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Issues in Designing and Implementing a Spanish-Language Multi-Site Clinical Trial

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Abstract

To address at least in part health disparities in Hispanic populations, the NIDA Clinical Trials Network implemented the first multi-site randomized clinical trial of substance abuse treatment conducted entirely in Spanish. This trial was intended to evaluate the effectiveness of Motivational Enhancement Therapy in a diverse population of Hispanics. In the conduct of this trial, several barriers to the successful implementation of a Spanish-language multi-site trial had to be addressed, including the appropriate translation of assessment instruments, shortage of appropriately trained Spanish-speaking clinical staff, and barriers to recruitment and retention of this population. To encourage similar research, strategies are described that were developed by the study team to meet these challenges.

INTRODUCTION

Substance abuse is a significant problem among Hispanic Americans, who represent the largest ethnic minority group in the United States.[1] The 2004 National Survey on Drug Abuse[2] reveals that 35% of Hispanics 12 years or older have used illicit drugs in their lifetime and 40% have used alcohol. National data on rates of treatment utilization suggest that Hispanics who meet diagnostic criteria for a psychiatric disorder who may benefit from treatment are less likely than Whites and African Americans to receive treatment services, and, moreover, those services are often delayed when they are available.[3] Furthermore, of those who receive treatment, Hispanics are more likely than the other ethnic groups to express dissatisfaction with their care.[3]

Compounding the disparities in treatment access and utilization among Hispanics is the under-representation of monolingual Spanish-speaking patients in clinical and research samples.[3–5] Many factors contribute to this under-representation, including difficulty with recruitment and retention, assumptions that ethnic minority populations do not differ in treatment response, and desire to maximize internal validity by reducing participant heterogeneity.[6] Another major barrier to participation by monolingual Hispanics is the

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inability to read consent forms or complete study assessments that are written in English. This likely affects a significant number of Hispanics, given estimates that 55% of the Hispanic adult population in the United States have limited English proficiency.[7] Thus, clinical trials that exclude Spanish-speakers by definition exclude a sizable proportion of the Hispanic population. Those few studies that have addressed language barriers with Hispanic patients have reported lower drop out rates, increased length of individual therapy, and improved treatment outcomes.[8,9]

To date, there are no efficacy trials of treatments specifically designed to meet the substance abuse treatment needs of Hispanic adults in the United States, and very few single site studies have been conducted primarily with Hispanic adult substance users.[10] One exception is a randomized clinical trial with injection drug abusers conducted in Puerto Rico.[11] Six sessions of motivational interviewing along with case management were more efficacious than two sessions of HIV counseling in engaging drug users into drug treatment, discontinuation of drug injection, and reduction of needle sharing. However, another randomized trial conducted in English where the majority of the participants were of Hispanic origin found that adding one session of motivational interviewing to standard care did not make a difference.[12]

To address the under-representation of Hispanics in clinical trials of substance use treatments, the National Institute on Drug Abuse (NIDA) Clinical Trials Network (CTN) implemented the first ever multi-site trial of treatments for monolingual Spanish speakers. The CTN is a nationwide network of collaborators from 17 academic research centers and more than 100 community treatment programs. Through multi-site studies, it provides a unique opportunity for conducting groundbreaking clinical research with diverse Hispanic populations throughout the United States.

This report describes the development and implementation of the first multi-site study conducted in Spanish with Hispanic substance abusers. The study evaluates the efficacy of Motivational Enhancement Therapy (MET) compared with standard counseling for substance use in the first month of outpatient treatment. With the aim of stimulating more rigorous research with Spanish-speaking groups, we describe the challenges confronted in developing and implementing a Spanish-language protocol in diverse community treatment settings across the United States and the strategies we used to address these challenges. Specifically, we discuss issues impacting the trial's design and implementation (see Table 1 for overview) and then summarize our recommendations for future monolingual Hispanic population research efforts.

