Research Article

CLINICAL INVESTIGATION

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An evaluation of recruitment methods utilized for a clinical trial with periodontal and diabetes enrollment criteria: the Diabetes and Periodontal Therapy Trial

Background: Diabetes and its complications are a major United States public health concern. **Methods**: The Diabetes and Periodontal Therapy Trial (DPTT) evaluated whether non-surgical treatment of periodontal disease influenced diabetes management among persons with Type 2 diabetes and periodontitis. The aim of this study was to evaluate DPTT's many recruitment strategies in terms of enrollment success. **Results/Conclusion:** Targeted recruitment strategies were more effective in identifying individuals who met periodontal and diabetes eligibility criteria. Individuals eligible for a baseline visit/enrollment were more often male, had a younger age at diabetes diagnosis, a longer diabetes duration, more often Hispanic and less often African–American. Tracking and evaluating recruitment sources during study enrollment optimized recruitment methods to enroll a diverse participant population based upon gender, race and ethnicity.

Keywords: clinical trial • diabetes • diabetes mellitus • periodontal disease • periodontitis • recruitment • Type 2

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A total of 29.1 million people in the United States, 9.3% of the population have diabetes today [1]. This disease and its associated complications have thus become a major public health and economic concern in the United States. Adding to the concern are apparent disparities between different racial/ethnic groups at risk for this disease within the United States. Compared to Non-Hispanic Caucasians, the risk for developing Type 2 diabetes is 18% higher among Asian–Americans, 68% higher among Hispanics and 74% higher among non-Hispanic Blacks [1].

Periodontitis, an oral inflammatory condition that destroys the supporting structures of the teeth is considered by some to be a diabetes complication [2,3]. Individuals with diabetes are about 2.5-times more likely to be diagnosed with periodontitis and their disease is more severe than among those without diabetes [4–6]. Among persons with diabetes, poor glycemic control is associated with more sever periodontitis [7]. Emerging evidence suggests that periodontal disease may impact glycemic control and the risk for Type 2 diabetes but the mechanism for this relationship is still not well established [8]. A common hypothesis poses that periodontal inflammation and pathogenic bacteria and their byproducts trigger the production of cytokines, acute phase proteins and oxidative stress molecules that over time impair insulin sensitivity or action [9]. Given the proposed bidirectional relationship between Type 2 diabetes and periodontitis, studies have evaluated whether periodontal therapy improves glycemic control in persons with Type 2 diabetes but these studies were small, some lacked controls and none were multicentered [10–12]. The Diabetes and Periodontal Therapy Trial (DPTT) was designed to address this gap in knowledge using a multisite randomized controlled trial design. The aim of DPTT was to determine the impact of nonsurgical periodontal treatment on the ability to maintain control of Type 2 diabetes within a population of adult subjects diagnosed with both Type 2 diabetes and

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chronic, untreated periodontal disease. Study details have been previously published [13,14]. Because of the racial and ethnic disparities associated with diabetes, studies such as DPTT have taken steps to recruit from diverse populations and from groups not typically well represented in clinical trials [15].

Efficacious recruitment is essential to any study's success. Achieving the target sample size within a prescribed time frame impacts both the study length and study cost [16]. Study investigators invest a considerable amount of time learning about the target population, developing recruitment strategies and identifying study partners who can successfully recruit participants. Though much has been written about the successes and challenges of various recruitment strategies, most of these publications describe the challenges of recruitment for a single disease or condition. DPTT was challenged to identify participants who meet eligibility criteria for two distinct chronic diseases. The results of our recruitment efforts are presented here. The paper explores the effectiveness of various recruitment strategies for identifying individuals who met the trial's diabetes and periodontal disease eligibility criteria by recruitment source and participant characteristics (e.g., gender, ethnicity).

Methods

The DPTT is a National Institutes of Health/National Institute of Dental and Craniofacial Research (NIH/NIDCR) funded multisite clinical trial. The study structure included: a Study Chair, independent Coordinating Center, Core Laboratory and five clinical sites in the United States. In collaboration with Diabetes Centers affiliated with each clinical site, DPTT recruited and enrolled participants from diverse communities centered at Schools of Dentistry within Academic Medical Centers. Clinical sites were located in Birmingham Alabama, Minneapolis Minnesota, Stony Brook New York, San Antonio and Houston Texas. Each clinical site was comprised a study team that included Periodontists, Hygienists, Diabetologists, Recruiters and Coordinators. Each clinical site developed recruitment strategies tailored to their individual communities in collaboration with the Study Chair's office and the Coordinating Center.

Using the following assumptions, a sample size of 468 participants was required to answer the study question (i.e., whether periodontal therapy is effective in improving diabetes management). This sample size was estimated assuming a 0.6% (SD, 2%) or greater reduction in HbA_{1c} level from baseline to 6 months in the treatment group compared with the control group; a 2-tailed, 2-sample *t*-test; a 0.05 type 1 error; and 90% power [17]. To account for 20% attrition, the target sample size was set at 600 participants (300 in each treatment group) to be enrolled over a two and a half year period. The study enrolled participants with moderate to advanced periodontitis because these individuals are generally believed to have more 'systemic' inflammation attributed to their disease than those with early periodontitis or gingivitis or a healthy periodontium. Furthermore, the study enrolled participants who were at risk for elevated levels of serum inflammatory biomarkers, in need of periodontal treatment and outside of the range of ideal diabetes control (i.e., <7.0%) [18].

Through a series of weekly and monthly recruitment reports, monthly steering committee and coordinator conference calls, the clinical sites shared their successes and challenges related to recruitment and retention of eligible study participants. With recruitment monitoring occurring on a monthly basis, study leadership was able to make adjustments to the recruitment plan as the study progressed. The study began initially with three clinical sites which had a monthly recruitment goal of 20 enrolled participants across all sites, 6–7 eligible participants enrolled per site. To accelerate recruitment, two additional sites were added, one in September 2010 and the second in August 2011 for a total of five clinical sites

Recruitment process

Recruitment and enrollment in DPTT was completed using a three stage process.

Stage 1: recruitment interview

Once a potential participant was identified, study recruiters obtained oral consent and administered a brief recruitment interview designed to screen out individuals who did not meet broad diabetes and oral criteria (e.g., not Type 2 diabetes, and/or less than 16 teeth). The study set the eligibility criteria for the minimum number of teeth at 16 (50% of all teeth/mouth) to optimize the potential to achieve a treatment effect. Based on the hypothesis that the diseased teeth may be the a source of inflammation contributing to glycemic control a minimum inflammatory burden, represented by a minimum number of teeth, needed to be present in order for the patient to benefit from the treatment intervention [2].

The recruitment interviews were completed either in person or via telephone. Recruitment data were maintained by the clinical sites for their use only and were not provided to the Coordinating Center for evaluation.

Stage 2: in-person screening visit

Individuals who passed the recruitment interview were invited to attend an in-person screening visit at one of

the five participating dental centers; potential participants provided written consent before the start of this visit. During this visit candidates met with a study coordinator and a periodontal specialist; individuals were screened for physician diagnosed diabetes and oral health, focusing on the presence of periodontal disease. Participants were evaluated to determine the presence of moderate to severe chronic periodontitis, defined as loss of clinical attachment and probing depth greater than or equal to 5 mm at two or more tooth sites in each of two or more quadrants in the mouth. Persons identified to have had recent periodontal therapy were excluded from further screening for enrollment. If an individual met these criteria, blood was drawn for hemoglobin A_{1c} (HbA_{1c}) testing at the Centralized Core Lab to determine HbA_{1c} eligibility.

