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Brief Report

Lessons learned in clinical research recruitment of midlife Latinas during COVID-19

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Abstract

Objective: The purpose of this brief report is to describe lessons learned in recruiting and enrolling midlife Latinas in a pilot study to reduce cardiovascular disease (CVD) risk during the menopause transition. We also discuss strategies implemented to overcome the challenges presented by the novel coronavirus (COVID-19) pandemic.

Methods: *Menopausia, Salud y Corazón* is a two-group (intervention, waitlist control), repeated measures study. The intervention consists of CVD risk education, coping skills training, physical activity, and stress management. Eligible participants are peri- and early postmenopausal Latinas age 40 to 60 years, free of CVD. From August 2020 to October 2021, we screened 110 women recruited from cultural events and health fairs ($n = 56$), local businesses ($n = 24$), and snowball sampling ($n = 30$). Of these, 60 were eligible for inclusion and 41 enrolled.

Results: Strategies that contributed to successful recruitment included: a primarily Latina bilingual (English, Spanish) research team; flexibility with location and scheduling of data collection; and multiple modes of communication (ie, mailings, phone calls, and text messages). Additionally, we addressed Latino cultural values such as *respeto* (respect), *familismo* (loyalty to family), and *confianza* (trust). In response to COVID-19, we included virtual recruitment strategies, limited in-person visits, and distributed community resources for COVID-19.

Conclusion: We have found that despite the challenges presented by COVID-19, midlife Latinas are receptive to clinical research engagement. Researcher flexibility, multiple recruitment modalities, a bilingual research team, and communication strategies that address cultural values are essential elements for the representation of midlife Latinas in research.

Key Words: Clinical trial – COVID-19 – Latinas – Middle aged – Research design.

***Video Summary*:** http://links.lww.com/MENO/A943.

In 2019, the number of Latinas age 45 to 54 years in the United States (US) reached over 3.5 million, accounting for 17% of US women in this age group.[1] Despite the National Institutes of Health mandating the inclusion of historically marginalized populations in clinical research, Latinas continue to be underrepresented in studies of midlife women, particularly during the menopause transition.[2,3] For example, only 4% of participants in the Women's Health Initiative and 8% of participants in the Study of Women's Health Across the Nation are Latina.[4,5] Thus, our current understanding of the menopause transition, its impact on health, and symptom management is mostly from data with non-Latina White women. Common barriers to the inclusion of Latinas in clinical research are: a lack of knowledge about research opportunities; culture and language discordance with the research team; logistical concerns such as transportation

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and time commitment; institutional mistrust; and fear of deportation.[6,7] Motivating factors for Latinas to participate in clinical research have included contributing to society, gaining knowledge that may benefit their families, and being recruited by a trusted individual.[7]

This brief report describes lessons we have learned in recruiting and enrolling midlife Latinas (age 40-60 y) in a multicomponent intervention to reduce cardiovascular disease (CVD) risk during the menopause transition. This is an important group to study given that CVD risk increases during the menopause transition and Latinas have a more adverse CVD risk factor profile than non-Latina White women.[8,9] Since the study was implemented during the novel coronavirus (COVID-19) pandemic, we also discuss the challenges COVID-19 introduced for recruitment and enrollment in the clinical trial, and strategies we implemented to overcome these challenges. The approaches described in this report may enhance the participation of midlife Latinas in future clinical research.

STUDY OVERVIEW

Menopausia, Salud, Corazón (Menopause, Health, Heart) is a two-group, repeated measures pilot study examining the feasibility and initial efficacy of a multi-component intervention to reduce CVD risk in peri-and early postmenopausal Latinas aged 40 to 60 years. The study rationale and protocol have been described elsewhere.[10] Briefly, after baseline assessment, two groups were randomly assigned to an intervention led by community health workers or a wait-list control. The intervention group received 12 weekly 2-hour sessions, including cardiovascular health education, coping skills training, physical activity, and stress management (eg, breathing techniques, mindfulness exercises). Educational messages included information about menopause and CVD risk during the menopause transition. During Phase II of the intervention, participants received three monthly sessions of continued support to problem-solve issues related to nutrition, exercise, sleep, anxiety, and depressive symptoms. Next, participants were expected to maintain skills on their own for 6 months. Body mass index, waist circumference, blood pressure, psychosocial factors, menopause symptoms, pregnancy history, and health behaviors were assessed at three time points: baseline, 6 months (completion of the intervention), and 12 months (after 6 mo with no contact from the study staff). Measures of arterial stiffness, lipid profile, glucose, high-sensitivity C-reactive protein, and hair cortisol were collected at baseline and at 12-month follow-up.

