Published in final edited form as:

Contemp Clin Trials. 2012 July ; 33(4): 633–640. doi:10.1016/j.cct.2012.03.009.

Differences in recruitment and early retention among ethnic minority participants in a large pediatric cohort: The TEDDY Study

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Abstract

Objective—The TEDDY Study is an international, multi-center prospective study designed to identify the environmental triggers of type 1 diabetes (T1D) in genetically at-risk children. This report investigates ethnic minority (EM) differences in patterns of enrollment and retention in the US centers.

Methods—As of June 2009, 267,739 newborns had been screened at birth for high risk T1D genotypes. Data collected at the time of screening, enrollment and at the baseline visit were used. Descriptive and multiple-logistic regression analyses assessed differences between EM groups regarding exclusion, enrollment and early withdrawal.

Results—Of the 10,975 eligible subjects, 6,912 (67%) were invited to participate. EM subjects were more likely to be excluded because of an inability to contact. Of those invited 3,265 (47%) enrolled by the age of 4.5 months. Adjusted analyses showed that except for those classified as other EM, the odds of enrolling were similar across groups. EM subjects had elevated early withdrawal rates. Adjusted models demonstrated that this was significantly more likely among Hispanic subjects.

Conclusion—Understanding patterns associated with EM participation in research extends our ability to make more accurate inferences and permits assessment of strategies that promote inclusion of EM to better address health disparities.

Keywords

Recruitment; Ethnic-minority; Type 1 diabetes; Retention; Prospective cohort

1. Introduction

The validity of findings emerging from observational studies rests on many factors associated with the design and conduct of the study. Among these design attributes, the importance of establishing and maintaining a representative cohort for longitudinal studies is central to reduce the risk of selection bias, increase and maintain the representativeness of the study sample, thereby enhancing the generalizability of findings. It is equally important to investigate response and attrition biases in order to assess the possible impact on interpretation and inference of study results. Patterns and factors affecting recruitment may be the same or different than those affecting retention. In longitudinal studies, patterns of attrition may change over time and reflect different conditions in the participant population. Given these factors, assessment of a prospective cohort study's design integrity requires a long-term focus on patterns and factors associated with recruitment and retention.

Under-representation of ethnic and racial minority groups in research is of concern and undermines efforts to address health disparities. Low participation of minority populations has been identified as a threat to understanding disease incidence and natural history across populations of interest. As noted by Sheikh [1] traditional explanations for low participation have generally cited issues associated with the ethnic minority groups involved such as knowledge of the research process, language barriers, or trust of treatment in a research setting and ignore important alternate explanations that rest with the research process [1]. A 2006 systematic review by Wendler et al. provided new evidence that ethnic minorities (EM) groups are as likely as majority groups to participate if invited to participate [2].

Two analyses have been published describing the TEDDY enrollment experience and the characteristics of TEDDY families who withdrew from the study during the first year [3,4]. Self-identified race and ethnicity data were not collected for the European centers; therefore this variable was not included in the earlier analyses. Because under-representation of ethnic and racial minority groups in research has been identified as a threat to understanding disease incidence and natural history [5] the present report focuses specifically on the US portion of the cohort to assess possible minority group differences associated with TEDDY enrollment and retention in the first year of the study.

Given the intensive nature of the TEDDY protocol and the long-term commitment asked of participating families, a thorough understanding of EM group factors associated with both study enrollment and withdrawal will inform the development of tailored and more effective strategies to assure representative sample recruitment and retention.

2. Methods

The TEDDY Study, an international, multi-center study designed to identify the environmental triggers of type 1 diabetes (T1D) in genetically at-risk children [6] provides an opportunity to investigate ethnic differences in patterns of enrollment and retention in a large prospective observational study. The study design included a screening phase to identify a newborn cohort at increased human-leukocyte antigen (HLA) conferred genetic risk based on cord blood screening for T1D in order to invite them to participate in the second phase—a 15-year observational study. Study sites include three centers in the United States (Seattle, WA; Denver, CO; and a combined site representing Atlanta and Augusta, GA and Gainesville, FL) and three centers in Europe (Finland, Sweden, Germany). The genotypes required for study inclusion have been described previously [7]. The study protocol is demanding. HLA eligible babies must enroll in TEDDY by 4.5 months of age and participate in study visits four times each year until the child reaches the age of four; two visits each year are required thereafter until the child reaches the age of fifteen. Study

procedures include repeated blood draws, nasal swabs, fecal collections, diet records, and interviews.