DESIGNING A MULTI-SITE RANDOMIZED TREATMENT TRIAL IN SPANISH

Rationale for a Spanish MET Trial

The Spanish MET trial is an adaptation of a completed CTN trial[13] that compared Motivational Enhancement Therapy (MET)[14,15] with counseling-as-usual in the first month of outpatient treatment in five community-based sites across the country (Santa Fe, NM; Denver, CO.; Miami, FL, New York, NY; Portland, OR). Briefly, in the original (English) version of this trial, individuals seeking treatment for any substance use disorder were randomized to receive either three individual sessions of manual-guided MET or three sessions of the standard individual counseling offered at the participating sites. Assessments at 28 days post-randomization and then one- and three-month follow-ups evaluated the extent to which participants remained in treatment and reduced their substance use. Clinicians (with little or no training in motivational interviewing) were volunteers from the staff of the participating sites and were randomized to be trained in and then implement MET or to continue to use the standard counseling approach in that clinic.[13,16]

The MET protocol was selected to be adapted for a monolingual Spanish-speaking population because it focused specifically on fostering engagement and retention in treatment and thus potentially addresses an important health disparity issue in this population. Hispanics have been shown to report poorer motivation for substance abuse treatment and higher dropout rates when they do seek treatment compared to their Caucasian counterparts.[17–19] In addition, the client-centered, collaborative style of MI was seen as a culturally sensitive approach that works well with ethnic minority populations.[20] Adapting a successfully implemented protocol evaluating MET for use with primarily Spanish-speaking Hispanic ethnic minority populations across the United States was a reasonable step in evaluating the differential effectiveness of MET and implications for treatment with this underserved and under-researched population.

Coordination and Complementary Roles of Two Lead Nodes

Because no single organization within the CTN had the necessary resources to coordinate and execute a complex multi-site Spanish-language proposal, two academic centers developed and led the protocol jointly throughout the trial. The New England Node, headquartered at Yale University, had developed and led the English versions of the protocols[13,21] and thus took the lead in the trial design, data management, quality assurance, and clinician training aspects of the trial. The Florida Node, headquartered at the University of Miami, oversaw translation of research materials (eg, assessments, consent forms, training materials), certification of bilingual interviewers and clinicians, and regulatory issues.

Site Requirements and Capability of Network to Conduct Protocol

A critical first step in implementing the trial was to determine if an adequate number of clinical sites treating sufficient numbers of Spanish-speaking patients were available within the CTN network, as many community treatment providers often lack the resources to treat this population.[22] A particularly scarce resource in community clinics is qualified bilingual clinical staff.[23] To be eligible to participate in the trial, community treatment clinics had to currently offer outpatient substance abuse treatment to Spanish-speaking individuals and have sufficient client flow to meet the recruitment goal of 80 randomized individuals per site within a two-year period, as well as have at least four bilingual clinicians on staff who were willing to participate in the protocol (given that half would be randomized to learn and implement MET, and the other half to deliver treatment as usual). As with the English MET trials, all clinicians were required not to have had previous formal training in MET, be willing to be randomly assigned to deliver MET (after training) or counseling as usual (not receive training), and have their sessions audiotaped.[13,16] Several sites that had indicated interest in the trial were excluded from participation because they did not offer treatment in Spanish and, hence, had no Spanish “counseling as usual” against which to compare the effectiveness of MET.

Availability of Research Instruments in Spanish

Because this protocol sought to recruit Spanish-speaking adult Hispanics, particularly those typically excluded from research protocols, the dearth of psychometrically sound Spanish-language instruments was a particular challenge. In the Spanish MET protocol, our aim was to replicate the original MET protocol assessment battery. From the original battery, the Addiction Severity Index (ASI)[24] has two Spanish versions, but with no published data on psychometric properties. A version developed by Gonzalez-Saiz and colleagues[25] was selected and adapted by supplementing items with word choice alternatives listed in parentheses to reflect regional variations in spoken Spanish across our sites. Moreover, the English version of the protocol used the Substance Dependence Severity Scale (SDSS),[26] which does not have a Spanish version to yield substance use disorder diagnoses. In its

place, the Spanish language version of the Composite International Diagnostic Interview (CIDI)[27] was used.