Participant eligibility and enrollment

Inclusion criteria for women in this study were age 40 to 60 years; self-identification as Hispanic/Latina; ability to understand spoken English or Spanish; perimenopausal or early postmenopausal (change in length of bleeding or interbleeding interval, or no menstrual bleeding in the past 3-24 mo); intact uterus and at least one ovary; not currently pregnant; no hormone therapy or birth control pills in the past 3 months. Exclusion criteria for this study were: a history of CVD (heart attack, stroke, coronary heart disease), heart murmur, congenital heart disease, family history of sudden death, or difficulty exercising. Women on anti-hypertensive, lipid-lowering, or diabetes medications were not excluded.

Between July 1, 2020, and October 15, 2021, we screened 110 women recruited from cultural events and health fairs ($n = 56$), community organizations and local businesses ($n = 24$), and snowball sampling ($n = 30$). Of these, 60 (54.5%) were eligible for inclusion, and 41 have been enrolled. Table 1 presents sociodemographic factors for participants screened and enrolled.

LESSONS LEARNED

Strategies for recruitment and enrollment

Bilingual research team

Mistrust and lack of accurate Spanish-language information about the research process are common barriers for Latino participation in clinical research.[11] To address these potential barriers and build trust, the Principal Investigator (bilingual Latina) assembled a primarily Latina bilingual (English, Spanish) research team that lives in the communities we targeted for recruitment. In addition, the Principal Investigator actively participated in recruitment events. Prior studies have found that Latinos may be more likely to participate in research when they feel understood and can communicate directly with bilingual research team members.[11] Having more diversity among researchers can enhance the recruitment of midlife Latinas because researchers with cultural and linguistic similarities to potential participants can better understand participant concerns and build rapport when interacting with them. Having a relatable research team that provided accurate information about COVID-19 in Spanish was particularly important. Nearly two-thirds (65%) of Latino adults say the COVID-19 outbreak is a significant threat to the health of the US population as a whole, and nearly half (49%) say that COVID-19 is a threat to day-to-day life in their local community.[12] Providing up-to-date information about the pandemic was essential to build trust and rapport with the community and facilitated recruitment.

Community engagement

Another strategy to build trust and reach potential participants is collaborating with community-based organizations (CBOs) that serve Latino communities. As in prior studies we worked with CBOs to attend public cultural events and health fairs, recruited from waiting rooms at community health clinics, and disseminated information in-person at parishes with a Latino ministry and/or Spanish-language services.[13] Understandably, we cutback this recruitment approach in response to the COVID-19 pandemic and shelter-in-place policies. We received Institutional Review Board approval for limited in-person recruitment at drive-thru health fairs, food distribution efforts, and local Latino-owned businesses. Additionally, we leveraged our existing community partnerships to recruit remotely by attending virtual town halls and health fairs, presenting online health workshops, and distributing recruitment materials electronically (eg, social

TABLE 1. *Characteristics of women screened for inclusion between July 2020 and October 2021*

Characteristics	Total screened ($n = 110$)	Eligible ($n = 60$)	Enrolled ($n = 41$)
Age, mean ± SD	48.0 ± 5.5	47.2 ± 4.6	47.5 ± 4.8
Recruitment site, *n* (%)			
Cultural events and health fairs	56 (50.9)	16 (26.7)	10 (24.4)
Church, Latino CBO or businesses	24 (21.8)	30 (50.0)	18 (43.9)
Referral/Snowball sampling	30 (27.3)	14 (23.3)	13 (31.7)
Hispanic/Latina, *n* (%)	110 (100)	60 (100)	41 (100)
Screened in Spanish, *n* (%)	110 (100)	60 (100)	41 (100)
Self-reported overall health, *n* (%)			
Poor	12 (10.9)	2 (3.3)	1 (2.4)
Good	65 (59.0)	38 (63.3)	25 (61.0)
Very good	24 (21.8)	14 (23.3)	11 (26.8)
Excellent	6 (5.5)	3 (5.0)	3 (7.3)
Don't know	3 (2.7)	3 (5.0)	1 (2.4)
Months since LMP, median [IQR]	1.4 [0.6,19.9]	0.9 [0.4, 3.4]	0.9 [0.2, 3.3]
Would you describe your menstrual cycle as..			
Very regular	8 (7.3)	4 (6.7)	1 (2.4)
Mostly regular with occasional irregularity	48 (43.6)	36 (60.0)	27 (65.9)
Most or always irregular, or absent	54 (49.1)	20 (33.3)	13 (31.7)
During the last year, did your menstrual flow usually start within 4 d of the day you expected it to start? *n* (%)			
No	82 (74.5)	45 (75.0)	29 (70.7)
Yes	15 (13.6)	2 (3.3)	2 (4.9)
Don't know	13 (11.8)	10 (16.7)	10 (24.4)
Have you EVER used birth control pills, menstrual hormone therapy, or hormonal patches, rings, injections, sprays, or topical cream? *N* (%)			
No, never	45 (40.9)	28 (46.7)	14 (34.1)
Yes, but not in last 3 mo	46 (41.8)	30 (50.0)	25 (61.0)
Yes, have used in last 3 mo	16 (14.5)	0	0
Don't know	3 (2.7)	2 (3.3)	2 (4.9)
Have you had a hysterectomy or oophorectomy? *n* (%)			
No	96 (87.3)	57 (95.0)	38 (92.7)
Hysterectomy only	7 (6.4)	1 (1.7)	1 (2.4)
Yes, one ovary removed	4 (3.6)	2 (3.3)	2 (4.9)
Yes, bilateral oophorectomy	3 (2.7)	0	0
Any history of CVD, *n* (%)			
No	107 (97.3)	60 (100)	41 (100)
Yes	2 (1.8)	0	0
Don't know	1 (0.9)	0	0