2.1. Study participants

The data reflect enrollment, exclusion, and early withdrawal experiences for the TEDDY study from September 2004 until December 2009. In this period, the three clinical centers in the United States screened 267,739 newborns for TEDDY eligible HLA high risk genotypes (Table 1); all were administered informed consent. The screened population included infants from the general population (GP) as well as those with a first degree relative (FDR) with T1D. Of all infants screened, 10,975 (4%) carried the HLA eligible genes required to participate in the 15-year follow-up portion of TEDDY. Families of newborns not eligible for further participation in TEDDY were sent a letter indicating that the baby did not have the high risk genes for T1D. TEDDY staff attempted to contact all families of HLA eligible infants by telephone or mail to invite them to participate in the second phase of the TEDDY study; 3,265 agreed to participate, 3,647 refused, and 4,063 were excluded primarily because of failure to contact the family or failure to schedule the child's TEDDY enrollment visit by 4.5 months of age (see Results below). Of the 3,265 enrolled subjects participating in TEDDY 23 were missing ethnic or minority group information; thus, to evaluate the aim of this paper there were a total of 3,242 TEDDY enrolled subjects included.

2.2. Definition of ethnic minority group, exclusion, enrollment, and early withdrawal

2.2.1. Ethnic minority (EM) group—Two questions on the infant screening form permitted the parent to self-identify the child's race (White, Black/African American, Asian, Native Hawaiian/or other Pacific Islander, Native American/Alaskan Native/Aboriginal Canadian/Aboriginal Australian, or unknown/not reported) and whether the child was of Hispanic, Latino or Spanish Origin (yes/no). For this report, non-Hispanic white (NHW) was defined as white with no mention of Hispanic or any other race; Hispanic (HIS) was defined as any mention of Hispanic, regardless of racial identification; African American (AA) was defined as any mention of African American (AA), with no mention of Hispanic; and other minority (OM) was defined as those with no mention of White, Hispanic, or African American. In this report, minority groups refer to all ethnic or racial groups other than non-Hispanic white which is used as the referent group in analyses.

2.2.2. Exclusion—An HLA eligible baby was excluded from the TEDDY study if (1) the child had an illness or birth defect that precluded long-term follow-up or involved a treatment that might alter the natural history of T1D (e.g. immunosuppressive medication), (2) the family refused storage of biologic study samples in the NIH Repository, or (3) the first TEDDY visit invitation could not be fully executed. Families with accurate contact information who did not respond to calls, messages, or letters from the TEDDY staff were excluded because the family could not be reached and the first TEDDY visit scheduled prior to the child reaching 4.5 months of age. Families, where the contact information provided at screening was no longer correct or who did not show up for a scheduled visit and a new visit could not be scheduled before reaching 4.5 months of age, were also excluded. Occasionally the HLA testing results were not available or the TEDDY site could not schedule the first TEDDY visit before the child was 4.5 months of age; though few, these cases were also excluded.

2.2.3. Enrollment—To enroll in TEDDY, parents of HLA eligible infants had to sign the informed consent and bring their infant to the first TEDDY study before the child was 4.5 months of age. Parents who were informed of their child's eligibility for the TEDDY study but refused to join the study were queried about the reasons for their decision. All reasons for refusal were recorded and fell into four categories: (1) the family was unavailable due to

moving out of the area, (2) the parents wanted to “wait and see” and manage diabetes if it occurred, (3) the parents declined participation due to characteristics of the protocol, and/or (4) the parents declined participation for family reasons (e.g., too busy to participate). Parents could provide more than one reason for refusal. If parents did not provide a reason for refusal, this was also recorded.