Translation Procedures—With the exception of the ASI and CIDI, all self-report and interview instruments used in this study had to be translated into Spanish. A team was assembled to translate assessment instruments, consent forms, local recruitment materials, and treatment manual. The team was composed of a bilingual coordinator who had assessment and measurement expertise, eight translators approved by the University of Miami Institutional Review Board, and volunteer bilingual consultants at each of the study sites who were familiar with local dialects and cultural nuances of their target Hispanic populations. Nationalities of the members of the translation team were representative of the largest Hispanic groups in the United States, including Mexican, Puerto Rican, and Cuban, as well as Colombian, Peruvian, Argentinian, and Nicaraguan. In recognition of the variety of nationalities and regional differences in Spanish language use in the United States, steps were taken to ensure that local variations in language were included in the translation of the instruments.

The translation team followed specific back-translation procedures to protect the integrity of previously validated instruments.[28] Specifically, in the initial translation from English to Spanish, we followed a structured process to accurately capture the intended meaning of the English items in all of the instruments, including initial translation to Spanish, back-translation of the Spanish version to English by different translators, and discussion of discrepancies between the two English versions. An additional step was taken for the purposes of capturing regional variations in language use. Bilingual consultants at participating sites reviewed translated instruments. These individuals suggested regional/national terminology to ensure the instrument's accessibility to a broad range of Spanish speakers. The suggested regional Spanish words were included in parentheses in the final Spanish-language translated instruments.

Issues with Translated Instruments in the Context of a Monitored Multi-Site Trial—A lack of bilingual trainers for these instruments further challenged our protocol training team. While mechanisms within the CTN existed for certifying the competent delivery of protocol assessment batteries across sites, resources for training and monitoring research staff in the use of Spanish instruments were largely unavailable. For example, we found only one credentialed trainer who could provide the training in Spanish for the Spanish version of the CIDI, and Spanish-speaking CTN-approved trainers for the other standardized interviews used in the study (eg, ASI-Lite and HIV Risk Behavior Survey) were not available. Therefore, the research staff at each site was trained and credentialed in English on these instruments by certified English-speaking trainers. In the case of the CIDI, although a Spanish trainer certified by the World Health Organization provided initial didactic training in Spanish, the credentialing and recertification process, as required by the CTN, had to be performed in English by English-speaking trainers. Additionally, the CTN did not have certified bilingual personnel to perform adherence checks of the Spanish administration of the CIDI throughout the trial. This practice created problems for the research assistants at the sites, who sometimes did not have easy access to English-speaking clients. It also did not allow for an independent measure of the research assistants' competence in administering these instruments in Spanish. Developing Spanish-speaking experts/trainers for assessment instruments to ensure the highest level of preparation and monitoring of research staff members who work within Hispanic population research protocols is a priority for the field.

Once implemented, the participants and research staff provided valuable feedback about the formality of the instruments' translations. Words chosen for the translations typically used a

formal tone in part to respect the linguistic rules of the Spanish language and some of the regional customs in Hispanic countries. However, many persons of Hispanic heritage prefer to be treated informally, especially as they get to know another person, a Hispanic preference known as personalismo.[29] Thus, participants sometime reported a discrepancy between the language used in the instruments and their personal relationship with the research assistant.

Diversity of Country of Origin, Acculturation, and Race Issues—Another issue related to the diversity of Hispanic populations is that the standard instrument used in most clinical trials to collect demographic and ethnicity information is insufficiently detailed or specific in its assessment of country of origin, immigration, and acculturation experiences—qualities that may be critical to evaluating site or subgroup differences in a multi-site clinical trial. Hence, we developed a brief addendum to our assessment to include country of origin, the country of birth of each parent, as well as primary language learned at home and used currently. Another question was added to assess the length of residence in the United States, which taps into the generational and/or immigration status of the participants in this sample. Finally, standard instruments force individuals into discrete categories that may not accurately describe person of mixed ethnic background (eg, a biracial Hispanic participant of indigenous and white racial background may not relate or identify with the terms for his/her race as either “American Indian” or “Caucasian”). In our study, we re-trained research assistants to ask participants to identify all the racial groups they identified with and allowed for multiple responses to this question.

