CLINICAL TRIALS

STUDY CONDUCT/ DATA MANAGEMENT

Clinical Trials 2008; **5:** 336–346

Recruiting and retaining pregnant women from a community health center at the US–Mexico border for the Mothers and Youth Access clinical trial

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Background Recruitment and retention in clinical trials of minorities is low, particularly in rural underserved populations. This has slowed progress in addressing racial/ethnic disparities in oral health.

Purpose To describe factors associated with successful recruitment, and identify predictors of continued retention of pregnant women attending a community health center into a randomized controlled clinical trial to prevent early childhood caries.

Methods The Mothers and Youth Access (MAYA) Trial recruited women in the second trimester of pregnancy. At baseline, consenting women completed an oral health questionnaire and received a dental exam and oral health counseling. Four months postpartum, women returned with their babies for randomization with follow up at 9-, 12-, 18-, 24-, 30-, and 36-month postpartum visits. To assess predictors of retention, data about respondents' demographics, and oral health-related knowledge, attitudes, and behaviors were obtained by questionnaire and analyzed by logistic and discrete time-to-event regression analyses.

Results Of 556 predominantly Mexican-American women recruited at baseline, 195 (35%) were excluded after baseline for not meeting inclusion criteria; 361 (65%) continued to randomization. Factors such as race/ethnicity, annual household income, household composition, oral health-related knowledge and behaviors significantly related to retention until randomization. In multivariable models, women reporting a higher annual household income were less likely to be lost to attrition before randomization (odds ratio = 0.73, 95% confidence interval (CI) 0.60–0.89); while Mexican/Mexican-American women were less likely to be lost beyond randomization (hazard ratio = 0.53, 95% CI 0.26–1.08).

Limitations Factors not measured at baseline may have been important in predicting attrition. The MAYA Trial is expected to finish by November 2008; therefore, complete results for total retention may differ from those reported here.

Conclusions Recruitment and retention efforts for pregnant Hispanic women should place heavy emphasis on culture as ethnicity remained the only borderline significant predictor in postrandomization retention. *Clinical Trials* 2008; **5**: 336–346. http://ctj.sagepub.com

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SAGE Publications, Los Angeles, London, New Delhi and Singapore 10.1177/1740774508093980

Glossary

CI	Confidence Interval
HR	Hazard Ratio
IRB	Institutional Review Board
MAYA	Mothers and Youth Access
MI	Multiple Imputation
NIDCR	National Institute of Dental and Craniofacial Research
OR	Odds Ratio
PI	Principal Investigator
SYHC	San Ysidro Health Center
WIC	Women, Infants, and Children

Introduction

Poor participation rates in clinical trials, particularly of lower income minority populations [1–3], can jeopardize the internal and external validity of a study, limit generalizability, and hinder progress in correcting health disparities in underserved populations. To increase the participation of certain populations in health-related research, the National Institutes of Health Revitalization Act of 1993, updated in 2001, mandated that women and underrepresented ethnic minorities – African Americans, Latinos, and American Indians – be included as subjects in randomized clinical trials [4]. Additional impetus for greater inclusivity came in light of the emergence of Hispanics as the largest, fastest-growing minority group in the U.S. In 2002, the Latino Consortium of the American Academy of Pediatrics Center for Child Health Research identified greater inclusion of Latino children in medical research as an urgent priority [5]. In 2004, a workshop convened by the Hispanic Dental Association and the University of Puerto Rico recommended advancing Latino oral health research to address the oral health disparities and growing needs of this population [6].

Since such mandates were implemented, the literature addressing recruitment and retention of minorities in clinical research has grown substantially. However, factors associated with retention have been less frequently reported and are not well understood [7]. Commonly reported factors include language barriers, family and community as gatekeepers, cultural differences between subjects and investigators, and lack of trust in research [7,8]. In one study, investigators identified barriers specific to minority women in clinical trials: lack of transportation, interference with work, family obligations, financial costs, and burdensome procedures [9].

The few studies documenting recruitment and retention strategies in the Hispanic population have stressed *personalismo* and other common cultural values [7,10,11]. For example, one study used *promotoras* (community lay-workers) and employed *simpatía* (respectful interaction), provided *botanas* (refreshments), used *respeto* (formal titles) when addressing participants, and acknowledged the importance of family by offering flexible scheduling [7].

In this present retrospective study, we sought to identify factors associated with recruiting and retaining pregnant women into the Mothers and Youth Access (MAYA) Trial, a randomized controlled clinical trial of interventions to prevent early childhood caries. The purpose of this article is two-fold: (1) to describe the overall study design with emphasis on the recruitment and retention strategies used and (2) to report factors associated with retaining pregnant women in the MAYA Trial. This information will be valuable for planning future trials especially in community health clinics or with Latino, pregnant, or low income populations.