Stage 3: in-person baseline visit

After successful completion of the screening visit and once the screening visit HbA_{1c} was determined to be within the study range (≥7 and <9%), the individual was scheduled for a baseline visit. The HbA_{1c} lower inclusion limit was set to 7.0% to minimize the potential for a basement effect. That was so the patient's HbA_{1c} measurement should not have started out at a level that was low enough that it would be difficult to achieve further lowering (improvements) of the HbA_{1c} values by an intervention (e.g., setting the lower cutoff value at 6.5% for inclusion versus the level chosen of 7.0%).

During the baseline visit, eligibility was confirmed, and the individual was enrolled and randomized. To minimize the possibility of changes in medical or diabetes management, or oral health that could affect eligibility, the baseline visit had to occur with 35 days of screening.

Each clinical site developed their own recruitment strategies to take full advantage of local community resources. This included recruiting from medical practices, diabetes-specific medical specialty practices and dental clinics primarily associated with the participating schools of dentistry. Each clinical site used local print and electronic media to develop paid print, radio and television advertisements, public service announcements and articles about periodontal disease and diabetes to recruit participants. Brochures and posters were developed and displayed throughout the participating universities, within the community, at local hospitals and pharmacies and within medical and dental care provider practices. Letters and brochures were sent to patients from the participating diabetes clinics, participants from prior diabetes studies and dental school patients; these media introduced DPTT and invited the recipients to schedule a recruitment interview. Study personnel developed relationships with the local chapters of the American Diabetes Association and with diabetes educators. Through these networks study personnel were informed of, and visited diabetes educational programs and health fairs that focused on persons with diabetes. Each clinical site advertised the study on their school's website with a sign-up mechanism for screening, and the study was posted on the clinicaltrials.gov website with contact information for each participating clinical site. Participants were also encouraged to tell their family, friends and coworkers about the study. Brochures were provided for distribution though this network. Study materials were translated into Spanish to help reach out to those in the Spanish-speaking communities. One clinical site expanded their institutional partnership with the Native American Community Dental Clinic to allow for participant recruitment through their clinic.

Potential participants who did not meet eligibility criteria at the first screening visit could be scheduled for additional screening visits if changes occurred in their situation that would make them a potentially eligible candidate (e.g., completion of routine dental care for caries). At the baseline visit, the participant was confirmed to be eligible for the trial, and if randomized to the treatment arm, scheduled for nonsurgical periodontal treatment.

Eligibility

The study was challenged to identify individuals who met inclusion criteria for both diabetes and periodontal disease. A summary of study eligibility criteria is presented below. Study details were reported previously [13,14]. The study was seeking individuals age 35 or older with physician diagnosed Type 2 diabetes of more than 3 months duration, and under the care of a physician for their diabetes. HbA_{1c} values were required to be ≥ 7.0% and < 9.0% at the time of screening. Candidates were required to not have changed their diabetes medications within the 3 months prior to screening, and agree to not change their diabetes medications during enrollment unless medically indicated. Women of child-bearing potential also agreed to avoid pregnancy during their participation. Oral and periodontal eligibility criteria included: a minimum of 16 teeth, moderate to advanced chronic periodontitis and an absence of periodontal treatment within the prior 6 months. Individuals found to require treatment for essential dental care (EDC) (e.g., tooth decay, root canal therapy) were excluded from initial enrollment but could be rescreened after successful dental treatment. In addition, candidates were excluded if they: had been treated in an emergency room for diabetes within 30 days, used nonsteroidal anti-inflammatory medications other than low dose aspirin, used

immunosuppressive medications, used antibiotics for more than 7 days within 30 days of enrollment, had a risk of bleeding completions, provided a self-report of heavy alcohol use and/or undergoing dialysis at the time of screening.

Data collection

Study data collection began with the screening visit; completed case report forms were sent to the Coordinating Center for processing and analysis. The screening visit was divided into three parts to determine eligibility – medical and personal, oral and laboratory eligibility. Medical and personal information were collected via interview (self-report). Individuals who met eligibility criteria from interview then completed an oral and periodontal examination. Only individuals who met all medical, personal, oral and periodontal requirements had blood drawn to determine if their HbA_{1c} level met eligibility criteria. As part of the medical and personal data collection, some basic demographic information including gender, race and ethnicity, birthdate, duration of and age at diabetes diagnosis was obtained from all participants. Determination of Spanish or Hispanic heritage was asked as a separate question from race. Race/ethnicity was selfreported as African–American/Black, American–Indian/Alaska Native, White, Asian or Other. Forms provided for the reporting of more than one race by an individual. Participants were also asked how they learned about the study, with sources provided by the participant recorded.

The study protocol provided for clinical site personnel to stop a screening visit when the first reason for ineligibility was identified. For ineligible individuals, clinical sites had the option to complete the remaining portions of the screening visit with the exception of blood draw, to determine the potential for future enrollment due to a modifiable ineligibility criteria (e.g., short-term antibiotic use).

Data analysis

Data presented in this report are based on information collected, and eligibility status from the first screening visit. Therefore, the data presented reflect the first screening visit eligibility status only, independent of whether or not an individual continued on to a baseline visit and randomization. Since not all individuals were evaluated for all possible reasons for ineligibility, this analysis examined the first reason for ineligibility at the first screening visit. To evaluate the recruitment source(s) as provided by participants, results were evaluated based on individuals who reported a single recruitment source, and also considered those who reported learning about the study from multiple sources. Recruitment sources reported by participants were grouped into nine major categories – medical practices/clinics, dental clinics, friends and relatives, newspaper articles, study advertisements, study brochures, radio and television spots, health fairs, web sites and multiple sources. These categories were further grouped to describe the recruitment focus. Medical and dental practices/clinics, friends and relatives were all grouped under the umbrella of targeted recruitment. The remaining six categories were grouped together as general recruitment. Targeted methods focus on recruiting individuals who may be more likely to meet eligibility criteria, and provides a more personal approach. In contrast, general recruitment efforts are broad based, reach a much larger population and are less personal. This method of categorizing recruitment strategies have been previously documented [16,19–20].

Recruitment yield (calculated as the number of persons identified as eligible/the total recruited × 100) was evaluated by recruitment source, and further evaluated by participant characteristics (e.g., gender). Differences in recruitment source by participant characteristics were assessed using chi-square tests, and Cochran-Mantel-Haenszel statistics for categorical data and *t*-tests for continuous data.

Results

Recruitment overview

IRB approvals were obtained from all participating centers prior to their start of recruitment and data collection. Subjects signed an IRB approved informed consent form prior to the start of the screening visit. Figure 1 provides a summary of the recruitment process for DPTT. A total of 1756 individuals completed at least one screening visit. Of these, 27% (n= 473) of individuals who completed the first screening visit were eligible to continue to the baseline visit for confirmation of eligibility and randomization. Screening yield varied by clinical site (17–51%). Four hundred and twenty individuals (420/473; 89%) who were screened and found eligible at the first screening visit were subsequently enrolled and randomized. From the remaining 53 individuals found eligible to continue to a baseline visit, 30 individuals were found ineligible at the baseline visit and 23 of these eligible individuals decided not to continue with the study after screening.