2.2.4. Early withdrawal—Any TEDDY family who had reached the age of 15 months and had left the study in the first year of TEDDY was defined as an early withdrawal for these analyses.

2.3. Predictors of exclusion, enrollment and early withdrawal

In addition to the racial and ethnic self-identification data described above, limited demographic information gathered at the screening interview is used to examine patterns of exclusion and enrollment. These variables include site of enrollment, FDR (sibling or parent of screened child), family history of T1D, maternal age at time of child’s birth (1 year increments), child’s gender, type of birth (singleton, twin, triplet), and whether family had another child enrolled in TEDDY. Mother’s education level was added to the screening form late in the screening period and captured on only 21% of the population. Descriptive analyses using this subsample are examined to assess further dimensions of exclusion and enrollment.

Data gathered at the enrollment visit further informed the analyses of early withdrawal. The predictor variables that emerged as significant in the earlier multivariate analyses and included in the present analyses are the following [4]: mother’s lifestyle behaviors during pregnancy smoked at any time during pregnancy (yes/no), alcohol consumption (no alcohol, 1–2 times per month, 3 times per month during each trimester), employment status (worked during all 3 trimesters, did not work at all or reduced work hours), mother’s emotional status including anxiety about the child’s risk of developing diabetes measured by a six-time scale adapted from the state component of the State-Trait Anxiety Inventory (STAI) [8,9], the accuracy of the mother’s perception of the child’s risk for developing diabetes (accurate: indicating the child’s T1D risk was higher or much higher than other children’s T1D risk; inaccurate: indicating the child’s T1D risk was the same, somewhat lower or much lower than other children’s T1D risk), and whether the child’s father completed the initial study questionnaire at the enrollment visit (yes/no).

2.4. Data analysis

Descriptive analyses were used to depict all data by EM groups with chi-square tests of statistical significance. Multiple logistic regression was used to test the effect of EM status as a predictor of exclusion, enrollment, and early withdrawal controlling for other relevant variables using SAS Software (version 9.2; SAS Institute, Cary, NC).

3. Results

3.1. HLA eligibility

The results of the genetic screening in TEDDY have been fully described elsewhere [7]. High risk genes for T1D were most commonly found in NHW and HIS newborns and less common in AA and OM screened newborns. Similarly, HLA eligible infants were 67% more likely to have a FDR with T1D if they were NHW compared to all EM groups (OR =1.67 95% CI 1.3–2.1, $p < 0.0001$). The number of HLA eligible children by minority status is shown in Table 1.

3.2. Exclusion

Table 1 also depicts the number (percentage) of HLA eligible infants excluded from TEDDY by EM status and the most common reasons for exclusion. Overall, 37% of all HLA-eligible subjects were excluded; the proportion of the HLA-eligible cohort excluded was significantly higher among all three minority groups (HIS 46%, AA 54%, and OM 40%) compared to NHW participants (33%, $p<0.0001$). The most common reason for exclusion was no response to calls or messages for all groups. Cold or incorrect contact information was twice as common in all minority groups (12–15%) compared to NHW participants (6.0%, $p<0.0001$). The first model shown in Table 2 shows the logistic regression results assessing predictors of exclusion. Controlling for study site, child's gender, maternal age, whether the infant had a FDR with T1D, whether the child was a singleton, and whether the family had another child in TEDDY, EM status was a highly significant predictor of exclusion for all groups compared to NHW participants. Participants from Georgia/Florida center were more likely and Washington participants were less likely to be excluded compared to the Colorado Center. Participants with older mothers and a FDR with T1D were less likely to be excluded.