Methods

The MAYA trial

The MAYA Trial is an ongoing, randomized, blinded, controlled, prevention trial designed to assess the efficacy of a dental disease prevention management model in reducing the incidence of early childhood caries in children of Hispanic women. The study is based at the San Ysidro Health Center (SYHC), located in San Diego County, California near the US–Mexico border at the world's busiest land border crossing [12]. As a federally qualified health center, SYHC has focused on integrated delivery of a full scope of services to high-risk, traditionally underserved populations, providing low-cost comprehensive primary care, oral health, and behavioral health services to approximately 50 000 patients. Most of the patients are Hispanic (85%) and live at or below the federal poverty level (70%).The MAYA Trial sought to recruit 512 pregnant women during a 36-month period.

Inclusion and exclusion criteria

To be eligible for the trial, women had to provide informed consent in English or Spanish and evidence of geographic stability (picture identification, proof of income, and two invoices showing proof of local US address). They also had to be 18–33 years of age, in the second trimester of a normal pregnancy

with a single fetus, residents of the South San Diego Bay area, and registered patients at the SYHC.

Women were ineligible if they had a high-risk pregnancy or complications, such as vaginal bleeding, premature contractions, or viral or bacterial infections. Other exclusion factors were complications requiring hospitalization during a previous pregnancy, the need for medication before dental treatment, evidence of more than two missed or rescheduled appointments at the SYHC (if applicable) before randomization, evidence of more than three missed MAYA appointments before randomization. Sisters or co-residents of enrolled MAYA participants were excluded, as were mothers already participating in the MAYA Trial through a previous pregnancy.

Human subjects

All study procedures and consent documents were approved by the institutional review boards (IRBs) at the University of California, San Francisco and San Diego State University. Compliance with the Federalwide Assurance for the Protection of Research Subjects was required and obtained to conduct research activities with human subjects at the SYHC, a federally qualified health center with no previous research activities.

All study participants provided written informed consent in English or Spanish. During the first appointment (baseline), the study was explained in the language most clearly understood. A computer presentation geared toward visual learners was provided along with the hard copy of the consent form. The presentation explained the study purpose and timeline, interventions, possible risks and benefits, and protocol that would be followed if the babies or mothers needed dental treatment. Bilingual interviewers reviewed each point on the consent form and addressed any questions or concerns. Upon birth of her child, the mother signed the consent form to allow for the child's participation in the MAYA Trial.

Randomization and study intervention

Mothers and their 4-month-old infants were randomly assigned (using computer-generated permuted blocks with varying block sizes) to one of the two treatment groups. Group A received oral health counseling only. Group B received counseling, chlorhexidine rinse for mothers, and fluoride varnish applications for their babies (Table 1). The counseling protocol was based on recommendations from the American Academy of Pediatric Dentistry for anticipatory guidance in pediatric dental care [13,14]. A culturally sensitive script was developed in consultation with health center staff, and pilot tested before implementation by the research assistant in the appropriate language (English or Spanish).

Starting at 4 months postpartum, mothers in Group B were instructed to rinse twice daily with 0.5 oz. of a chlorhexidine gluconate 0.12% solution (Peridex® OMNII Oral Pharmaceuticals) for 14 days followed by a 14-day rinse-free interval for three consecutive months, as recommended by Brambilla *et al*. [15]. Babies in Group B received an application of 0.25 mL of fluoride varnish containing 5.6 mg of fluoride (CavityShield® OMNII Oral Pharmaceuticals) every 6 months, from 12 to 30 months.

At each follow-up visit, participants were monitored for precavitated white spot (demineralized) lesions, dental caries, and adverse events. Children with white spot lesions or dental caries were referred to the SYHC dental clinic and were allowed to continue in the study. In addition, at the Data and Safety Monitoring Board's recommendation, those in Group A (counseling only) received *therapeutic* fluoride varnish applications once signs of disease were identified, according to the same

Table 1 Study timeline – Control Minimal Intervention Group (A) and Moderate Intensity Intervention Group (B)

	Prenatal (2nd trimester)	4 mos.	6 mos.	9 mos.	12 mos.	18 mos.	24 mos.	30 mos.	36 mos.
Questionnaire	A,B	A,B		A,B	A,B	A,B	A,B	A,B	A,B
Oral Health Counseling[a]	A,B	A,B	A,B	A,B	A,B	A,B	A,B	A,B	A,B
Dental exam Mother	A,B	A,B		A,B	A,B	A,B	A,B	A,B	A,B
Dental screening Baby					A,B	A,B	A,B	A,B	A,B
Salivary assay Mother	A,B	A,B		A,B			A,B		A,B
Salivary assay Baby		A,B		A,B	A,B		A,B		A,B
Chlorhexidine Mother[b]		B	B						
Fluoride varnish Baby					B	B	B	B	

[a]Counseling at 6 months conducted by telephone.
[b]Chlorhexidine rinse regimen for three consecutive months starting at 4 months postpartum.

periodicity as children in Group B. Any mother with acute dental infection as referred immediately for dental treatment.

Outcomes and data collection

The primary outcome for the trial is dental caries in the children. A secondary outcome is precavitated white spot lesions. The National Institute of Dental and Craniofacial Research (NIDCR) Criteria are being used to diagnose dental caries [16] with supplemental information from a NIDCR workshop for precavitated lesions [17]. Other secondary outcome measures include salivary levels of mutans streptococci and lactobacilli, and oral health-related behavior changes in the mothers from baseline to postintervention.