Based on results of an interim analysis for futility [13], the Data Safety and Monitoring Board stopped enrollment after 29 months and 514 enrolled participants. Of the 514 individuals enrolled, 82% (420/514) were enrolled based upon a single screening visit. From the 1283 individuals not eligible at the first screening visit, 94 individuals (7.3%) were rescreened between 1 and 4 additional times and enrolled in DPTT for a

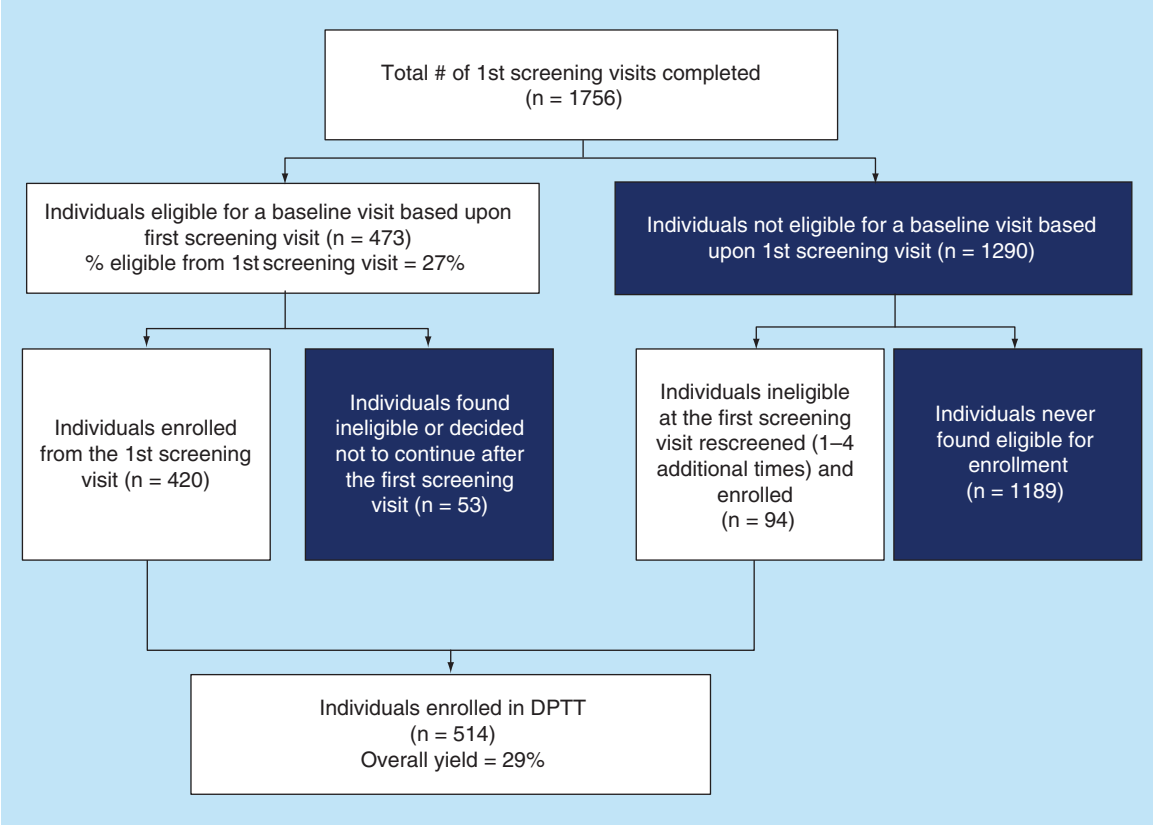

Figure 1. Diabetes and Periodontal Therapy Trial recruitment flow including all screening visits.
DPTT: Diabetes and Periodontal Therapy Trial.

final enrollment total of 514 individuals. The overall recruitment yield based upon all screening visits was 29%. The yield from those rescreened was 18%.

First screening visit outcome

Ninety-three percent of screened individuals met all medical and personal eligibility criteria at their first screening visit. From the 1635 individuals who continued to the oral and periodontal examination, 55% (892/1635) continued to testing for HbA_{1c} eligibility. Just over 50% (473/892) of individuals who otherwise met all medical, personal, oral and periodontal eligibility criteria had an HbA_{1c} value within the study range (≥7 and <9%) and were invited for a baseline study visit (Figure 2).

Comparison of eligibility status based on demographic characteristics

Demographic characteristics of screened individuals determined to be eligible versus ineligible for a baseline visit are presented in Table 1. A significantly greater percentage of males was found eligible to continue to baseline ($p = 0.05$). Eligible individuals were significantly younger at diabetes diagnosis (45.4 vs 48.0 years; $p < 0.01$) and had diabetes for a longer period of time (12.1 vs 10.4 years; $p < 0.01$). Overall, race/ethnicity differed between eligible and not eligible groups. A significantly greater percentage of persons who identified themselves as Hispanic were eligible at the screening visit (34.2% eligible vs 16.4% not eligible; $p < 0.01$). A significantly lower percent of African–Americans meeting eligibility criteria moved on to a baseline visit (28.3% eligible vs 33.5% not eligible; $p = 0.01$).

Reason for ineligibility

Table 2 presents the reasons for ineligibility at the first screening visit regardless of whether an individual was rescreened and eventually enrolled in DPTT. As noted previously, only the first reason for ineligibility is presented because not all reasons for ineligibility were assessed during the screening visit.

The most common reasons for ineligibility at the first screening visit were: failure to meet oral or periodontal criteria (n = 743; 57.9%), and HbA_{1c} values out of range (n = 419; 32.7%). Close to a quarter (23.1%) of individuals ineligible based on HbA_{1c} levels were moderately to well controlled ($HbA_{1c} < 7\%$). Less than 10% of screened individuals were ineligible based upon personal and medical criteria; this metric reflects the success of the recruitment interviews to eliminate the majority of ineligible individuals for these reasons.

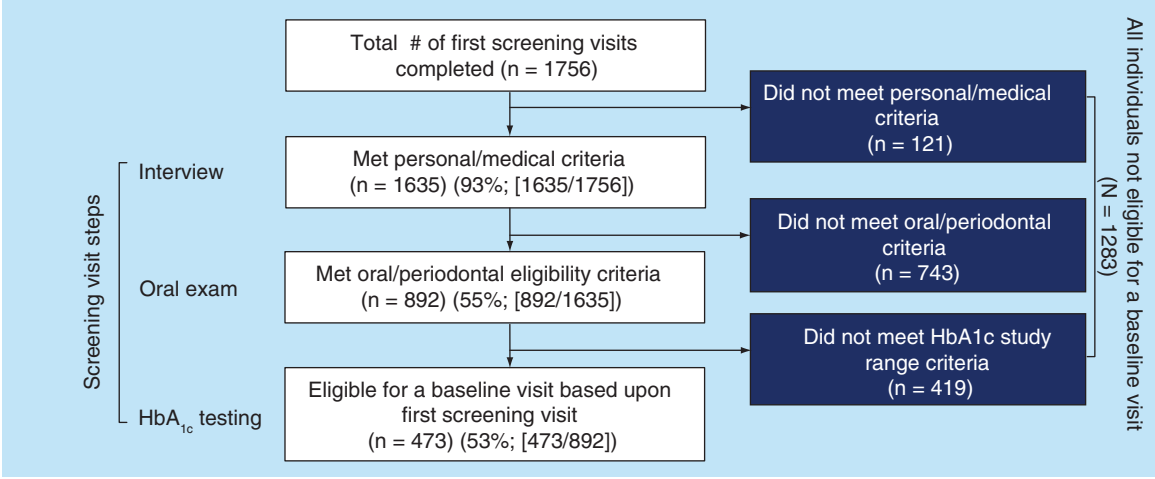

Figure 2. Screening visit outcomes at the first screening visit based upon grouped eligibility criteria.