Cultural issues related to the adaptation to a new culture are crucial to immigrant minority populations; therefore, they are important as they relate specifically to Hispanics. Biculturation refers to the level that individuals maintain the culture of their country of origin as they acquire behaviors and values associated with the new culture.[30] In general, biculturalism[31] has been related to psychological adjustment in Hispanic groups. In particular, higher acculturation levels (or adherence to mainstream culture) have been related to increased substance use in adult populations.[32,33] To better understand the role that cultural change may have in the study population and how it might affect treatment outcomes, a measure of biculturalism was included in the protocol. We selected the Bicultural Involvement Questionnaire[31] to measure separately comfort with Spanish and English language, as well as enjoyment of cultural customs and behaviors associated with the Hispanic and American cultures. Given the centrality of this construct to both Hispanic participants enrolled in the study and their bilingual Hispanic therapists, we also administered the Bicultural Involvement Questionnaire to the study therapists. Because there is no preliminary data on the association between participant outcome and therapist biculturalism, we will explore this question in a future article.

Adapting MET Intervention to Spanish-Speaking Populations

The “translation” or adaptations of MET treatment techniques and style to another language and cultural group was a particular challenge. This first became apparent as the MET expert trainers began the process of “translating” the MET treatment manual from the prior English MET CTN study and determining the best ways to train counselors.

Some of the terms used to label MET techniques were difficult to translate and explain to therapists in training. For example, the trainers spent quite a bit of time during the initial training going over the technique “rolling with resistance,” which does not have a literal translation into Spanish; thus, trainers used different concepts or words to relay the purpose of the intervention and how it is supposed to be delivered. In general, trainers expressed that Hispanic counselors tended to grasp the spirit and style of MI/MET fairly well, as the

Hispanic culture shares commonalities with MI (eg, relationship-based, empathy-based, and emphasizing collaboration). In contrast, the structure or format of the MET manualized sessions was more difficult for Hispanic counselors to learn. Supervisors expressed that counselors often deviated from the structure of the sessions and had difficulty introducing structured tasks (eg, session worksheet); thus, therapists often had to be reminded to follow the structure specified in the study manual.

Although "translating" an English version of an empirically supported therapy like Motivational Enhancement Therapy is an important task and the first step toward testing its applicability in Spanish-speaking populations, it does not ensure that the study intervention is culturally appropriate or sensitive, or delivered in a cultural competent manner. For example, the English version of the trial offered three individual weekly sessions, but anecdotal reports from the study staff in this study suggested many Hispanic participants expressed starting to feel comfortable to open-up in therapy by the third session and often wanted more sessions. In addition, review of tapes during supervision revealed that Hispanic clients responded well to MET style, as evidenced by their willingness to open up, share their substance use experiences, and explore the pros and cons of their substance use with their therapists. Therapists implementing MET realized that Hispanic clients became very talkative and collaborative in treatment, whereas in prior clinical experiences with other treatment approaches, therapists expressed that they had learned to accept the Hispanic client as reserved and unwilling to engage in treatment.

Vulnerability of Population and Human Subjects Protection

The population in the Spanish MET trial met several human subject protection criteria relevant to vulnerable populations. Most of the participants were immigrants from Latin American countries, and in some sites, many were in the country illegally. The vast majority had not participated previously in clinical research and was not aware of the rights or federal protections governing clinical research. Hence, special attention was given to the issues of language and unfamiliarity with research procedures throughout the study, in particular during the informed consent process. For example, the consent forms used in the study were translated into Spanish and read aloud to the participants to assure they understood all the procedures involved in the research and their rights as participants. Issues of confidentiality and possible limits of confidentiality were explained in detail. In particular, the research staff offered participants detailed examples of how confidentiality of research records would be maintained, including using code numbers and not sharing any results of the research with clinic staff or government entities. Moreover, Hispanic cultural values, related to high respect for authority,[34] might have limited the perceived freedom of clients to decline study participation. Thus, careful explication of study procedures underscoring participants' rights was essential.