Demographic and socioeconomic data and oral health-related knowledge, attitudes, and behaviors were measured with an instrument based on a questionnaire used in the SYHC's Infant Oral Care project. The latter questionnaire was expertly reviewed, validated, and pilot tested in focus groups and intercept interviews with participants from the target population.

The primary method of data entry involved customized web-based forms that were accessed over a secure internet connection by the research assistants. Ongoing data management and cleaning included automatic data-coding and variable checking upon data entry.

Recruitment and retention strategies

The intervention was developed to be specific for this community, based on the results of an SYHC needs assessment, which demonstrated a high prevalence of early childhood caries among young children and lack of access to dental care. Considerable effort, beginning in the design phase, was directed toward developing the recruitment and retention infrastructure, which can be summarized into three categories: (1) barrier reduction, (2) incentives, and (3) relationship building.

Cultural sensitivity and competence were considered overarching and essential elements, and steps were taken to ensure these were incorporated into the study. This effort was enhanced by the principal investigator's (PI) expert knowledge of Hispanic culture. He is a bicultural and bilingual US citizen born and raised in Mexico with years of research experience with Hispanic populations. A bilingual, bicultural staff was assembled from the target population's community.

Importantly, input on the local cultural and economic climate was obtained from community members, including longstanding health care providers, members of the clinic board, representatives of local organizations, regional policy makers, and lay people. These consultants and the PI made recommendations about recruitment strategies, hiring outreach coordinators, and how to monitor and encourage participation.

Several strategies were used to recruit participants. An outreach representative gave a brief presentation about the MAYA Trial at the SYHC prenatal orientation classes held at its four clinics, SYHC Medi-Cal (federal Medicaid program in California) orientations, and meetings of the Women, Infant, and Children program (WIC). The presentation emphasized the importance of oral health during pregnancy and provided information on the purpose of the study, the time required, criteria for participation, and monetary incentives. In addition, flyers were posted at the SYHC and WIC. The SYHC staff from the OB/GYN department notified pregnant women in their second trimester already enrolled in the SYHC prenatal program about MAYA during their appointments.

Recruitment also occurred at MAYA-sponsored monthly baby showers at the SYHC and the WIC center in National City. Free breakfast and raffles with prizes, such as baby clothes, diapers, wipes, and bottles, were provided. Health fairs sponsored by the SYHC and WIC provided additional recruitment opportunities. MAYA staff were available at booths to provide information and distribute flyers and toothbrushes to promote the study.

A comprehensive approach to retention was implemented at the beginning of the study. Efforts were made to establish a warm personal bond, or *personalismo* – an important cultural value in Latino population [18] – with the study participants. These efforts included spending time without rushing, showing interest in the participant's life, and displaying socially appropriate physical contact.

Maintaining contact: In an effort to remain in close contact and verify current phone numbers and addresses, appointment cards and notification cards were sent and phone calls were made between recall appointments. Handwritten, personalized birthday cards were sent to mothers and children on the month of their birthday, and phone calls were made to mothers on their birthday. All active participants received a quarterly newsletter with information on oral health issues for pregnant women and children and upcoming MAYA project activities and events. A procedure for registering MAYA babies over the telephone also helped to maintain up-to-date contact information.

Convenience: For greater convenience to working mothers, Saturday appointments were made

available 1 day per month. In addition, MAYA participants could use the SYHC shuttle service, allowing transport between their homes and the clinic.

Incentives: After each visit, participants received a $20 grocery voucher, as an incentive to continue with the study. Child vaccination vouchers were also provided by the SYHC along with a reminder and guide to notify mothers of when their babies should be brought into the main clinic for vaccinations.

Compensation: Compensation for expenses related to participation included free dental cleanings and discounted dental services offered by the SYHC. Mothers randomized into Group B who expressed concerns about stained teeth from chlorhexidine were offered a free cleaning. In addition, starting from pregnancy to 9 months postpartum, mothers received a 75% discount for dental exams, radiographs, cleanings, deep scaling and root planing, fillings, and extractions.

Social support: To provide opportunities for social interaction, numerous parties were held for special occasions. A 3% dividend bonus from the bulk purchase of $20 grocery vouchers was used to supply food, beverages, and gifts at these parties. Baby showers and welcome baby parties were held until recruitment efforts were completed and all MAYA babies were born. Each May, at a Mother's Day party, all mothers received flowers and useful gifts, such as plastic food containers and detergent. Similarly, a party was thrown each April in celebration of Child's Day in the Hispanic culture, and children were given gifts of toys and clothing. At the end of each year, the Winter Festival party was organized to commemorate accomplishments of the past year and look ahead to a successful coming year. Additionally, a gathering for all was held at the end of every month, with an appropriate monthly theme. Gifts along with key rings with MAYA staff phone numbers were distributed.

Miscellaneous gifts: Along with the gifts at each party, other items were distributed at specific milestones of the study. Beverage mugs were given to mothers in Group B upon completion of chlorhexidine treatment, and to mothers in Group A at the 9-month recall visit. MAYA children received spin toothbrushes (Butler®) at 18 months of age. Finally, after completion of the trial, each child received a personalized, engraved, gold-colored medal, and recognition certificate.