CBO, community based organization; CVD, cardiovascular disease (angina, angioplasty, coronary artery disease, heart attack, heart failure, heart murmur or arrhythmia, kidney failure, stroke); LMP, last menstrual period; SD, standard deviation.

media, email, newsletters, parish bulletins). At all in-person recruitment sites, we distributed personal protective equipment, hand sanitizers, COVID-19 education materials, and local resources for testing and support (Table 2).

Screening and informed consent processes

Screening for eligibility was completed via phone. During the phone screening, research personnel assessed the participant's level of comfort with technology (ie, text messaging, mobile applications, use of a computer or tablet, navigating the internet) and, if eligible, scheduled a time to complete the informed consent process and baseline visit. Participants had the option of completing the informed consent using a Research Electronic Data Capture e-consent, on the phone, via video conference (eg, Zoom, Facetime, WhatsApp), or during a limited in-person visit. As of today, none of the participants have opted to complete an e-consent. Most participants have preferred to receive the consent form in the mail and review it with research personnel via video conferencing ($n = 6$) or in person ($n = 33$). Two participants preferred reviewing and giving consent over the phone with the opportunity to ask additional questions during the limited in-person visit. This preferred method has worked well for us since participants have ample time to review the consent and ask questions during this one-on-one time with the research staff. An important takeaway from this approach is that researchers must be flexible and adjust research protocols to meet participants' level of comfort, understanding, and need. Our current observations suggest that we would not have met the enrollment goal thus far if we did not offer multiple options to complete screening and informed consent.

Strategies for data collection

Flexibility and collecting data remotely

To protect research participants and personnel from COVID-19 exposure, we used alternative data collection methods such as phone, mail, and video conferencing. We received permission for limited in-person interactions to collect biological/physiological data. While collecting data on an online platform such as Research Electronic Data Capture can facilitate the data collection process, many of our participants prefer paper documents and may not have consistent access to the internet.[14] We mailed baseline questionnaires to eligible participants and scheduled a time to review them with research personnel via phone or video conferencing along with the consent forms. We shortened the in-person biological/physiological data collection visit to 60 to 75 minutes by first remotely completing the

TABLE 2. *Challenges and countermeasures outlining various challenges and COVID-19 specific adaptations implemented in Menopausia, Salud, Corazón since the Summer of 2020 through the Spring of 2021*

Challenges	Countermeasures
Recruitment during COVID-19	Primarily bilingual, Latina research team.
	Worked with Latino community based organizations and local parishes. Attended public cultural events, health fairs, town hall meetings, and resource distribution events.
	Remote recruitment via phone, email, social media, and word-of-mouth.
	In-person, outdoor recruitment with physical distancing and personal protective equipment.
	Distribution of personal protective equipment (ie, hand sanitizer, alcohol swabs, gloves, masks) and information related to COVID-19 vaccines, testing, and community resources.
Data collection	Completed informed consent remotely via phone, videoconferencing, or e-consent.
	Participants had option to complete surveys by phone, videoconference, or to self-administer questionnaire.
	Collected biological/physiological data during a shortened in-person visit at the participant's home or the University's Biobehavioral Laboratory.
	Participant completed standardized COVID-19 screener the day before the in-person visit and at the beginning of the visit. At the beginning of the visit, participant temperature was assessed.
	If in-person visit was conducted in the home, requested a private area when possible. Family members in the vicinity were asked to socially distance, wear a mask, and temperature assessed as well.
Participant engagement and retention	Maintained contact with participants via phone, mail, text message, Whatsapp, and social media. Mailings included holiday cards, birthday cards, and a quarterly newsletter.
	Provided participants results or their biological/physiological measures, including weight, blood pressure, lipid panel, blood glucose, and pulse wave velocity. A nurse practitioner reviewed results with participants via phone or in-person.
	Connected participants to timely, appropriate healthcare resources in their community that were Spanish-inclusive and offer services at free or reduced costs.
Delivery of intervention	Pivoted in-person intervention sessions to a virtual format. Intervention materials were delivered to participant homes.
	Assessed participant technology needs during enrollment and baseline—provided infographics, videos, and technical support to help participants manage remote intervention sessions.

interviewer-administered baseline questionnaire, which was critical to success. Participants who decided to self-administer the questionnaire could still clarify any uncertainties during in-person biological/physiological data collection with research personnel. Data were not collected until the completion of the informed consent process.