Another vulnerability of our study population was the fact that a large proportion of the participants were involved with the criminal justice system, and many were mandated to receive substance abuse treatment by local or state court systems. For all participants, the consent forms included detailed explanation of their rights as a research participant, clarifying that court-mandated clients would have the same rights as any other participant to volunteer or withdraw from the research at any time and that no special treatment, such as reduced sentencing or probationary period, would be granted for participation in research. It was further explained to mandated clients that clinic attendance would be shared with the criminal justice system; however, information gathered through research assessments would remain confidential. In addition, we translated and received approval for a Spanish Certificate of Confidentiality from the National Institute of Health, which protects research information from being released under subpoena and court order.

IMPLEMENTATION OF THE TRIAL

Staffing and Availability of Bilingual Staff

Staffing issues became the single most crucial factor in determining the study's feasibility at each of the sites. The study required that sites have qualified English-Spanish bilingual individuals on staff, including at least one research assistant to conduct participant interviews, at least four clinicians willing to participate in the study (two for MET and two for treatment as usual), one local supervisor at each site to review session audiotapes, and an expert MET trainer. Other staff (project directors, quality assurance monitors) who did not have direct contact with the participants were not required to speak Spanish. Finding qualified bilingual research staff was a challenge at some of the study sites. In large metropolitan areas with substantial Hispanic populations, hiring qualified bilingual staff was fairly simple. Levels of Spanish fluency were lower in areas where Hispanic persons had lived for generations, and level of English fluency was an issue for recently immigrated staff or those who lived in isolation from the broader English speaking culture. Sites in these areas tended not to have Spanish-speaking staff in place and had to advertise for research staff. Hence, issues of verifying Spanish language competency and fluency became critical.

Spanish-Language Fluency of Study Staff

To ensure an acceptable level of Spanish fluency by the research and clinical staff across the sites, bilingual Hispanic researchers at the Florida Node Lead Team, in consultation with a Spanish language expert, developed a Spanish fluency test (available from first author) to be administered to research assistants and therapists to ensure that adequate levels of competence in Spanish word knowledge, language fluency (and for research assistants, reading fluency), and comprehension were established before staff was hired into the protocol. The Spanish fluency task differed for the research assistants and clinicians. The research assistants were required to respond in Spanish to brief questions about their education and interest in the study after reading the questions aloud. It was particularly important that the research assistants could comprehend and read the questions fluently, because they would be required to conduct standardized assessments in Spanish and clarify any questions the participants might have. For the clinicians, it was more important that they be able to express complex clinical issues fluently in Spanish; hence, the Spanish fluency task for therapists involved two scenarios, one requiring them to describe their educational background and the other one asking about a challenging therapeutic experience.

To determine Spanish fluency, two Hispanic researchers from the Florida Node Lead Team evaluated the responses to each scenario using the following four categories: topic/theme comprehension, topic/theme development, clarity of expression, and use of professional terminology. Ninety-two percent of the staff evaluated nationally passed the exam. For individuals whose fluency level was determined to be questionable, a phone interview was arranged with the evaluators. As expected by the diversity of Hispanic nationalities and immigration and/or generational level of Hispanics living in the United States, the bilingual research and clinical staff's level of Spanish fluency, use of Spanish slang and colloquial expressions, and Spanish accents varied considerably across sites.

Adaptation of Clinical Training and Supervision

The original English version of the MET protocol called for clinical supervisors and experienced MET trainers to be available at each of the participating sites.[13] While qualified bilingual clinical supervisors who, after training, could monitor session audiotapes for adherence and competence in MET were identified for each site, we had more difficulty identifying bilingual MET expert trainers or fidelity monitors at each site. The MET expert trainer had the responsibility for training and supervising the local clinical supervisor,

monitoring and supporting the supervisor, and checking therapist adherence to the intervention throughout the trial. To bring Spanish MET expertise to all sites, it was necessary that a centralized rather than site-specific training and monitoring system be adopted for the protocol. Specifically, bilingual, experienced MET trainers were identified who provided MET training in Spanish to all site clinical supervisors and therapists during a three-day didactic training session. After the didactic training, we assigned a Spanish-speaking MET expert trainer/fidelity monitor to each of the participating sites. The expert trainer was responsible for the credentialing process, first of the supervisors at these sites, and then in assisting the supervisor in the credentialing of the MET therapists.