In contrast, oral, periodontal and HbA_{1c} eligibility required a clinical visit for evaluation. The greatest percentage of individuals ineligible for personal or medical reasons was due to diabetes medication changes within 3 month of the screening visit (n = 58; 4.5%). This represents a potentially rectifiable eligibility category that clinical sites tracked to invite these individuals back for rescreening at a later time.

Both essential dental care (EDC) defined as the need for treatment of an oral problem, and HbA_{1c} levels were eligibility criteria that the coordinators tracked, and recalled participants who were found to be otherwise potentially eligible for study enrollment. Of individuals found on their first screening visit to be ineligible due to EDC, 12% (27/222) were rescreened and enrolled in the study. Of individuals with an HbA_{1c} level out of study range at their first screening visit, 7% (30/419) were rescreened, determined to have an HbA_{1c} level within study range and enrolled. Among individuals rescreened due to out of range HbA_{1c}, an equal percentage of initial HbA_{1c} values were above and below the study range.

Recruitment source

Overall 68.4% of individuals recruited were identified from generalized recruitment sources compared with 31.6% of people recruited from targeted sources. In contrast, a significantly larger percentage of individuals identified from targeted recruitment efforts were found eligible to move to a baseline visit compared with a greater percentage of individuals identified using a generalized community wide recruitment effort who were found ineligible ($p < 0.0001$).

Based upon individual recruitment source, study advertisements (38.8%) provided the largest percentage of recruits. Study advertisements represent a generalized recruitment source that included print and electronic advertisements in local papers, magazines, television and radio; fliers displayed throughout the community and letters sent through the university partner, dental and diabetes clinics. Though the largest percentage of individuals were identified from this source, only a quarter (175/677) of individuals recruited from study advertisements were found eligible on screening to continue to a baseline visit. Greater than 10% of individuals were successfully identified for screening from each of three other sources – medical practices/clinics which were primarily diabetes specialty practices (13.5%); articles about the study and periodontal disease among persons with diabetes published in local newspapers (11.3%); and dental practices/clinics primarily associated with the investigators own practice/clinic (10.8%). Fewer than 5% of individuals were recruited through health fairs, website advertisements and multiple sources with little difference between eligibility statuses. Individuals identified from newspaper articles were more often determined not to be eligible (Table 3).

Recruitment yield by recruitment source & demographic characteristics

Table 4 examines the recruitment yield by source and demographic characteristics looking first at all screened individuals (Table 4A) and then only the subset of individuals who were found eligible to move to a baseline visit (Table 4B). To determine whether yield by recruitment source varied by race/ethnicity or gender, we examined each recruitment source and compared the yields for all screened individuals (Table 4A) compared with the yield from individuals eligible for a baseline visit (Table 4B). Since Hispanic origin and race were asked as separate questions during interview, the data are presented separately. Over half of all individuals identifying themselves as His-

Table 1. Demographic characteristics for all individuals screened for Diabetes and Periodontal Therapy Trial by eligibility status from the first screening visit.

Demographic characteristics	Eligibility status at the first screening visit				Total screened		p-value
	Eligible		Not eligible				
Totals	(n = 473)		(n = 1283)		(n = 1756)		
	n	%	n	%	n	%	
Gender							
Male	250	52.9	610	47.5	860	49.0	0.05†
Female	223	47.1	673	52.5	896	51.0	
Age							
<35	0	–	1	0.1	1	0.1	0.02†
35–40	23	4.9	73	5.7	96	5.5	
41–50	95	20.1	267	20.8	362	20.6	
51–60	182	38.5	429	33.4	611	34.8	
61–70	132	27.9	327	25.5	459	26.1	
70+	41	8.7	186	14.5	227	12.9	
Mean (SD)	57.2 (9.9)		57.9 (10.9)		57.7 (10.6)		0.20‡
Median (min, max)	57 (35, 86)		58 (34, 86)		57 (34, 86)		
Age diagnosed§							**<0.01‡**
Mean (SD)	45.4 (9.6)		48.0 (11.5)		47.3 (11.1)		
Median (min, max)	46 (21, 78)		48 (13, 82)		47 (13, 82)		
Years since diagnosed§							**<0.01‡**
Mean (SD)	12.1 (8.2)		10.4 (8.1)		10.8 (8.2)		
Median (min, max)	11 (0, 55)		9 (0, 50)		10 (0, 55)		
Hispanic origin§							
Hispanic	162	34.2	211	16.4	373	21.2	**<0.01†**
Not Hispanic	311	65.8	1071	83.5	1382	78.7	
Ethnicity							**0.01†**
African–American/Black	134	28.3	430	33.5	564	32.1	
American–Indian/Alaska Native	41	8.7	72	5.6	113	6.4	
White	255	53.9	698	54.4	953	54.3	
Asian	15	3.2	42	3.3	57	3.2	
>1 Ethnicity Reported	9	1.9	10	0.8	19	1.1	
Other	19	4.0	31	2.4	50	2.8	

†Based on Chi-square test.
‡Based on *t*-test.
§Missing data (not eligible): Age diagnosed (n = 26); Years since diagnosis (n = 15); Hispanic (n = 1).

panic were recruited from study advertisements and medical practices (27.4 and 27.1%, respectively) (Table 4A). Medical practices provided 32.7% of eligible individuals who identified themselves as Hispanic (Table 4B) followed by study advertisements. Persons identifying themselves as non-Hispanic were more successfully recruited and found eligible based upon recruitment from study advertisements. A similar pattern was seen for recruitment by race and gender. A comparison of the percentage of individuals identified overall by recruitment source to those found eligible was significantly different. The yield of eligible individuals from medical practices was at least two-times greater than the yield of not eligible individuals from the same source for those identifying themselves as African–American ($p = 0.001$) or White ($p < 0.0001$), and for both genders (males $p < 0.0001$; females $p = 0.001$).

Table 2. First reason Ineligible for individuals excluded from and enrolled in Diabetes and Periodontal Therapy Trial. Total # of first screening visits (n = 1756).

Total # of first screening visits	n (1756)	Percentage (%)
Eligible	473	26.9
Total Ineligible after first screening visit	1283	100.0
First reason noted for ineligibility at first screening visit	Reason for ineligibility for all participants at the first screening visit whether or not they eventually enrolled in DPTT	
Personal and medical criteria from interview		
Total personal and medical criteria	121 (9.4%)	
Diabetes medication change within 3 months of screening visit	58	4.5
Other diabetes related factors (e.g., no treating physician, diabetes medication change)	11	0.9
Non-steroidal anti-inflammatory drug use	18	1.4
Antibiotic or Corticosteroid use	26	2.0
Personal factors (e.g. age, ability to participate)	8	0.6
Oral and periodontal criteria from oral exam		
Total oral and periodontal criteria	743 (57.9%)	
EDC required	**222**	**17.3**
Prior periodontal therapy	89	6.9
Recent deep cleaning	1	0.1
Other periodontal exclusions	2	0.2
increased bleeding risk	20	1.6
< 16 natural teeth	54	4.2
Oral problems identified	6	0.5
Insufficient periodontal disease	**349**	**27.2**
HbA_{1c} criteria from HbA_{1c} testing		
Total HbA_{1c} out of range	419 (32.7%)	
HbA_{1c} <7	**296**	**23.1**
HbA_{1c} ≥9	**123**	**9.6**

DPTT: Diabetes and Periodontal Therapy Trial.