Referral services: For issues not related to oral health, a protocol was established for the most common services needed. For mental health services, a directory list was created and maintained of all county Medi-Cal and indigent services, including access and crisis lines, hospitals, outpatient centers, and individual private practice providers. Referral options for postpartum depression or other emotional difficulties depended on the type of healthcare insurance coverage, residence, and level of severity. If covered by Medi-Cal, referrals were usually made within the SYHC for outpatient psychiatric evaluations, medication management, and other therapeutic services. In the absence of Medi-Cal coverage, referrals were made to no-cost or low-cost county public facilities nearby. In every instance, MAYA staff including a licensed clinical psychologist were available to assist in the process. Other assistance involved obtaining WIC services and applying for medical and dental insurance, mostly through Medi-Cal and California's State Children's Health Insurance Program.

Assessing recruitment and retention

The outcome measures of interest for the purpose of this article were recruitment and retention. Recruitment activity was defined as approaches used to enroll women into the study. Retention was defined as the percentage of women who remained active participants in the study from enrollment (baseline) to randomization (4-month postpartum visit) or beyond; the complement of retention is attrition.

Questionnaire data about respondents' demographics, knowledge, attitudes, and behaviors related to early childhood caries prevention were candidate predictors. A systematic review of recent scholarly work in recruitment or retention of racial/ethnic minority populations in research studies identified 10 influential barriers or facilitators to participation [19]. These major themes or factors cited by Yancey *et al*. were used to group the questionnaire data for analysis.

Statistical analysis

The survey instrument was the questionnaire administered at the baseline visit. Its 68 questions were divided into five general dimensions (domains) of our focus: sociodemographics, oral health status, oral health-related knowledge, attitudes, and behaviors. Participation yields were calculated as the number randomized divided by the number enrolled separately for sociodemographics, method of recruitment, and oral health-related factors dichotomized at the median.

Using batch scripts, Windows scheduler, and SAS/Graph to automate weekly report generation and distribution from the SAS database, accrual plots [20] for enrollment and randomization were e-mailed to investigators and staff to

facilitate tracking of recruitment and randomization. The randomization accrual plots projected future randomization from the report date by randomly sampling prerandomized participants under various retention scenarios (20, 40, 60, 80, and 100%). Projected paths represent participants expected for randomization at 4 months postpartum for each retention scenario. The projections extended about 9 months forward from any given date, reflecting the time required for the most recently enrolled participants to be randomized.

Even though individual items were each missing 5% or less, the combined 76 explanatory variables resulted in 42% of individuals having at least one missing variable (casewise deletion). Thus, multiple imputation (MI) [21] was performed with Markov chain Monte Carlo using SAS proc mi to produce 10 imputations. Bivariable and multivariable analyses were conducted to determine relationships between the independent variables and the two binary outcomes (retention to the randomization visit and retention after randomization). Factor analyses with maximum likelihood estimation and scree plots determined factors to be retained from dichotomized questions for each oral health specific domain (knowledge, attitudes, behaviors, and parent health); the factor analysis factors were determined for each of the 10 imputations. Factor analysis factors were dichotomized at the median since they were not normally distributed.

Logistic regression was used to estimate odds ratios (ORs) and 95% confidence intervals (CIs) of items (sociodemographics and factor analysis factors) related to attrition before (lack of retention until) randomization. Discrete time-to-event proportional hazards regression was used to assess items (sociodemographics and factor analysis factors) related to postrandomization retention through December 31, 2007, censoring those not yet due for follow up; hazard ratios (HRs) and 95% CIs were estimated. Logistic and time-to-event analyses were combined across the 10 imputations with the standard MI formulas [21] using SAS proc mianalyze.

Results

Description of participation and sample characteristics

The various outreach efforts yielded a total of 2891 referrals. Of these, 556 subjects consented to participate, exceeding the recruitment goal of 512. This goal was accomplished 26 months after recruiting began, earlier than expected.

Of the 555 enrollees, 361 (65%) participated through randomization at the 4-month postpartum visit. Most exclusions (78%) occurred before the 4-month visit, either due to missed appointments or relocation. Reasons for exclusion thereafter were high-risk pregnancy (7%), voluntary exit (7%), abortion or child death (2%), and other (6%). Table 2 shows the study retention, those lost to follow-up, and active participants at each visit as of December 31, 2007.

Actual and planned randomization is shown in Figure 1. The initial lag was due to delays in obtaining IRB and Federalwide Assurance approvals. To illustrate trial monitoring, a plot generated on July 31, 2005 shows a vertical line separating actual cumulative randomizations (pre-July 2005) from the projections (post-July 2005) of prerandomized participants. On that date, the projections suggested that retaining about 40% of the baseline participants would allow for the target of 361 to be met on schedule. However, since the actual retention after July 2005 was nearly 80%, randomization was completed ahead of the revised target date.