Supervision throughout the study consisted of a weekly review of study audiotapes and biweekly group supervision with the 2–3 MET counselors by the clinical supervisor at each site. Group supervision included a review of session audio tapes, role plays, as well as a review of the manual materials and sessions. In addition, the MET expert working with each site reviewed and discussed the ratings of a randomly chosen session each month with the site supervisor. Any performance issues were addressed in supervision. A future paper will examine in detail issues of specific adherence to the MET manual and competence of MET counselors.

Staff Replacement and Back-up Issues

An unforeseen but important feasibility issue arose because of the difficulty in finding qualified bilingual research assistants at most sites, which resulted in most sites having only one trained research assistant for the protocol. The research assistant had primary responsibility for the day-to-day operations of the study, including tasks such as recruitment and screening of participants, scheduling of treatment sessions, administration of the research battery, handling and submission of research and clinical data, and following up research participants. Thus, major difficulties arose when research assistants took a long vacation, were absent due to illness, or left their employment site. During these periods, the protocol effectively stopped at that site, adversely affecting all study-related tasks, particularly recruitment and follow-up.

Experiences of this sort and the difficulties finding replacements for the vacant research assistant positions during the early part of the study prompted the Lead Team to recommend that sites identify back-up research assistants. This practice met with only limited success as back-up research assistants often lost interest or familiarity with study procedures when they did not participate for extended periods and then were ill-prepared to quickly step in when necessary. Planful preparation of the back-up research assistants to cover for the primary research assistant for short periods of time, such as during vacations, became a standard practice to compensate for their lack of ongoing protocol involvement.

Fortunately, most of the therapists in both conditions were retained in the study during its two-year duration. This experience is noteworthy given that therapist turnover at community treatment centers is generally high.[35] Another common, positive research staff characteristic created some difficulty for the continuity of study operations, namely the strong connection many had with their family residing in their country of origin. Study staff often traveled back to their home countries to visit for several weeks at a time. Beyond the challenges these absences posed to the implementation of research assistant duties described above, therapists' prolonged absences also required significant problem solving to ensure that the same therapist delivered three treatment sessions (either MET or treatment as usual) within 28 days following randomization (protocol requirement). In case of an extended vacation, the other therapists had to increase availability to avoid slowing subject recruitment into the study. In some clinics, however, therapists could not increase their workload and subject recruitment slowed. Ideally, having multiple clinicians per condition is methodologically

preferable as it reduces the impact of possible therapist effects in determining treatment efficacy.[36]

Recruitment Issues

The recruitment of Spanish-speaking participants in this trial required special attention. All sites, at some point during the protocol, were faced with low levels of referral, as Hispanics are less likely to seek or receive treatment for substance use disorders than other groups.[3] Participating sites relied heavily on criminal justice and other social service agencies referrals of individuals mandated to receive substance abuse treatment. Sites that introduced the study to the judges or probation officers, obtained their support to refer cases to the study, and maintained this collaborative relationship throughout the trial were more likely to experience a consistent flow of referrals. Those sites without a strong relationship with the courts experienced the most recruitment problems and had to rely on other methods for recruitment, including outreach to community centers and churches serving the Hispanic community. It is notable that at least one site recruitment was stymied for a period because it was reported that immigration officials were in the area. With time and continued assurances regarding confidentiality, this problem was resolved.