Reasons for ineligibility by recruitment source

Oral and periodontal criteria (740/1276; 57.9%) and HbA_{1c} criteria (415/1276; 32.5%) accounted for over 90% of individuals found ineligible at their first DPTT screening visit. A lower percentage of individuals ineligible due to these criteria were identified from targeted sources (23.8 and 33.3%, respectively) compared with individuals ineligible due to personal or medical criteria (40.5%). In contrast generalized recruitment sources identified greater percentages of individuals who were ineligible due to oral and periodontal criteria or out of range HbA_{1c} values (Table 5).

Within each category of ineligibility the largest percent of individuals found ineligible was identified from study advertisements (range: 32.2–42.7%) (Table 5). Detailed reasons for ineligibility for oral and periodontal criteria and HbA1c are presented in Tables 6 & 7, respectively, by recruitment source and eligibility status. Ineligible individuals with a history of periodontal therapy were more likely to have been recruited from a study advertisement (56/92; 60.9%) (Table 6). Individuals identified from medical practices more often were excluded due to oral problems (10/79; 12.7%) or required EDC (25/220; 11.4%) than other oral or periodontal exclusion criteria (Table 6). As expected a larger percentage of those excluded with a history of periodontal therapy were identified from dental clinics (12/92; 13.0%) (Table 6). Individuals with out of range HbA1c were overall less likely to be identified from targeted sources compared with generalized sources (40.2 vs 59.8%); there was no difference

Table 3. Recruitment source by eligibility status at the first screening visit.

Recruitment source	Eligibility status at first screening visit				Total screened	
	Eligible		Not eligible			
	n	%	n	%	n	%
Targeted sources						
Medical practice/clinic	99	21.1	136	10.7	235	13.5
Dental clinic	57	12.1	132	10.3	189	10.8
Friend/relative	33	7.0	95	7.4	128	7.3
Generalized sources						
Newspaper article	37	7.9	161	12.6	198	11.3
Study advertisement	175	37.2	502	39.3	677	38.8
Brochure	16	3.4	76	6.0	92	5.3
Radio/TV	19	4.0	83	6.5	102	5.8
Health fair	17	3.6	30	2.4	47	2.7
Website	10	2.1	27	2.1	37	2.1
Multiple sources	7	1.5	34	2.7	41	2.4
Total[†]	470	100.0	1276	100.0	1746	100.0
Total targeted source	189	40.2	363	28.4	552	31.6
Total generalized source	281	59.8	913	71.6	1194	68.4

[†]Ten individuals did not have information on recruitment source.

in the percent with HbA_{1c} lower or higher than the study range identified within source type ($p > 0.05$) (Table 7).

Discussion

DPTT recruitment data provided some interesting insights into recruiting diverse participant populations for two chronic conditions of periodontitis and Type 2 diabetes by age, gender, race and ethnicity. This is the only published report available to date that describes recruitment for these two diseases and one of only a handful of studies that report on recruitment for more than one chronic disease. Furthermore, only a few papers have reported on the methods for and success of recruiting for oral health trials.

Given the challenges of recruiting individuals for a clinical trial that required meeting eligibility criteria for more than one chronic disease, it was essential to closely monitor recruitment progress to identify and target avenues on an ongoing basis that resulted in high participant yield. Close monitoring of recruitment sources throughout the recruitment period helped to adjust efforts to maximize yield and achieve the target sample size.

Individuals who moved onto a baseline visit were more often male, had a younger age at diabetes diagnosis, a longer diabetes duration, more often Hispanic and less often African–American. Both broad-based and targeted recruitment methods proved effective in identifying different populations. Targeted methods differed from generalized methods in the reasons for ineligibility that candidates presented with. Targeted recruitment methods recruited lower percentages of individuals ineligible due to periodontal disease and diabetes criteria. Differences in recruitment methods employed by each clinical site provided the study an opportunity to examine strengths and challenges of each recruitment method.

This study brought together a new network of investigators who collectively had not previously collaborated on clinical trials as a full investigative group. Through the use of investigator training meetings, weekly coordinator and monthly steering committee calls, the team worked together to optimize recruitment efforts. The sum of these collective efforts and collaborations have been reported here. As part of the screening visit, the study collected data about recruitment, participant demographics and eligibility. With this extensive dataset, the study was able to document the challenges of identifying individuals who met both periodontal disease and diabetes eligibility criteria. At the outset the investigators, the DSMB and the funding agency discussed the optimal HbA_{1c} level to target where the study might make a difference yet not jeopardize patient safety. Discussions also included the extent of periodontal therapy to include that would have the potential to influence reduction in HbA_{1c}. Likewise there were discussions on the minimal number of available teeth knowing that those with less teeth would have poorer

Table 4. Recruitment yield by recruitment source and demographic characteristics.

Recruitment source	Race/ethnicity												Gender			
	Hispanic origin				African–American		American–Indian		White		Other		Male		Female	
	Hispanic		Not Hispanic													
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
(A) All screened																
Targeted sources																
Medical practice/clinic	99	27.1	136	9.9	72	12.8	20	17.7	123	13.0	20	15.9	116	13.6	119	13.4
Dental clinic	61	16.7	128	9.3	40	7.1	2	1.8	132	14.0	15	11.9	92	10.7	97	10.9
Friend/relative	41	11.2	87	6.3	43	7.6	1	0.9	76	8.1	8	6.3	64	7.5	64	7.2
Generalized sources																
Newspaper article	13	3.6	185	13.4	92	16.3	0	--	0	--	0	--	90	10.5	108	12.1
Study advertisement	100	27.4	577	41.8	198	35.1	67	59.3	361	38.3	51	40.5	350	40.9	327	36.7
Brochure	15	4.1	77	5.6	34	6.0	14	12.4	38	4.0	6	4.8	45	5.3	47	5.3
Radio/TV	5	1.4	97	7.0	55	9.8	1	0.9	41	4.3	5	4.0	45	5.3	57	6.4
Health fair	12	3.3	34	2.5	11	2.0	4	3.5	22	2.3	10	7.9	16	1.9	31	3.5
Website	13	3.6	24	1.7	8	1.4	0	--	28	3.0	1	0.8	17	2.0	20	2.2
Multiple sources	6	1.6	35	2.5	11	2.0	2	1.8	24	2.5	4	3.2	21	2.5	20	2.2
Total	365	100	1380	100	564	100	113	100	943	100	126	100	856	100	890	100
(B) Eligible																
Targeted sources																
Medical practice/clinic	52	32.7	47	15.1	28	20.9	6	14.6	57	22.6	8	18.6	55	22.2	44	19.8
Dental clinic	28	17.6	29	9.3	9	6.7	0	--	41	16.3	7	16.3	25	10.1	32	14.4
Friend/relative	16	10.1	17	5.5	7	5.2	0	--	24	9.5	2	4.7	20	8.1	13	5.9
Generalized sources																
Newspaper article	5	3.1	32	10.3	14	10.4	2	4.9	17	6.7	4	9.3	19	7.7	18	8.1
Study advertisement	38	23.9	137	44.1	55	41.0	23	56.1	80	31.7	17	39.5	99	39.9	76	34.2
Brochure	8	5.0	8	2.6	5	3.7	6	14.6	4	1.6	1	2.3	8	3.2	8	3.6
Radio/TV	1	0.6	18	5.8	10	7.5	1	2.4	6	2.4	2	4.7	9	3.6	10	4.5
Health fair	6	3.8	11	3.5	5	3.7	2	4.9	8	3.2	2	4.7	4	1.6	13	5.9
Website	4	2.5	6	1.9	1	0.7	0	--	9	3.6	0	--	6	2.4	4	1.8
Multiple sources	1	0.6	6	1.9	0	--	1	2.4	6	2.4	0	--	3	1.2	4	1.8
Total	159	100	311	100	134	100	41	100	252	100	43	100	248	100	222	100

Table 5. The first reason for Diabetes and Periodontal Therapy Trial ineligibility from the first screening visit by recruitment source.