Table 2 Study Retention through December 31, 2007

Visit (month)	Marginal retention percentage[b] (%)	Sample completed (N)	Lost to follow-up after visit	Number awaiting this visit
Baseline		556	195	n/a
4[a]	$1-(195/556)\times 100=65.0$	361	39	0
9	$1-(39/361)\times 100=89.2$	322	10	0
12	$1-(10/322)\times 100=96.9$	312	22	0
18	$1-(22/312)\times 100=93.0$	290	21	0
24	$1-(21/290)\times 100=92.8$	268	13	1
30	$1-(13/268)\times 100=95.1$	197	2	58
36	$1-(2/197)\times 100=99.0$	124	n/a	71

[a]Randomization.
[b]Each marginal, or between visit, retention rate illustrates retention using only those who were lost to follow-up from a previous interval to the current recall. For instance, the 4-month rate shows the percentage of people who attended both the current and 4-month recalls.

Predictors of participation

Sociodemographic characteristics, method of recruitment, and dental health-related factors of participants at enrollment and randomization, along with corresponding retention yields, are summarized in Table 3. Both groups exhibited similar distribution of characteristics. The mean age was 25 years. Most were, Spanish-speaking Mexicans born in Mexico, who had at least a high school education, had an annual household income less than $15 000, belonged to a dual parent household, and were recruited within the SYHC. These characteristics closely corresponded to those producing the highest yields of randomized women from those who enrolled at baseline, with the exception of greater yields from women of higher annual income households. In unadjusted analyses, several factors were significantly associated with randomization, including race/ethnicity, household income, household composition, dental knowledge, and dental behavior.

Oral health-specific domain factor analyses: First, factor analyses were conducted to condense the large number of variables in the questionnaire for further predictive analysis. This resulted in one factor for each of the four oral health-specific domains. For the knowledge domain (21 items), the factor essentially corresponded to knowledge about adult tooth decay and plaque prevention (flossing, water fluoridation, fluoridated toothpaste, and limiting sweets). For attitude (18 items), the factor corresponded to opinions about adult tooth decay and plaque prevention (flossing, water fluoridation, fluoridated toothpaste, and limiting sweets). For behavior (15 items), the factor basically corresponded to tooth-brushing frequency. For parent oral health status (9 items), the factor related to oral health (perceived oral health status, current active tooth decay, and tooth sensitivity to temperature and sweets). Each resulting factor accounted for at least 83% of the variation of all the items in its domain. Since the dental knowledge factor and dental attitude factor were so similar, they were used separately in multivariable models; the more significant factor was reported.

Multivariable analysis: The MI adjusted baseline odds and independent predictors of attrition from logistic regression with odds ratios (ORs) and of time-to-post-randomization-lost-to-follow-up proportional hazards regression with hazard ratios (HRs) are presented in Table 4. The multivariable model controlling for all other factors simultaneously showed that Mexican/Mexican-Americans were more likely to be randomized (OR = 0.51, $p = 0.040$) and less likely to be lost-to-follow-up after randomization (HR = 0.53, $p = 0.079$) than women of other ethnic heritage. Household income was significantly related to being rando-mized (OR = 0.73, $p = 0.002$). Worse dental knowledge (OR = 0.72, $p = 0.072$) and lower self-reported dental health (OR = 0.72, $p = 0.086$) were close to statistical significance for not being randomized.

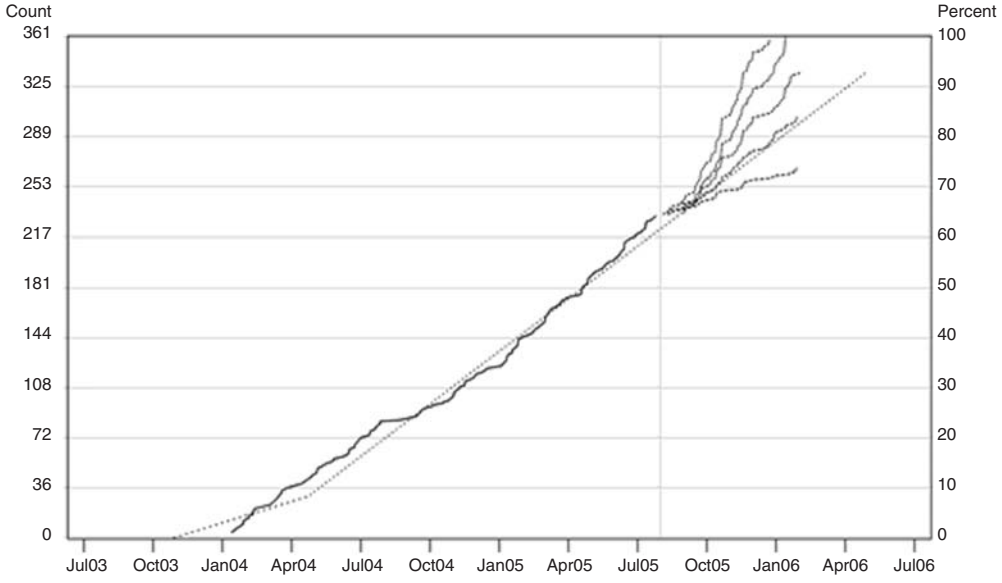

Figure 1 Targeted randomization (dashed line) and actual randomization (solid line); with mid-study projections of randomization at 20, 40, 60, 80, and 100 % retention rates (branching dashed lines)