3.3. Enrollment

As described in Table 1, 47% of the 6,912 HLA eligible participants who were not excluded from TEDDY enrolled in the follow-up observational phase of TEDDY. Overall, ethnic differences in enrollment rates were minor, with HIS and AA participants showing no significant differences from NHW subjects. Only OM participants had substantially lower enrollment rates than NHW. The primary reasons for not enrolling in TEDDY are also provided in Table 1. For all groups, the two most common reasons subjects gave for not enrolling were the demands of the study protocol and family considerations. The AA and OM groups were more likely to provide no reason for refusing enrollment. The OM group was also more likely to list moving and wanting to wait and see as reasons for refusing.

Multiple-logistic regression analysis controlling for clinical site, child's gender, maternal age, FDR status, child's singleton status, and whether the family had another child in TEDDY confirmed no EM status effect on enrollment for HIS and AA subjects (Table 2). Subjects classified as OM were significantly less likely to enroll (OR=0.36 95% CI 0.23–0.56). The Washington clinical center was less likely to enroll subjects compared to the other centers. Being a twin was associated with not enrolling. As expected, enrollment rates were higher among FDR than GP participants and among those families with another child already enrolled in TEDDY, regardless of EM status (Table 2).

In examining mother's education level as a surrogate for SES in a 21% subsample of those screened it is clear that lower maternal education was associated with patterns of exclusion and enrollment. Forty-one percent (41%) of those excluded had less than 12 years of education, compared with 22% of those who were not excluded ($p<0.0001$). Ethnic minorities with less education were more likely to be excluded than NHW with less education (58% vs. 42%, $p=0.003$). A similar pattern is observed comparing those who refused/were excluded to those who enrolled, where a higher proportion of mother's who chose to enroll their child in TEDDY had 12 years or more of education compared to those that refused/excluded for both the NHW (84% vs. 77%, $p=0.0002$) and HIS (55% vs. 41%, $p=0.0032$). There was no significant difference noted for AA ($p=0.71$) or OM ($p=0.95$) (data not shown in table).

3.4. Early withdrawal

For the analysis testing minority status effects controlling for other known predictors of early withdrawal, the sample was restricted to only those participants who were at least 15

months of age and therefore, have been in the TEDDY study for 1 year. In this sample, the early withdrawal rate was very low in the FDR cohort (9%); therefore, the analysis was restricted to GP age-eligible subjects. A prior analysis of predictors of early withdrawal in the full TEDDY cohort was used to identify the predictor variables to be controlled for [4] in this analysis of the additional independent contribution of EM status. The analysis was further restricted to those participants who had no missing data on all variables in the multivariate analysis ($N=1,909$; 435 early withdrawals and 1,474 active TEDDY GP participants). In this sample, the overall early withdrawal rate was 20.5%, with withdrawal rates higher in EM participants compared to NHW (NHW: 16.7%, HIS: 32.6%, AA: 32.7%, OM: 29.4%). The primary reasons for study withdrawal were protocol reasons (i.e., blood draw, frequency of visits, and stool sample collection), being too busy and passive withdrawal (i.e., stopped visits without talking to staff and/or no response to attempts to schedule). Withdrawal due to protocol reasons was only significantly different for HIS vs. NHW ($p=0.0213$).

Table 3 provides the results of the multiple-logistic regression of the effects of EM status on early withdrawal controlling for other known predictors of early withdrawal. Hispanic ethnicity remains a significant predictor of early withdrawal with a 70% (OR=1.71 95% CI 1.28–2.30, $p=0.0004$) greater withdrawal compared to NHW. The remaining variables in the model replicate previously reported associations with early study withdrawal [4]. Younger mothers, those who smoked and/or never drank alcohol during pregnancy were more likely to leave the TEDDY Study in the first year; the prior association noted in the full cohort between reducing work hours or not working at all during pregnancy was not significant but was in the expected direction where mothers who worked throughout pregnancy were more likely to stay in TEDDY. Families with a female TEDDY child and/or no father participation were also more likely to leave TEDDY. Mothers who underestimated their child's risk for T1D were more likely to withdraw ($p=0.0002$); among mothers with accurate risk perceptions, those with very high anxiety over their child's risk were more likely to stop participating in TEDDY ($p=0.0018$).

