while passive refusals included adolescents and parents who initially expressed interest verbally, but did not follow through with participation requirements. Active refusals ( $n = 207$ ) occurred during Step 1 ( $n = 146$ ), Step 2 ( $n = 54$ ), or after completing Step 2, but before the baseline visit ( $n = 7$ ). Common reasons for declining to participate were treatment burden and travel distance. Passive refusals ( $n = 114$ ) also occurred during Step 1 ( $n = 36$ ), during Step 2 ( $n = 67$ ), or after completing Step 2, but before the baseline visit ( $n = 11$ ). In most cases, passive refusers verbally agreed to participate initially, but then later stopped responding to any attempts to contact them. Passive refusers who agreed during Step 2 either never scheduled the baseline visit, or they scheduled a baseline visit, but did not keep their appointment.

### 5.2. Representativeness

Preliminary medical record queries identified 855 patients who were eligible for the study and mailed introductory letters. After eliminating those who were later found to be ineligible and those who were still in process when full enrollment was reached, there were 694



\*Active refusal: verbally declined

\*\*Passive refusal: expressed interest, but stopped responding or did not follow through

Fig. 2. Recruitment outcomes.

adolescents invited to participate; 258 of these enrolled and completed a baseline visit. The mean age of those who participated was 14.7 years with a mean diabetes duration of 6.3 years. The majority were Non-Hispanic White (79.8%) and 50.4% were male. At the time of enrollment, 53.9% of the participants had an HbA1c > 9.0%; and the mean value was 9.4%. We compared demographic and disease characteristics of those who enrolled in the study (n = 258) to those who did not enroll (n = 436), which included active and passive refusals as well as those who were no response (Table 2).

P-values were calculated at a significance level of 0.05 using chi-square tests for categorical variables or t-tests for continuous variables. Adolescents who enrolled and completed a baseline visit compared to those who did not were more likely to be Non-Hispanic White and have private insurance. There was no significant difference in HbA1c, sex, age, or disease duration.

### 5.3. Retention

Of the 258 participants who enrolled in the study and completed a baseline visit, 241 families (93.4%) remained in the study and completed the 18-month visit (Fig. 3).

Of the 12 adolescents who withdrew, eight were randomized to the intervention group; and the remaining four were in the control group. Five of these 12 families withdrew because of time conflicts or being "too busy"; two participants stated they were no longer interested; two parent participants lost guardianship or custody; one family moved out

of the area; another passively withdrew by failing to respond to scheduling requests; and one family withdrew because they were randomized to the intervention group. Completion rates for measurement visits remained high throughout the study: 96.5% for 3-month; 94.2% for 6-month; 92.2% for 12-month; and 93.4% for the 18-month visits. See Fig. 4 for a detailed breakdown of visit attendance.

### 5.4. Participant feedback

Upon completion of the 18-month visit, adolescents and their parents were asked whether or not they found the Step 2 follow-up phone call helpful in making the decision to participate in the study; and their responses were audiotaped. Of the 241 participants who completed the 18-month visit, 225 parents and 230 adolescents were interviewed and gave responses to this question. Because of the time lapse between the follow-up phone call and the interview conducted at the 18-month visit, 43 (19%) parents and 90 (39%) adolescents were unable to recall the Step 2 follow-up call or were unsure whether or not the conversation with the researcher was helpful in making the decision to participate in the study. Of the remaining 182 parents, 167 (92%) found the phone call helpful; and of the remaining 140 adolescents, 131 (94%) found the discussion helpful. Five major themes emerged from their responses: 1) understanding the overall study; 2) understanding the commitment to complete all study requirements; 3) making the decision to participate; 4) resolving fears and anxiety; and 5) making a personal connection with the research team. To help illustrate these themes, the following

**Table 2**  
Comparison of demographic characteristics for participants who did and did not attend a baseline visit (N = 694).