Other factors that presented challenges for recruitment were internal clinic procedures during the intake and referral process. In some sites, intake procedures were complex and involved a long process of assessment with a variety of different intake staff before the clients were referred to the appropriate level of treatment or an appropriate bilingual staff member. Sometimes this process occurred at a facility within the agency other than where the research office was located. Research assistants in these sites faced the difficult task of having to track down potential Spanish-speaking participants, which constituted the main criterion for study eligibility, to whom to introduce the study and to schedule the consent and baseline assessment. Another unforeseen informal clinic procedure that complicated subject recruitment was the common practice of English-speaking staff referring Spanish-speaking clients to the research assistant without first considering their study eligibility. As a result, the research assistant often consented and evaluated many individuals only to realize that they did not meet eligibility for participation in the study. Thus, the research staff invested time in establishing a good working relationship with the clinic referral staff, whether they were intake workers, therapists, or receptionists. These individuals were instrumental in introducing the potential participants to the research assistant as early in the process as possible and to channel them to other clinical services when they were clearly ineligible for study participation. This collaboration between the referral staff and the research assistants often required that clinic directors and other administrative officials of the agency formalized their support of the study to facilitate new procedures in the clinic as well as the recruitment work entrusted to the research assistant.

Participation Issues

Although participants expressed an understanding of the procedures to which they had committed during the consent process, many did not come back after the first meeting with the research assistant. Research assistants observed that Hispanic clients often needed a longer period of time than one session to establish rapport.

Because full literacy in Spanish was not a study requirement, some participants had difficulty with reading and responding to some of the self-report assessment instruments. Research assistants often assisted participants with completing self-reports, sometimes by systematically reading self-report instruments to participants, a method often used in research with Hispanics.[10] Moreover, for many of the participants, this encounter was the first time they had participated in a research study and were asked several detailed and

sensitive questions by a person they had just met. We attempted to keep our assessment battery as brief as possible (two hours) to enhance engagement and to allow sufficient time for rapport building. A brief assessment battery or one administered in parts over more than one meeting and allowing additional time to establish rapport may be particularly important when conducting clinical trials with Hispanic populations.

Practical issues surrounding the scheduling of treatment and research visits appeared problematic in some sites. For example, a number of participants worked very long hours, often as migrant agricultural workers or in multiple low paying jobs. As a result, treatment sessions were scheduled at night, and the research staff was expected to be extremely flexible in accommodating individual schedules and in offering make-up sessions when participants could not get to the clinic because of job responsibilities.

Challenges to Follow-up

The challenges in follow-up experienced in this trial were very similar to those typically experienced in research with substance abuse populations.[37,38] Participants who stopped coming to treatment, mostly likely due to a relapse in their substance use, were also less likely to attend follow up research visits. Other common reasons were being in jail, having a warrant for their arrest, or moving out of the area. The latter reason was particularly prevalent in sites with significant immigrant and migrant populations. Like their therapists, many participants in some of the sites would visit their country of origin for extended periods either for vacation, better working opportunities, or during the off-crop season. Several mildly assertive techniques were used to address difficulties with follow-ups, including mailing letters and reminders, contacting family members or friends specified in the participants' contacts, scheduling visits outside of normal business hours, offering participants who could not attend the clinic to conduct follow ups by telephone, and attending scheduled therapy visits to reach participants who were still in treatment.

SUMMARY AND RECOMMENDATIONS

Our experience implementing the first multi-site clinical research trial with Spanish-speaking Hispanics who were seeking treatment for substance use demonstrates that successful and much-needed treatment outcome research with this ethnic minority population can be accomplished. Furthermore, we found that clinical treatment agencies that serve this minority population are very supportive and encouraging of research efforts that contribute to the knowledge of efficacious treatments for Hispanic populations. Based on our experience, we offer several recommendations to stimulate further substance abuse treatment research with Hispanic minorities:

A team of research investigators, coordinators, translators, bilingual trainers, supervisors, and therapists should be assembled prior to the start of any behavioral therapy trial for Hispanic substance users.

Mechanisms for bi-directional feedback and communication between providers at participating sites who are familiar with the issues of Hispanic ethnic minorities in their treatment programs and research staff should be established at the time of the study design and throughout all phases of implementation. Early collaboration could assist researchers in designing implementation, recruitment, and retention strategies that facilitate successful coordination of clinical trials.