4. Discussion

These findings confirm and extend earlier analyses of the TEDDY cohort by examining similarities and differences in rates and predictors of exclusion, enrollment and retention across minority groups restricted to the US population. The proportion of HLA subjects excluded because of no response to calls, incorrect contact information and unable to schedule enrollment visit by 4.5 months was more common in the US compared to the European clinical centers. This report extends our understanding of this pattern in the US sites by demonstrating that minority groups are more likely to be excluded. Further, minority families who participated in screening were more likely than NHW families to have incorrect contact information, thereby increasing the likelihood of being excluded because of no opportunity to be invited to participate. The exclusion rates observed for Georgia/Florida clinical center reflect the experience in the field of a more mobile and hard to reach population.

With regard to enrollment, as observed by Lernmark et al. [3] factors associated with lower enrollment included being from the GP cohort, younger maternal age, and multiple birth. Furthermore, there was no difference in the enrollment between HIS, AA and NHW families; however, OM families, made up of Native American/Alaskan Native/Asian HLA eligible persons, were less likely to enroll. It should be noted that the number of screened subjects from these groups was small and generally the risk of T1D is lower. Enrollment was lower in the Washington center. A possible reason for this may be due to screening

across a wide geographic area which may lead to a much higher proportion of subjects living further away from the center compared to other sites, reducing their overall response rate.

Though our data are limited, we were able to examine in a subsample, possible socioeconomic patterns as marked by mother's education that are worth noting. Those with less education are more likely to be excluded and less likely to enroll than those with more education, a pattern which was particularly pronounced for Hispanic participants. This suggests that methods addressing socioeconomic barriers to study participation should be considered and incorporated at study initiation. Examples include better developed communications (brochures, posters, and informed consents) that incorporate health literacy, not just grade level assessments and purposeful attempts to provide resources that address access barriers such as transportation, child care, and time away from work.

Other studies reporting recruitment challenges and successes in minority populations have noted that study protocols need to use culturally competent approaches, build relationship and trust between study staff and participants, and consider appropriate incentives [10,11]. The TEDDY Study provided examples of how these strategies may well have minimized differential recruitment at least for HIS and AA subjects by being more conscious of population diversity. In particular, the Colorado center made the decision to screen and recruit Spanish only speaking HIS subjects. This required Spanish-speaking staff and Spanish translated forms for the screening phase and a commitment to continue with a bilingual program for the entire 15-year follow-up.

The higher exclusion rate among our minority families due to contact information going "cold" in the 10 weeks following the child's birth reflects the higher mobility in certain segments of the population. This provides a clear indication of the need to solicit multiple types of contact information from participants at the time of initial contact with a 2-stage process such as TEDDY employed. Although the TEDDY Study screening protocol called for a 3-stage approach to contact information that included multiple phone numbers, participant's address and the name of someone living outside of the participant's home who would know how to contact them, we still found locating subjects difficult.

The logistic regression results assessing likelihood of early withdrawal for the US GP cohort with the addition of minority group status as a variable found similar results as previously published. Smoking, no alcohol consumption, and reducing work hours or not working during pregnancy all remained significant predictors of early withdrawal. Father's participation and accurate risk perception remained significant predictors of retention. However, among a subset of mothers with accurate risk perception whose anxiety scores were high, early withdrawal was more likely.

Younger mothers were more likely to withdraw and this was more evident in all minority groups compared to NHW participants. This is consistent with other reported studies [12–14], though explanations are speculative. Higher enrollment exclusions for reasons of incorrect contact information, the high rate of passive withdrawal and a greater numbers of HIS withdrawing because they are unavailable or have moved provide substantial evidence of frequent moving and possible instability early in the child's life. Younger mothers who are more likely to be from any of the minority groups represented in TEDDY may have fewer resources available to them and have less motivation for sustained participation if circumstances become challenging.