Demographic Variable		All invited who were eligible (N = 694)		Did <u>not</u> complete baseline visit (N = 436)		Completed baseline visit (N = 258)		p-value
		Mean (SD) or N (%)	Range	Mean (SD) or N (%)	Range	Mean (SD) or N (%)	Range	
Sex	Male	367 (52.9)	–	237 (54.4)		130 (50.4)		0.31
	Female	327 (47.1)	–	199 (45.6)		128 (49.6)		
Race/Ethnicity	African American	50 (7.2)	–	37 (8.5)		13 (5.0)		0.02*
	Hispanic	18 (2.6)	–	15 (3.4)		3 (1.2)		
	Caucasian	537 (77.4)	–	331 (75.9)		206 (79.8%)		
	Other	19 (2.7)	–	11 (2.5)		8 (3.1)		
	More than one	47 (6.8)	–	24 (5.5)		23 (8.9)		
	Unknown	23 (3.3)	–	18 (4.1)		5 (1.9)		
Age (years)		14.7 (1.1)	13.0–16.9	14.7 (1.1)	13.0–16.9	14.7 (1.1)	13.0–16.9	0.59
Duration of diabetes (years)		6.6 (3.7)	1.0–15.9	6.7 (3.6)	1.0–15.9	6.3 (3.7)	1.0–15.9	0.09
HbA1c (%)		9.4 (1.2)	7.3–13.0	7.4 (1.2)	7.3–13.0	9.4 (1.1)	8.0–13.0	0.61
HbA1c category	8.0–9.0%	336 (48.4)	–	217 (49.8)		119 (46.1)		0.35
	9.1–13.0%	358 (51.6)	–	219 (50.2)		139 (53.9)		
Health insurance	Private insurance	471 (67.9)	–	275 (63.1)		196 (76.0)		0.001*
	Public Insurance (Medicaid/Other state- or federally-funded)	182 (26.2)	–	135 (31.0)		47 (18.2)		
	Private and Public	20 (2.9)	–	9 (2.1)		11 (4.3)		
	Other	2 (0.3)	–	2 (0.5)		0 (0)		
	None	15 (2.2)	–	12 (2.8)		3 (1.2)		
	Unknown	4 (0.6)	–	3 (0.7)		1 (0.4)		

Note: p-values from either chi-square test (categorical variables) or t-test (continuous variables).

\*significant p-value (< 0.05).

are examples of some of the comments made by participants.

5.4.1. *Understanding the overall study*

“We were able to understand what the study was about and how long it would take, all the details. We were very well informed about how we were going to be participating.”

“I had questions; and I remember writing them down on a piece of paper and having the conversation with her; and she answered them effectively.”

“It was nice to know everything that we were getting into upfront.”

“I was able to ask questions and get honest answers about the commitment instead of just trying to read about it.”

5.4.2. *Understanding the commitment to complete all study requirements*

“We had to have a conversation to get a better feel for what the commitment would be.”

“It gave us all the details to talk over about what we were committing to.”

“I understood what was going to happen ... so I was able to make sure I was going to be committed and everything.”

“That was definitely helpful. I didn't want to sign up for something and then not be able to fill my end of the obligation.”

5.4.3. *Making the decision to participate*

“It definitely helped [my son] make the decision because he was on the fence initially.”

“It gave me extra time to think if I wanted to do it or not.”

“I think it just validated that we definitely wanted to do it and ... to move forward.”

“I just remember it really helped push my decision to want to do it.”

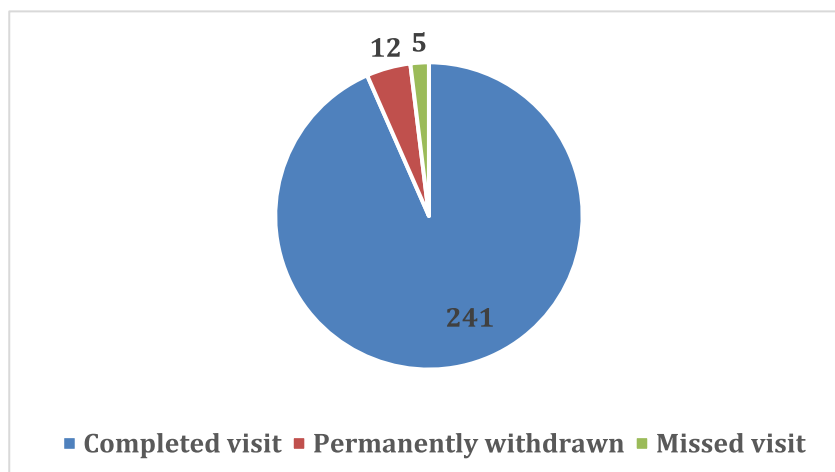


Fig. 3. Retention outcomes: 18-month visit.