Recruitment source	Ineligibility criteria									
	Personal and medical		Oral/periodontal		HbA_{1c}		Total ineligible†		Total eligible†	
	n	%	n	%	n	%	n	%	n	%
Targeted sources										
Total targeted	49	40.5	176	23.8	138	33.3	363	28.4	189	40.2
Medical practice/clinic	23	19.0	65	8.8	48	11.6	136	10.7	99	21.1
Dental clinic	16	13.2	62	8.4	54	13.0	132	10.3	57	12.1
Friend/relative	10	8.3	49	6.6	36	8.7	95	7.4	33	7.0
Generalized sources										
Total generalized	72	59.5	564	76.2	277	66.7	913	71.6	281	59.8
Newspaper article	15	12.4	93	12.6	53	12.8	161	12.6	37	7.9
Study advertisement	39	32.2	316	42.7	147	35.4	502	39.3	175	37.2
Brochure	9	7.4	45	6.1	22	5.3	76	6.0	16	3.4
Radio/TV	4	3.3	62	8.4	17	4.1	83	6.5	19	4.0
Health fair	2	1.7	13	1.8	15	3.6	30	2.4	17	3.6
Website	1	0.8	12	1.6	14	3.4	27	2.1	10	2.1
Multiple sources	2	1.7	23	3.1	9	2.2	34	2.7	7	1.5
Total	121	100.0	740	100.0	415	100.0	1276	100.0	470	100.0

†Includes only those with information available for both eligibility criteria and recruitment source (missing recruitment source for seven ineligible individuals and three eligible individuals).

prior oral health and may lack a sufficient number of teeth to impact inflammation. Through monthly evaluation of recruitment progress and sources of recruitment, the team was able to modify their recruitment focus as needed and recruitment staff were able to learn from one another about successes and challenges from different recruitment sources.

The recruitment process was very complex and required trained and certified personnel knowledgeable about all aspects of eligibility. Personnel were not permitted to begin recruitment until they passed a study specific training program. Study personnel were asked to review the study Manual of Procedures, complete two mock study visit forms and complete the study knowledge assessment form. Data Entry personnel were also trained and certified in using the program prior to being provided access.

The study opted to use the described filtering method of recruitment so as not to overwhelm the dental clinic with potentially ineligible individuals. The initial phone interview, while time consuming, proved successful in achieving this goal; 93% of individuals invited for an in-person screening visit met all medical and personal eligibility criteria. Almost half of individuals were excluded for oral and periodontal reasons and then half of those meeting these oral criteria were excluded due to good diabetes control (HbA1c < 7.0%). Even with these very extensive evaluations 11% of individuals found to be eligible on screening were eventually not enrolled in DPTT primarily due to changes in status between screening and baseline (e.g., antibiotic use, changed mind). These findings further substantiate the challenges and complexities of study recruitment for multiple diseases and the importance of study visit timing.

Every study develops a recruitment strategy that addresses both the disease being studied and the target audience being recruited. In general there are two approaches to recruitment, a general broad stroke approach versus a targeted and focused approach with each having its advantages and challenges as highlighted by previous investigators [16,20]. Few studies with the exception of DPTT and the Action to Control Cardiovascular Risk in Diabetes (ACCORD) Trial have addressed the challenges of recruiting individuals with diabetes and another chronic disease [19]. The ACCORD trial took place at 77 clinical sites across the United States and Canada enrolling 10,251 adults with Type 2 diabetes who were at high risk for cardiovascular disease events. Though the ACCORD sample size goals were larger than those of DPTT, the ACCORD trial also demonstrated the success of combining targeted (local) and generalized (outside) recruitment strategies to achieve sample size goals. Though ACCORD was successful in recruiting from their clinic populations,

Table 6. Reasons for oral and periodontal ineligibility identified from the first screening visit.

Recruitment source	Oral and periodontal criteria not met								Total eligible	
	Oral problems, <16 teeth, Increased risk of bleeding		Essential dental care		History of periodontal therapy		Periodontal severity			
	n	%	n	%	n	%	n	%	n	%
Targeted sources										
Medical practice/clinic	10	12.7	25	11.4	5	5.4	25	7.2	99	21.1
Dental clinic	5	6.3	21	9.5	12	13.0	24	6.9	57	12.1
Friend/relative	7	8.9	18	8.2	4	4.3	20	5.7	33	7.0
Generalized sources										
Newspaper article	14	17.7	28	12.7	5	5.4	46	13.2	37	7.9
Study advertisement	32	40.5	88	40.0	56	60.9	140	40.1	175	37.2
Brochure	2	2.5	8	3.6	3	3.3	32	9.2	16	3.4
Radio/TV	4	5.1	16	7.3	1	1.1	41	11.7	19	4.0
Health fair	1	1.3	4	1.8	1	1.1	7	2.0	17	3.6
Website	1	1.3	5	2.3	3	3.3	3	0.9	10	2.1
Multiple sources	3	3.8	7	3.2	2	2.2	11	3.2	7	1.5
Total	79	100.0	220	100.0	92	100.0	349	100.0	470	100.0

they also were required to expand recruitment to include generalized, broad based strategies, to reach their recruitment goals within their timeline. Both ACCORD and DPTT have shown that combining both targeted and generalized recruitment strategies provide for recruitment success [19]. Thus, ACCORD encouraged clinical sites to utilize at least three different recruitment strategies at any one time to achieve recruitment goals.

Similar to ACCORD, DPTT recruited from diverse sources with the majority of individuals recruited primarily from four recruitment sources: study advertisements, medical and dental practices/clinics and articles in newspapers. These sources represent both targeted and generalized recruitment efforts. DPTT targeted individuals within the diabetes clinics based upon HbA_{1c} levels; those in the dental clinics were targeted based upon their periodontal disease severity or their oral health status (e.g., number of teeth). Utilizing this targeted approach resulted in a good yield from these sources and helped DPTT achieve its recruitment goals. Despite the intensive recruitment efforts, clinical sites were slow to achieve their monthly recruitment goals since many of the cross-disciplinary collaborations were newly established and took time to reach their stride. Using estimates from the last few months of recruitment, the study could have achieved the planned recruitment goal of 600 with three additional months of recruitment; extending the planned recruitment period by only 2 months. Clinical sites that utilized more generalized recruitment strategies (e.g., study advertisements) had to screen eight individuals to identify one eligible participant in contrast to the clinical sites that worked closely with the diabetes clinic for recruitment efforts with over half of all screened individuals eligible for a baseline visit. Several of the sites, stationed DPTT recruiters within diabetes clinics during patient treatment hours; this proved to be a very effective method of direct recruiting.

Though the study did not specifically collect data for a cost analysis, one can appreciate the impact on study personnel needs, paperwork, data management and ultimately screening cost from these different recruitment yields. MacEntree *et al.* did report on the costs of various methods of recruitment for a dental clinical trial [20]. Though not standardized to 2014 dollars in 2000 the cost for general population advertising was 20% higher than personal recruitment at local community centers which further supports the advantages of implementing targeted recruitment. Recruitment efforts for a clinical trial of depression in the United Kingdom provide further evidence for the differing recruitment costs by yield and source [21]. Their analysis identified in-person exhibitions (e.g., health fairs), advertisements and general practitioner referrals as the most costly in decreasing order of cost. General practitioner costs were primarily related to personnel costs to identify those potentially eligible for recruitment. Of these costly methods, only the general practitioner was listed in the top recruitment methods in terms of

Table 7. Reasons for HbA_{1c} ineligibility identified from the first screening visit.