Of particular note among those who withdrew, NHW mothers had a higher proportion with high anxiety scores and were more likely to report demands of the protocol and being too busy as reasons for withdrawing. Hispanic mothers were less likely to work during pregnancy and were more likely to report being too busy, being unavailable or moving and

protocol demands as withdrawal reasons. African Americans were less likely to have the father's involvement in the enrollment visit and note being too busy, protocol demands, and family issues as withdrawal reasons.

Our goal in replicating these analyses was to assess minority group status as a predictor of early withdrawal adjusting for other known predictors. Hispanic participants are significantly more likely to withdraw compared to NHW. Similarly, the point estimate for AA and Native American–Alaskan Native/Asian also indicated increased odds of early withdrawal in the fully adjusted prediction model; although not significant these estimates are likely reflecting true differences among minority groups and/or the smaller sample size for these segments of the cohort. As previously noted, the Colorado Center of TEDDY is the clinical home of a majority of the HIS participants and the only site that enrolled Spanish-only speaking participants. It has been observed in local analyses (data not shown) that there is greater withdrawal among the Spanish-only speaking portion of the cohort, with the observation that many have returned to their country of origin or have left no forwarding address.

The TEDDY Study has developed both study-wide and local retention efforts, which include the following: (1) development of a long-distance protocol (i.e., allowing subjects who move away from the clinical centers to remain involved); (2) study events that encourage connection outside of the demanding clinic visits; and, (3) development of local systems to monitor a family's progress in the study. This monitoring effort includes the development of a high-risk of early drop-out score based on the study-wide early withdrawal analyses previously published [4]. Participants with high scores received targeted and tailored interventions to support their continued participation. In the US, these interventions were implemented equally across EM groups in subjects enrolled in 2010. We will be assessing the impact of this risk score and earlier intervention for reducing attrition in all segments of the study population.

These findings related to exclusion and enrollment among minority groups screened for the TEDDY Study indicate that challenges to minority research participation rest both with factors associated with the research process and with characteristics of the population. Less stable living arrangements and language barriers may be more common in minority groups, making communication difficult. However, if contacted and given similar opportunity to participate, the TEDDY experience demonstrates that minority participants are equally likely to enroll. The ongoing participation in a longitudinal study may also be affected by similar reasons.

Further, investment in the design of protocols, communication materials, and most importantly research staff that builds an understanding of study objectives and fosters a good initial relationship supports successful recruitment and retention efforts. Generalizability of findings to subpopulations depends upon minimizing attrition across all groups and a detailed understanding of factors associated with drop-out to tailor retention strategies that meet the needs based on specific characteristics of diverse groups. Accurately presenting a protocol to potential subjects and providing a positive atmosphere that invites questions for a well informed decision are critical to the research process. To do this without overwhelming the participant or using technical language is challenging. Connection and communication with subjects at the outset are critical for recruitment for all potential participants. Further specific approaches which address the demands and flexibility of the study protocol once enrolled may increase retention in general and minority retention, specifically, if these approaches are tailored to the issues affecting particular groups. The TEDDY Study experience to date suggests that such tailored enrollment and retention efforts can be effective.

The TEDDY Study provides a unique opportunity to examine issues of minority recruitment and retention in a pediatric cohort. Given the focus on the issues of health equity, as well as the inclusion requirements in nationally funded research studies, it is important to gain as much understanding of the factors that affect minority representation in research. The earlier analyses and those presented here provide possible insight into the avenues for encouraging enrollment and interventions that may reduce attrition over the life of the study.

Acknowledgments

The TEDDY Study Group (see Appendix A).

Funded by DK 63829, 63861, 63821, 63865, 63863, 63836, 63790 and UC4DK095300 and Contract No. HHSN267200700014C from the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), National Institute of Allergy and Infectious Diseases (NIAID), National Institute of Child Health and Human Development (NICHD), National Institute of Environmental Health Sciences (NIEHS), Juvenile Diabetes Research Foundation (JDRF), and Centers for Disease Control and Prevention (CDC).