Special attention should be given to issues of staffing for a bilingual or Spanish monolingual protocol to ensure continuing availability of this most important study resource. Cultural competency and language fluency of the research and clinical staff should be established

prior to hiring and training. In addition, back-up bilingual personnel should also be identified and trained during the preparation phase of the study.

In conclusion, we encourage researchers to make the effort to identify the necessary resources to develop and implement future single and multi-site clinical trials with this constantly increasing and yet still underserved ethnic minority population. A key component of the planning and implementation process is recognition of the value of a team approach that involves collaborators both nationally and internationally. We believe the Miami/Yale collaboration was a model for the kind of work that is necessary to move empirically supported treatments from English to Spanish and from studies of treatment efficacy to treatment effectiveness and dissemination with diverse patients, providers, and practice settings.

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TABLE 1

Overview of challenges and strategies for designing and implementing clinical trials research with monolingual Hispanic populations

Challenges	Strategies
Select an evidence-based treatment appropriate for monolingual Hispanic clients.	MET has established efficacy in areas relevant to Hispanic clients (eg, treatment engagement and retention) and works well with ethnic minority populations.
Convene necessary expertise and resources to coordinate and execute a complex multi-site Spanish language protocol.	Partnership between New England Node (Yale University) and Florida Node (University of Miami) to bridge clinical trials and Hispanic population clinical research expertise.
Assure participation of sites already treating sufficient numbers of monolingual Spanish-speaking individuals.	Require that participating sites currently deliver substance abuse treatment in Spanish and have at least four bilingual clinicians currently on staff.
Lack of availability of assessment instruments in Spanish.	Use of psychometrically sound Spanish research instruments and translation and back translation of multiple assessment instruments where no Spanish instrument exists.
Variation in regional dialects across the five participating nodes.	Local review by bilingual staff of study instruments, manuals, etc., to assure adequacy of translations.
Lack of bilingual expert trainers in assessment battery instruments.	Use Spanish-speaking expert trainers for instrument administration in Spanish whenever possible. Until more expertise develops among Spanish-speaking professionals, train, credential, and monitor staff in English on selected instruments. Incorporate participant and research staff feedback to fine-tune future versions and administration of instruments.
Hispanic participants have diverse acculturation issues that may impact treatment outcomes.	Use mechanisms (eg, Bicultural Involvement Questionnaire) to identify important acculturation issues (eg, comfort with Spanish and English and related cultural customs).
Participants are a vulnerable human subject population.	Develop parallel English-Spanish consent forms for each site for local IRB review. Research staff carefully read aloud consent forms to participants to ensure comprehension, encourage queries, and underscore protections. Protect subjects via federal Certificate of Confidentiality.
Need to assure competence of local staff in delivering assessments or treatment in Spanish.	Centralized review and certification of Spanish fluency exercise for all clinicians, local supervisors, and interviewers.
Lack of appropriate bilingual MET “expert” supervisor/trainers in all centers.	Provision of centralized training/certification/supervision for clinicians; four bilingual MET experts provide certification, where bilingual supervisors monitor session tapes and provide feedback to clinicians in Spanish.
Required Spanish language skills of research assistants and protocol therapists made backup difficult when staff left for extended visits to their country of origin, were absent due to illness, or left study.	Hire back-up research assistants and carefully prepare them for anticipated protocol involvement. To the extent possible, increase therapist's hours to compensate for another therapist's absence.
Accessing monolingual Hispanic individuals for study recruitment is difficult in that they are less likely to seek or receive treatment.	Maintain collaborative relationship with court systems and probation offices that are likely to refer/mandate clients to treatment. Outreach to Hispanic community centers and churches. Establish good working relationships with clinic staff who could introduce potential participants to research staff.
Retaining monolingual Hispanic participants in a clinical trial is difficult because of Spanish literacy issues and practical barriers like work hours, relocations, or extended visits or return to countries of origin.	Systematically read self-report instruments to participants. Offer early morning, evening, and weekend sessions. Anticipate seasonal variability in residential stability.