Recruitment source	HbA_{1c} criteria not met					
	HbA_{1c} < 7%		HbA_{1c} ≥ 9%		Total eligible	
	n	%	n	%	n	%
Targeted sources						
Medical practice/clinic	32	10.9	16	13.2	99	21.1
Dental clinic	36	12.2	18	14.9	57	12.1
Friend/relative	27	9.2	9	7.4	33	7.0
Generalized sources						
Newspaper article	35	11.9	18	14.9	37	7.9
Study advertisement	106	36.1	41	33.9	175	37.2
Brochure	13	4.4	9	7.4	16	3.4
Radio/TV	13	4.4	4	3.3	19	4.0
Health fair	12	4.1	3	2.5	17	3.6
Website	11	3.7	3	2.5	10	2.1
Multiple sources	9	3.1	0	0.0	7	1.5
Total	294	100.0	121	100.0	470	100.0

enrollment success. Their most successful enrollment methods included specialty care providers and posters. Women more often were recruited from websites and general physician practices; older individuals from posters. Investigators noted the hidden personnel costs for otherwise cost-free methods (e.g., physician patient lists). They further note the changes in yield over the course of a study as researchers alter their methods which may not truly reflect a recruitment sources full potential.

Because of the large number of screened individuals categorized as being recruited for DPTT from a study advertisement, a more detailed analysis was performed using data from one of the DPTT clinical sites where detailed logs of recruitment source(s) were available. Comparing the recruitment source information from the detailed log to that available from the screening visit, we were able to determine that for this clinical site 85% (257/302) of individuals were incorrectly included in the study advertisement category; these individuals were actually recruited from a letter sent to patients in the partnering diabetes clinics or formally participated in other diabetes studies at the institution. Of the 339 letters sent, only 38 individuals correctly had their recruitment source listed at the screening visit. After accounting for letter receivers misclassified into the study advertisement category, the remaining 44 letter receivers were classified at screening as being recruited from medical practices (n = 13), brochures (n = 27), health fairs and friends (n= 2); and other source (n = 2). Of the 518 individuals recruited for a screening visit at this one institution, based upon their logs, 65% were recruited from their letter campaign. Sixty-nine percent (112/162) of persons randomized were recruited from the letter campaign which is slightly higher than the 66% of individuals who did not enroll in DPTT. This yield is higher than the other recruitment sources presented and the study advertisement category overall, further supporting the advantages of utilizing targeted recruitment sources. The study team at this institution had a long standing collaboration for the conduct of clinical research. The effective letter campaign exemplifies the usefulness of having ongoing research partnerships. Patients of these clinics had an established commitment to the institution, understood the definition of 'study participation' and, were more likely to meet eligibility criteria. These data also stress the difficulties and importance of documenting recruitment source for monitoring recruitment success and sharing results with others. Another clinical site also partnered with a large diabetes center in their region. Though this partnership took time to develop, once solidified, their recruitment yield exceeded expectations, surpassing 50%.

The success of using targeted recruitment in DPTT was significantly better for persons identifying themselves as Hispanic, African–American or white and men, where the yield from recruitment through medical practices was higher than other methods. Beaton *et al.* used the health plan records to screen for and send invitation letters to potential participants in a diabetes education intervention [16]. The success rates observed in DPTT were higher than reported by this previous study. The IDEA study identified prospective participants through

a health plan electronic database then sent letters and followed up recipients for recruitment. DPTT clinical sites sent letters of study introduce to diabetes clinic patients and former diabetes study participants who met basic DPTT eligibility criteria and provided permission for such contact. Prescreening using electronic methods similar to the IDEA study proved successful in targeting potentially eligible individuals.

A strength of DPTT was the ability to rescreen individuals for eligibility and the success that was achieved by rescreening. Because we were enrolling individuals with two chronic diseases that included a number of potentially changeable eligibility criteria, we were able to rescreen individuals who meet all but one of the eligibility criteria, such as requiring essential dental care prior to enrollment. A recent study reported on using a similar method of rescreening to recruit participants with multiple sclerosis [22]. Their study reported a 31% success rate from rescreening but did not note how many rescreens occurred. DPTT's conversion rate from not eligible to eligible was much higher (81%), supporting the practice of rescreening individuals with reasons for ineligibility that resolve during the study recruitment period.

Reflections

Previous reports have highlighted the success of recruitment planning and creating a strong research team for clinical trials in general and periodontal studies in particular [23,24]. Using these previous experiences as the model, DPTT followed exemplary protocols for personnel training and study conduct to achieve the recruitment goals as highlighted in this report. The entire study team was involved in developing the recruitment plans, the DSMB and funding agency monitored achievements on a monthly basis and mid-trial alterations (e.g., adding additional clinical sites) were made to ensure recruitment success. The study team at each clinical site included designated recruiters and study coordinators to oversee recruitment and usher participants through the study process. This system provided continuity throughout the entire process from recruitment through study completion to ensure that individuals were not lost in the process. Maintaining a recontact list of individuals with modifiable non-eligibility criteria to rescreen proved to be a valuable pool of individuals with a commitment to participation and high rates of eligibility conversion.

Collaborations with the medical communities that treat persons with diabetes were initially slow to develop since DPTT was based within schools of dentistry. Each clinical site initially had varying degrees of prior collaborations with local medical/endocrinology practices. To help shepherd new and strengthen ongoing relationships with the diabetes community, during study planning, each clinical site identified a diabetologist from their institution to serve as a coinvestigator on the study. The clinical sites that either had ongoing or established new relationships with diabetes practices were the sites with the highest recruitment yield. These relationships though slow to develop provided a strong partnership for study recruitment success. In addition, the study leadership planned for and was able to address the initial slow recruitment pace through identifying additional clinical sites and closely monitoring recruitment progress. This proved an effective strategy for DPTT to achieve their recruitment goals within the initial recruitment timeline.

Limitations

From the outset, DPTT tracked recruitment sources at the screening visit. These data are limited since they relied on self-reports by individuals that were interpreted and documented by different study personnel. These differences highlighted by the additional analyses based on one clinical site that showed targeted recruitment letters from diabetes clinics were incorrectly recorded as a generalized study advertisement. Furthermore, since the study used a two stage recruitment process, recruitment source data on individuals who were not eligible for a screening visit were lost. The yield from initial study contact through screening and enrollment may differ from that reported beginning with the screening visit.

Conclusion

This study demonstrated the successful collaboration of different healthcare groups to recruit and conduct a study involving participants with two different chronic diseases. Planning, training and certification of study personnel helped contribute to achieving the targeted study enrollment. Data obtained during screening helped to highlight the success of using different recruitment methods to recruit a diverse participant population based upon gender, race and ethnicity.

Future perspective

DPTT recruitment data provided some interesting insights into recruiting diverse participant populations by age, gender, race and ethnicity. Future clinical trials and epidemiologic studies should consider combining a broad based generalized recruitment approach with targeted methods to achieve recruitment success. Incorporating social media as a recruitment method will reach younger audiences as well. Study leadership should incorporate into their study methodology ongoing tracking of cross-study site recruitment methods to periodically evaluate suc-

cesses and challenges. Adjusting recruitment methods over time based upon these kinds of data will help to optimize study recruitment.

With the expansion of mobile health technologies the options for participant recruitment will expand over the next 5–10 years. Use of social networking for recruitment is an avenue that will become more prevalent in future studies. Knowing more about a person's health through use of smart health devices and big health data will offer additional new techniques used for study promotion and recruitment.