Abbreviations

T1D	type 1 diabetes
EM	ethnic minority
HLA	human-leukocyte antigen
NHW	non-Hispanic white
HIS	Hispanic
AA	African American
OM	other minority

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Appendix A

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Description of TEDDY Study recruitment and enrollment experience in the US Clinical Centers by ethnic minority group status as of December, 2009.

Table 1

Ethnic minority group	NHW N %	HIS N %	AA N %	OM N %	ALL N %
Number of HLA eligible children ^a	7846	2479	395	191	10,975
Number of excluded children (% of HLA eligible children)	2615(33)	1136(46)	215(54)	76(40)	4063(37)
General population	2532(34)	1121(47)	209(55)	73(40)	3955(38)
First degree relative	83(19)	15(19)	6(35)	3(43)	108(20)
<i>Primary reasons^b for exclusion: Number excluded by reason (% of children excluded)</i>					
No response to calls/messages	1988(76)	840(74)	126(59)	54(71)	3008(74)
Incorrect contact information	156(6)	147(13)	32(15)	9(12)	344(9)
Unable to schedule visit by 4.5 months	409(16)	130(11)	53(25)	10(13)	602(15)
<i>Characteristics of TEDDY eligible and invited participant^c</i>					
Total ^d	5231	1343	180	115	6912
General population	4884	1279	169	111	6483
First degree relative	347	64	11	4	429
Total refusing to enroll (% within group)	2724	726	88	89	3647
No reason given	346(12.7)	104(14.3)	19(21.6)	18(20.2)	490(13.4)
Moving	150(5.5)	45(6.2)	3(3.4)	7(7.9)	208(5.7)
Wait and see	123(4.5)	38(5.2)	4(4.6)	8(8.9)	173(4.7)
Protocol too demanding	1088(39.9)	262(36.1)	23(26.1)	19(21.4)	1399(38.3)
Family reasons	1019(37.4)	277(38.2)	39(44.3)	37(41.6)	1379(37.8)
<i>Characteristics of enrolled subjects</i>					
Total	2507(76.8)	617(18.9)	92(2.8)	26(0.8)	3265 ^d
Enrollment rate (% within group)	48%	46%	51%	23%	47%
General population	2241(46%)	574(45%)	85(50%)	23(21%)	2943(45%)
First degree relative	266(77%)	43(67%)	7(64%)	3(75%)	322(75%)
Clinical center (% within group)	768(52.9)	440(49.5)	9(50.0)	6(33.3)	1224(51.4)
Colorado	734(54.7)	56(53.9)	66(64.7)	5(23.8)	879(54.8)
Georgia/Florida	1005(41.3)	121(34.6)	17(28.3)	15(19.7)	1162(39.6)
Washington					
Maternal age mean years (SD)	30.9(5.6)	27.4(6.0)	27.4(6.1)	30.0(6.4)	30.1(5.9)

Ethnic minority group	NHW N %	HIS N %	AA N %	OM N %	ALL N %
Child's gender	1206(48.1)	333(54.0)	45(48.9)	12(46.2)	1610(49.3)
% Female					

NHW: non-Hispanic white; HIS: Hispanic; AA: African American; OM: other minority: an ethnic/minority other than NHW, HIS or AA.

^aOf those with HLA genotyping for genetic risk of T1D, 64 were missing race/ethnicity (60 GP and 4 FDR).

^bOnly most common reasons for exclusion are listed; therefore total N does not equal total HLA eligible excluded. A detailed explanation of reasons for exclusion is provided in text.

^cNumber of TEDDY eligible and invited subjects is equal to the number of HLA eligible minus number of children excluded from participation.

^dRace was not identified in 43 TEDDY eligible and invited subjects (20 who refused to enroll and 23 who enrolled).

Table 2

Logistic regression results assessing predictors of exclusion and enrollment in TEDDY Follow-up Study, US Clinical Centers as of December 31, 2009.