Table 3 Randomization yields by sociodemographic strata, method of recruitment, and dental factors

Characteristic	Enrolled ($N = 556$)	Randomized ($N = 361$)	Yield (%) overall 65%
Age (mean ± SD)	24.6 ± 4.4	24.8 ± 4.5	N/A
Race/Ethnicity (%)*			
Mexican/Mexican–American	512 (92)	338 (94)	66
Other Hispanic	18 (3)	8 (2)	44
Other/Non-Hispanic	26 (5)	15 (4)	58
Primary language at home (%)			
Spanish	324 (59)	221 (61)	68
English	41 (7)	19 (5)	46
Both/Other	191 (34)	121 (34)	63
Birth place (%)			
US	210 (38)	135 (37)	64
Outside US	346 (62)	226 (63)	65
Education level (%)			
< 12th grade	230 (41)	146 (40)	63
≥12th grade/vocational	326 (59)	215 (60)	66
Annual household income (%)*			
< $15 000	312 (56)	187 (52)	60
$15 000-$49 999	237 (43)	167 (46)	70
≥$50 000	7 (1)	7 (2)	100
Household composition (%)*			
Two parents	349 (63)	238 (66)	68
Single parent	207 (37)	123 (34)	60
Method of recruitment (%)			
SYHC	224 (40)	155 (43)	69
WIC program	178 (32)	106 (29)	60
Other[a]	170 (31)	111 (31)	65
Dental knowledge > P_{50} (%)*	274 (49)	190 (53)	69
Dental behavior > P_{50} (%)*	349 (63)	239 (66)	68
Dental attitude > P_{50} (%)	325 (58)	214 (59)	66
Dental health > P_{50} (%)	280 (50)	192 (53)	69

P_{50} = 50th percentile (median).
*$p \leq 0.05$ multiple imputation univariable logistic regression.
[a]Other recruitment sources include advertisement, other prenatal programs, and personal referral by dentist, medical doctor, friend, or relative.

Table 4 Predictors of attrition through December 31, 2007

Predictor	OR	95% CI		HR	95% CI	
Intercept (i.e. baseline odds)	0.30	0.13	0.70	–	–	–
Annual Household Income[a]	0.73	0.60	0.89	0.96	0.78	1.19
Mexican Ethnicity	0.51	0.27	0.97	0.53	0.26	1.08
Dental Knowledge Factor > P_{50}	0.72	0.50	1.03	1.08	0.72	1.63
Dental Behavior Factor > P_{50}	0.74	0.49	1.12	0.82	0.49	1.37
Dental Health Factor > P_{50}	0.72	0.50	1.05	0.97	0.65	1.45

OR = odds ratio.
CI = confidence interval.
HR = hazard ratio.
P_{50} = 50th percentile (median).
[a]Increase in 1 income category.

Discussion

This study shows that clinical disease prevention trials can successfully recruit and retain pregnant Hispanic women. The 65% retention from enrollment to randomization is due, in large part, to the creation of a culturally appropriate and targeted recruitment and retention plan. These efforts covered an extensive range of strategies aimed to reduce the study's burden, provide

tangible and intangible incentives, and establish personal relationships with the participants. Overall, findings from this study indicate that belonging to a higher household income category was the only significant predictor of being randomized, while being Mexican/Mexican-American was the only borderline significant influence on retention after the randomization visit.

Several studies show a higher participation of Hispanics in research studies in comparison to Whites and African Americans [22–24]. However, only one study examined participation within the Hispanic subgroups, reporting that Mexican women had higher odds of being retained than Puerto Rican women. This was attributed to the study's intervention being tailored to Hispanic culture, and their Puerto Rican participants tending to be more acculturated to mainstream US culture [25]. This finding may also apply in the present study as the environment of the MAYA Trial tended to be Hispanic oriented, and the non-Mexicans as a group were less likely to speak Spanish, an indicator for Hispanic acculturation.

Our results regarding income corroborate other studies which also reported women or minorities with less income were less likely to participate in clinical trials or intervention studies [22,26,27]. Because economic and cultural circumstances are intertwined, it is difficult to ascertain whether ethnicity or socioeconomic status is the stronger influence on participation in clinical trials. However, our data indicate ethnicity more strongly affects retention over time than income, an indicator of socioeconomic status. This suggests that willingness to remain in the study may be influenced more by psychosocial and cultural factors associated with ethnicity than by economic factors.

In contrast to previous reports, we did not find that lower levels of disease-specific knowledge [28–30] or worse self-perceived health status [31–33] are barriers to research participation. This result suggests that sociodemographic factors, especially those associated with culture and ethnicity, are more important determinants of continued participation in long-term research studies than are most health status or health-related knowledge or behavior characteristics. The lack of association could also be attributed to self-reports that may include social desirability bias.

Limitations

There were several limitations in this study. First, the MAYA Trial was not designed to empirically evaluate different recruitment and retention strategies. There was no planned differentiation in the participants' exposure to the strategies used. In addition, different strategies were employed at various times throughout the study, as staff learned more about the participants. As a result, this precluded any well-controlled analyses of these methods. This also relates to the reason for using two of 10 themes identified by Yancey's review article. The remaining eight related to study design issues (5) or person-level factors (3) that were not measured in the questionnaires.