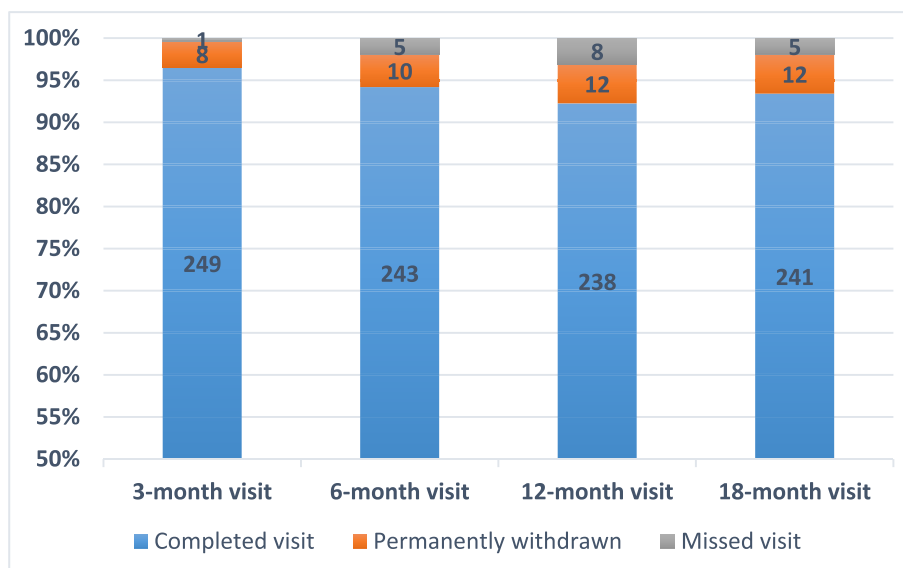


Fig. 4. Retention outcomes: all visits.

#### 5.4.4. Resolving fears and anxieties

“It was comforting ... She answered everything thoroughly and ... put [my daughter’s] mind totally at ease; and that’s when she went ahead and decided to do it.”

“It kind of explained it more and made it less scary.”

“She seemed to understand that there are reasons teenagers might or might not join and why they would be nervous, and ways to stop that nervousness.”

#### 5.4.5. Establishing a personal connection with the research team

“It was easy to read, but at the same time, she could give us the details as far as what to expect during the visits and what the purpose was. So it was definitely – just that personal touch, you know.”

“I felt like I could ask her anything about it before I decided that this is something that I wanted to be in and it just felt more like you guys really wanted me to join.”

“I think we had pretty much fully decided already, but it was nice to kind of have that personal touch with the study, that ... I knew we weren’t going to be a number.”

## 6. Discussion

According to a Cochrane review, it is estimated that less than half of all studies achieve their recruitment targets [25]. Eccleston et al. report an average study completion rate of 82% [7]. The present study was able to achieve a retention rate of 93.4%, while still meeting enrollment goals throughout the recruitment period.

The two-step recruitment process encourages potential participants to thoughtfully evaluate their willingness to participate in research, as well as their ability to make a commitment to the full completion of study requirements. This process is easy to implement, involves a low burden to recruitment staff and could be readily incorporated into the recruitment process for many controlled trials and other research studies. It requires the development of Step 2 information packets, as well as the training of recruitment staff members regarding how to assist potential participants in making a well-informed decision about their willingness to enroll in the study. Staff recruitment training emphasizes

the importance of familiarity with all aspects of the study (e.g., study purpose, randomization, intervention vs. control arms), as well as telephone scripts and practice sessions to help the recruiter feel comfortable as they lead discussions with potential participants during the Step 2 follow-up calls. It is also important to stress to recruiters that, although the study has a recruitment target to meet, retention is equally important. And, therefore, recruiters must be willing to accept that some of the potential participants who agree to participate during Step 1 may decide that they no longer wish to participate during Step 2 of the process. Although the recruitment period for individual participants is lengthened by about four weeks, this additional time can be important to participants as they weigh the advantages and disadvantages of participation, and as they consider potential barriers to participation and how to best overcome these barriers. Investing more study staff time during the recruitment phase may result in enhanced retention and more effective use of study personnel for the long run. When demonstrating the efficacy of a randomized controlled trial, it may be preferable to accept lower recruitment rates in order to optimize retention rates. Adding Step 2 to the recruitment process is a valuable and novel clinical trial management method, which may have led to our success in having high levels of retention rates throughout FLEX. The successful recruitment of this study cohort with a high level of retention suggests that this method is useful, although a formal test of this method versus standard recruitment and retention methods would be required to definitively state this.

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