Appendix 1

The DPTT Study Group includes the following individuals:

Study Chair (Stony Brook University): S Engebretson (Study Chair); M Gelato; B Moonga (7/08–3/10); R Tenzler (4/10–present).

Coordinating Center (Stony Brook University: L Hyman (PI); E Schoenfeld (Co-PI); Li Ming Dong (7/09–6/10); M Fazzari (5/11–5/12); W Hou (11/12–present); G Lerner (1/10–1/13); H Chen (1/12–present); S Lee (11/12–present); C Knuth (3/09–8/10); J Mendelsohn (9/09–12/10); G Pietrzak (12/10–11/11); C Hytner (5/11–1/13); L Snelling (8/11–3/13); S Ahmed (1/09–8/10); M Rodriguez; M Merin (9/10–4/11); J Merin (3/11–6/12); L Merill (11/11–present); L Seib (8/08–present).

Clinical Centers

University of Alabama at Birmingham: M Reddy (PI); C Lewis; N Geurs; P Vassilopoulos; A Abrahams (8/09–6/11); J Doobrow (8/09–7/10); M Geisinger; S Kukunooru (8/09–7/10); C Leavitt (8/09–7/10); J Pardo (8/09–6/11); R Abou Arraj; A Reganato (8/09–7/10); K Simmons (8/09–6/11); E Unger (8/09–6/11); J Bain; K Beaudry (10/09–8/12); M Nguyen (2/10–6/12); R Sauceda (11/10–6/12); J Bauerle (3/11–present); M Madigan (3/11–6/13); A Ntounis (3/11–6/13); M Kaur (5/11–6/13); A Stevens (7/11–present); S Goggin (10/11–present); L Pitman (10/11–present); K Trammel (10/11–6/13); C Peterson (1/12–present); S Haigh; J Jackson (8/09–4/11); E Finch (10/11–4/12); S Akers; V Grant (3/11–5/12); S Acharya (4/11–8/11); S McLean (10/11–present); J Turman; J Roche (2/10–3/12); C Bragg (8/09–10/10); R Rajanna (8/09–8/10); E Bolton.

University of Minnesota/Hennepen County Medical Center (HCMC): B Michalowicz (PI); D DiAngelis(PI-HCMC); E Seaquist; J Danielson; P Lenton; L Wolff (2/10–present); P Thibado (2/10–9/12); S Molletti (4/10–11/12); L Long-Simpson; Y Okorocha; B Hadfield; L Bartels (5/10–5/12); C Dunn; K Meyer (10/09–6/10); K Reibel (10/09–5/10); A Jordan (5/10–12/10); R Hedge (6/10–5/11); O Herrera (8/10–2/11); E Romero (2/11–3/11); S Mohamed (7/11–11/12); C Stull (10/11–12/11).

University of Texas Health Science Center at San Antonio: T Oates (PI); D Tripathy; P Alexander; D Lasho; H Gregory (10/10–12/10); G Huynh-Ba (9/10–4/13); J Jordan; S Pena (3/10–4/13); C Pacheco-Vera (8/11–4/13); M Carrera (2/10–3/10); A Munoz (1/10–5/11).

Stony Brook University (site became active 09/2010): D Paquette ((PI) 10/11-present); S Engebretson ((PI) 9/10–10/11); M Gelato; T Sayasith; Y Gu (2/11–12/12); A Roth; A Urbankova; M Ryan (10/11–12/12); J Tuthill (12/11–12/12); J Hughes; S Grewal; R Tenzler; B Houshmand (10/11–6/12); V Iacono (4/11–12/12).

University of Texas Health Science Center at Houston (site became active 08/2011): J Katancik ([PI] 8/11–6/12); B Wang ([PI] 8/12–4/13); P Orlander; S Eswaran; K Parthasarathy; R Weltman; M Wehmeyer; A Arastu (3/12–4/13); R Thomas (3/12–4/13); J Headley; A Cavender; NJ Harrison; T Dancsak (12/11–4/13); M Galpin (4/12–4/13); M Ruscheinksy (4/12–4/13).

University of Minnesota Core Laboratory: M Tsai (PI); N Hanson; M Nowicki; V Le.

Executive Committee: S. Engebretson (Chair); L Hyman; M Gelato; B Michalowicz; H Hamilton (ex officio); J Atkinson (ex officio).

Steering Committee: S. Engebretson (Chair); L Hyman; M Gelato; B Michalowicz; H Hamilton (ex officio); J Atkinson (ex officio); E Schoenfeld; LM Dong; M Fazzari; W Hou; E Seaquist; M Reddy; C Lewis; T Oates; D Tripathy; J Katancik; B Wang; P Orlander.

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No writing assistance was utilized in the production of this manuscript.

Ethical conduct of research

The authors state that they have obtained appropriate institutional review board approval or have followed the principles outlined in the Declaration of Helsinki for all human or animal experimental investigations. In addition, for investigations involving human subjects, informed consent has been obtained from the participants involved.

Executive summary

Background

- Diabetes and its associated complications have become a major public health and economic concern in the United States.
- Periodontitis may be considered a complication of diabetes.
- Individuals with diabetes are about 2.5-times more likely to be diagnosed with periodontitis and their disease is more severe than among those without diabetes.
- Periodontal disease may impact glycemic control and the risk for Type 2 diabetes. The mechanism for this relationship is still not well established.

Methods

- Study objectives
  - The Diabetes and Periodontal Therapy Trial (DPTT) was designed to evaluate the impact of nonsurgical treatment of periodontal disease on patients' diabetes control.
  - This paper presents an evaluation of the effectiveness of various recruitment methods for identifying individuals who met study eligibility criteria for both diabetes and periodontal disease.
- Recruitment process
  - Recruitment and enrollment in DPTT used a three stage approach.
  - Each clinical site developed unique recruitment strategies to take full advantage of local community resources. This information was recorded for all individuals screened for the study.
  - Recruitment source(s) were self-reported by participants as part of their screening visit interview.

Results

- Recruitment yield
  - A total of 1756 individuals completed at least one DPTT screening visit.
  - A total of 27% who completed the first screening visit were eligible to continue to the baseline visit for confirmation of eligibility and randomization.
  - Screening yield varied by clinical site (17–51%).
  - A total of 514 individuals were enrolled in DPTT.
  - A total of 82% enrolled based on a single screening visit.
- Eligibility status by demographic characteristics
  - Eligibility differed significantly by gender, age at diabetes diagnosis and diabetes duration.
  - A significantly greater percentage of persons self-identified as Hispanic were eligible.
  - A significantly lower percentage of African–Americans met eligibility criteria.
- Reasons forineligibility
  - Oral, periodontal and HbA_{1c} criteria accounted for over 90% of individuals found ineligible at their first DPTT screening visit.
  - The majority of individuals ineligible due to HbA_{1c} had a value <7%.
  - Less than 10% of screened individuals were ineligible due to personal and medical criteria.
- Eligibility status by recruitment source
  - Utilization of broad and targeted recruitment methods proved effective in identifying different populations.
  - Each recruitment method resulted in different reasons for ineligibility.
  - Targeted methods differed from generalized methods in the reasons for ineligibility.
  - The largest percentage of individuals were recruited from advertisements (e.g., print, electronic, television and radio).
  - A lower percentages of individuals recruited via targeted methods were ineligible due to periodontal disease and diabetes criteria.
  - One-fourth of these individuals recruited by study advertisements were found eligible.
  - Recruitment source was closely tied to the reason for ineligibility.

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