Several of the eligibility criteria such as requiring evidence of geographic stability and exclusion after three missed appointments likely contributed to the successful retention observed in the study. However, these criteria were considered necessary as border communities are highly migratory. Selective inclusion and exclusion criteria relates to diminished generalizability of results, the next limitation. The relatively homogeneous sample may limit the external validity of our findings. All subjects were recruited from a single rural US–Mexico border city, with most sharing similar sociodemographic characteristics. Therefore, it is unclear how these predictors of retention might differ for other minority groups or in other cities. However, this study targets a large and important population known to carry a high overall and oral disease burden [34]. Applying successful recruitment and retention strategies in trials focused on such communities could be an effective approach to reducing oral health disparities through increased participation.

Another limitation was the static nature of the predictor variables for retention. Retaining participants is likely to be a complex, dynamic, and interpersonal process between the participants and research staff. Components such as *personalismo* were neither measured nor controlled for in analyses, though strongly implicated as an important retention factor in the MAYA Trial. Thus any variability in staff may have influenced the formation of personal relationships, and therefore retention.

Lastly, since the MAYA Trial is expected to complete all visits in November 2008, predictors of retention to the end of the study may differ from those reported from this analysis. However, since most of the attrition so far has been early, factors relating to early attrition are likely to be related to total attrition when the trial is completed.

Conclusion

This study seems to legitimize the use of a culturally sensitive, comprehensive, and targeted recruitment and retention plan in the MAYA Trial, as race/

ethnicity remained the only borderline significant predictor of retention over time. Disentangling the relative contribution of any one of the various recruitment and retention strategies is difficult, and would require further research using controlled variables. However, this study does show that successful recruitment and retention of racial/ethnic minorities in clinical trials, in particular with pregnant Hispanic women, can occur through culturally appropriate, comprehensive and targeted efforts. These efforts are necessary to ensure scientific rigor and to facilitate the research needed to support clinical practice with this growing population.

Acknowledgments

The authors thank the San Ysidro Health Center for their generous contributions and support in providing resources and services for the MAYA Trial and participants; OMNII Oral Pharmaceuticals for providing fluoride varnish and chlorhexidine supplies, and all study participants. The authors also wish to acknowledge others on the study team and their contributions to various aspects of the study. These include: Mr Ed Martinez, Dr Greg Talavera, Mr Terry Whitaker, Dr Joachim Reimann, Dr Sergio Cuevas, Ms. Laura Paniagua, Dr Beverly Martinsons, Ms Teresa Cabrera, Ms Olga Lopez, Dr Oscar Rivera, Dr Natasha Brambila, Dr Yolanda Garcia, Dr Ariel Rodriguez, Dr Susan Stewart, The Maria Sardinas Center, SYHC WIC, Chula Vista WIC, First 5 California.

The MAYA Trial is supported by US DHHS/NIH/NIDCR & NCMHD Research Grant U54 DE142501, UCSF Center to Address Disparities in Children's Oral Health.