Predictor variable	Prediction model for exclusion (N=10,975) ^a					Prediction model for enrollment (N=6912) ^{b,c}				
	β	SE	p-Value	OR	95% Confidence interval	β	SE	p-Value	OR	95% Confidence interval
Intercept	0.591	0.116	<0.0001			-0.448	0.143	0.0017		
Ethnic minority group	Ref.					Ref.				
	NHW									
	HIS	0.456	0.053	<0.0001	1.58	1.42	0.068	0.1584	0.91	0.80
	AA	0.573	0.108	<0.0001	1.77	1.44	0.156	0.5820	1.09	0.80
Clinical site	OM	0.357	0.153	0.0196	1.43	1.06	0.228	<0.0001	0.36	0.23
	Colorado	Ref.				Ref.				
	Georgia/FL	0.539	0.056	<0.0001	1.72	1.54	0.037	0.071	0.6040	1.04
	Washington	-0.301	0.052	<0.0001	0.74	0.67	-0.505	0.059	<0.0001	0.60
Female child	No	Ref.				Ref.				
	Yes	-0.003	0.041	0.934	1.00	0.92	-0.006	0.050	0.9070	0.99
Maternal age (years)		-0.043	0.004	<0.0001	0.96	0.95	0.017	0.004	0.0002	1.02
First degree relative status	GP	Ref.				Ref.				
Baby birth type	FDR	-0.870	0.112	<0.0001	0.42	0.34	1.238	0.116	<0.0001	3.45
	Singleton	Ref.				Ref.				
	Twin	-0.152	0.150	0.3127	0.86	0.64	-0.522	0.167	0.0017	0.59
	Triplet	-0.681	0.819	0.405	0.51	0.10	0.181	0.758	0.8113	1.20
Other child enrolled in TEDDY	No	Ref.				Ref.				
	Yes	-0.193	0.122	0.1141	0.82	0.65	0.655	0.149	<0.0001	1.93
										2.58

NHW: non-Hispanic white; HIS: Hispanic; AA: African American; OM: other minority; ethnic/minority other than NHW, HIS or AA.

^aModel includes all HLA eligible subjects including excluded, enrolled, and refused subjects.

^bModel includes only those HLA eligible and invited to participant (excluded subjects not included).

^cRace not identified in 43 TEDDY eligible and invited participants (20 who refused to enroll and 23 who enrolled).

Table 3

Logistic regression results testing ethnic minority status as a predictor of study withdrawal in the first year of TEDDY controlling for other known predictors, US Clinical Centers—December 2009.

Predictor variable	β	SE	p-Value	OR	95% Confidence interval
Intercept	1.25	0.526	0.0174		
Ethnic minority group					
NHW	Ref.				
HIS	0.539	0.151	0.0004	1.71	1.28 2.30
AA	0.401	0.335	0.2308	1.49	0.77 2.88
OM	0.152	0.695	0.8274	1.16	0.30 4.55
Female child					
No	Ref.				
Yes	0.268	0.126	0.0336	1.31	1.02 1.67
Maternal age (years)					
No	-0.067	0.012	<0.0001	0.94	0.91 0.96
Smoked during pregnancy					
No	Ref.				
Yes	0.845	0.175	<0.0001	2.33	1.65 3.28
Alcohol consumption in last trimester					
None	Ref.				
1–2 times/month	-0.377	0.199	0.0582	0.68	0.46 1.01
>2 times/month	-0.274	0.371	0.4593	0.76	0.37 1.57
Worked all trimesters					
No	Ref.				
Yes	-0.192	0.128	0.1333	0.83	0.64 1.06
Dad participation					
No	Ref.				
Yes	-0.501	0.177	0.0047	0.61	0.43 0.86
Risk perception					
Underestimate	Ref.				
Accurate	-1.956	0.520	0.0002	0.14	0.05 0.39
State Anxiety Inventory score					
	-0.009	0.008	0.2690	0.99	0.98 1.01
State Anxiety Inventory score*risk perception					
	0.037	0.012	0.0018	1.04	1.01 1.06

NHW: non-Hispanic white; HIS: Hispanic; AA: African American; OM Other Minority: ethnic/minority other than NHW, HIS or AA.