References

1. **Blumenthal DS, Sung J, Coates R, Williams J, Liff J.** Recruitment and retention of subjects for a longitudinal cancer prevention study in an inner-city black community. *Health Serv Res* 1995; **30**: 197–205.
2. **Miranda J, Azocar F, Organista KC, Munoz RF, Lieberman A.** Recruiting and retaining low-income Latinos in psychotherapy research. *J Consult Clin Psychol* 1996; **64**: 868–74.
3. **Naranjo LE, Dirksen SR.** The recruitment and participation of Hispanic women in nursing research: a learning process. *Public Health Nurs* 1998; **15**: 25–9.
4. **National Institutes of Health N**. NIH policy and guidelines on the inclusion of women and minorities as subjects in clinical research. Available at http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm. Accessed November 20, 2006.
5. **Flores G, Fuentes-Afflick E, Barbot O** *et al*. The health of Latino children: urgent priorities, unanswered questions, and a research agenda. *JAMA* 2002; **288**: 82–90.
6. **Ramos-Gomez F, Cruz GD, Watson MR, Canto MT, Boneta AE.** Latino oral health: A research agenda toward eliminating oral health disparities. *J Am Dent Assoc* 2005; **136**: 1231–40.
7. **Keller CS, Gonzales A, Fleuriet KJ.** Retention of minority participants in clinical research studies. *West J Nurs Res* 2005; **27**: 292–306.
8. **Levkoff S, Sanchez H.** Lessons learned about minority recruitment and retention from the Centers on Minority Aging and Health Promotion. *Gerontologist* 2003; **43**: 18–26.
9. **Brown DR, Fouad MN, Basen-Engquist K, Tortolero-Luna G.** Recruitment and retention of minority women in cancer screening, prevention, and treatment trials. *Ann Epidemiol* 2000; **10**: S13–21.
10. **Gallagher-Thompson D, Solano N, Coon D, Arean P.** Recruitment and retention of latino dementia family caregivers in intervention research: issues to face, lessons to learn. *Gerontologist* 2003; **43**: 45–51.
11. **Preloran HM, Browner CH, Lieber E.** Strategies for motivating Latino couples' participation in qualitative health research and their effects on sample construction. *Am J Public Health* 2001; **91**: 1832–41.
12. **U.S. Department of Transportation, Bureau of Transportation Statistics**. Border Crossing/Entry Data. Available at http://www.transtats.bts.gov/Fields.asp?Table_ID=1358. Accessed December 2, 2006.
13. **Casamassimo P.** *Bright Futures in Practice: Oral Health*. National Center for Education in Maternal and Child Health, Arlington, VA, 1996.
14. **Nowak AJ, Casamassimo PS.** Using anticipatory guidance to provide early dental intervention. *J Am Dent Assoc* 1995; **126**: 1156–63.
15. **Brambilla E, Felloni A, Gagliani M** *et al*. Caries prevention during pregnancy: results of a 30-month study. *J Am Dent Assoc* 1998; **129**: 871–7.
16. U.S. Department of Health and Human Services, Public Health Services, National Institute of Health, National Institute of Dental Research. Oral health surveys of the National Institute of Dental Research, Diagnostic criteria and procedures. In: NIH Publication No. 91-2870, Bethesda, MD, 1991.
17. **Drury TF, Horowitz AM, Ismail AI** *et al*. Diagnosing and reporting early childhood caries for research purposes. A report of a workshop sponsored by the National Institute of Dental and Craniofacial Research, the Health Resources and Services Administration, and the Health Care Financing Administration. *J Public Health Dent* 1999; **59**: 192–7.
18. **Flores G.** Culture and the patient-physician relationship: achieving cultural competency in health care. *J Pediatr* 2000; **136**: 14–23.
19. **Yancey AK, Ortega AN, Kumanyika SK.** Effective recruitment and retention of minority research participants. *Annu Rev Public Health* 2006; **27**: 1–28.
20. **Probstfield JL, Wittes JT, Hunninghake DB.** Recruitment in NHLBI population-based studies and randomized clinical trials: data analysis and survey results. *Control Clin Trials* 1987; **8**: 141S–149S.
21. **Schaefer JL.** *Analysis of Incomplete Multivariate Data*. Chapman & Hall, London, 1997.
22. **Lewis CE, George V, Fouad M** *et al*. Recruitment strategies in the women's health trial: feasibility study in minority populations. WHT:FSMP Investigators Group. Women's Health Trial:Feasibility Study in Minority Populations. *Control Clin Trials* 1998; **19**: 461–76.
23. **Marin G, Marin BV.** *Research with Hispanic Populations*. Sage, Newbury Park, CA, 1991.
24. **Unson CG, Ohannessian C, Kenyon L** *et al*. Barriers to eligibility and enrollment among older women in a

clinical trial on osteoporosis: effects of ethnicity and SES. *J Aging Health* 2004; **16**: 426–43.
25. **Kim YJ, Peragallo N, DeForge B.** Predictors of participation in an HIV risk reduction intervention for socially deprived Latino women: a cross sectional cohort study. *Int J Nurs Stud* 2006; **43**: 527–34.
26. **Baquet CR, Commiskey P, Daniel Mullins C, Mishra SI.** Recruitment and participation in clinical trials: socio-demographic, rural/urban, and health care access predictors. *Cancer Detect Prev* 2006; **30**: 24–33.
27. **Coatsworth JD, Duncan LG, Pantin H, Szapocznik J.** Differential Predictors of African American and Hispanic Parent Retention in a Family-Focused Preventive Intervention. *Fam Relat* 2006; **55**: 240–251.
28. **Hoyo C, Reid ML, Godley PA** *et al***.** Barriers and strategies for sustained participation of African-American men in cohort studies. *Ethn Dis* 2003; **13**: 470–6.
29. **Lopez VA, Castro FG.** Participation and program outcomes in a church-based cancer prevention program for Hispanic women. *J Community Health* 2006; **31**: 343–62.
30. **Siddiqui O, Flay BR, Hu FB.** Factors affecting attrition in a longitudinal smoking prevention study. *Prev Med* 1996; **25**: 554–60.
31. **DiFranceisco W, Kelly JA, Sikkema KJ** *et al***.** Differences between completers and early dropouts from 2 HIV intervention trials: a health belief approach to understanding prevention program attrition. *Am J Public Health* 1998; **88**: 1068–73.
32. **Goldberg M, Chastang JF, Zins M, Niedhammer I, Leclerc A.** Health problems were the strongest predictors of attrition during follow-up of the GAZEL cohort. *J Clin Epidemiol* 2006; **59**: 1213–21.
33. **Matthews FE, Chatfield M, Brayne C.** An investigation of whether factors associated with short-term attrition change or persist over ten years: data from the Medical Research Council Cognitive Function and Ageing Study (MRC CFAS). *BMC Public Health* 2006; **6**: 1–10.
34. **Beltran-Aguilar ED, Barker LK, Canto MT** *et al***.** Surveillance for dental caries, dental sealants, tooth retention, edentulism, and enamel fluorosis–United States, 1988–1994 and 1999–2002. *MMWR Surveill Summ* 2005; **54**: 1–43.