Prior studies have shown that it is feasible and acceptable to collect data at community sites such as parishes and CBOs.[15] After these spaces closed in response to COVID-19, we gave participants the option of an in-person data collection visit at the Biobehavioral Laboratory at the University or during a home visit. We implemented stringent safety precautions for biological/physiological data collection such as a symptom checklist, temperature assessment, use of personal protective equipment (ie, mask, goggles, gown, shoe covers), hand hygiene, and equipment sanitization. To reduce potential cancellations (<5% thus far), we completed the COVID-19 symptom checklist over the phone the day before the scheduled visits and sent a reminder text message the day of the visit. If conducted at home, research personnel completed a symptom checklist and temperature assessment of all family members in the vicinity. Participant incentives, in the form of a reloadable debit card, were distributed at the time of the in-person visit.

Our approach addressed several barriers to research participation and retention including, limited time/scheduling conflicts and lack of transportation.[11] First, our flexible scheduling procedures included evenings and weekends. Thus, we accommodated participants with various work schedules. Our option for home visits also accommodated participants with limited transportation and individuals in need of childcare or eldercare (≈25%). This strategy is particularly important for our age group (40-60 y) since many participants are responsible for children, grandchildren, or aging parents.

Providing biological/physiological data and referrals

We implemented several precautions to protect participants and research personnel during biological/physiological data collection. During in-person visits, we explained each step of the data collection process. To instill trust, we were transparent about the purpose of each piece of data collected and our handling of any biospecimen. Storage of biospecimens has been a concern for participants in prior studies, particularly given historical abuses marginalized populations have endured when their biospecimens are stored without their knowledge or informed consent.[16,17] We reiterated the importance of social distancing during home visits, which helped ensure privacy during data collection.

Moreover, we provided participants with the results of their lipid panel, fasting blood glucose, blood pressure readings, pulse wave velocity measurements, and other clinical indicators of wellness. Participants reviewed their physiological data with a licensed Family Nurse Practitioner securely via telephone or in-person. This individualized wellness session provided a safe, private space for participants to discuss concerns and for potential referrals to be made within the community. We referred participants as needed to local health clinics that provided low-cost care, extended hours, accepted uninsured patients and Spanish-speaking personnel. These strategies were consistent with prior studies showing participant desire for more transparency in research, including reviewing results, meeting the lead investigator, working with staff from the community, and observing professional-standard specimen collection procedures.[18]

Delivering intervention remotely

To maintain COVID-19 safety precautions, we delivered a technology-assisted intervention using a video conferencing format. Participants were sent pre-recorded videos of the intervention content when they missed a session. In preparation for this delivery format, community health workers contacted participants to decide the most convenient time for these group sessions. Participants were sent an infographic and video recording demonstrating how to use the video conferencing format. Those participants that were still having difficulty connecting to the live video conferencing sessions were personally contacted by phone for further assistance. To help offset the cost of the internet and the use of their technology device, participants were provided a $5 incentive after each session they attended.

Several strategies were implemented to engage participants remotely in the intervention to maintain social connections and interactive discussions. During the education session, the community health worker integrated illustrations, videos, and group activities. Physical activity sessions were conducted by videoconferencing, or participants were sent a video of the session, including a warm-up, stretches, Zumba, and a cool down. Various stress management strategies such as meditation, mindfulness, art therapy, and aromatherapy were incorporated in each session. Participants received a tote bag with all necessary materials for the intervention, including a yoga mat, stretch bands, essential oils, recipes, and workbook/handouts. One strength of providing the intervention remotely was that we extended our outreach to individuals unable to attend in-person sessions due to logistical concerns such as lack of time, transportation, or lack of childcare. Since it may be difficult to maintain social connections and a sense of social support when delivering the intervention remotely, community health workers created a WhatsApp group so that participants could ask questions and share their experiences.

Retention strategies

Addressing sociocultural factors

Cardiovascular health promotion interventions for Latinos typically have attrition rates of 10% to 30%.[19] This is the first intervention to target Latins during the menopause transition. To strengthen recruitment and retention, we developed a plan that integrated key sociocultural factors such as *familismo* (ie, commitment and loyalty to family), *personalismo* (ie, emphasis on building relationships), *confianza* (trust and familiarity), and *respeto* (ie, respect, politeness). We addressed these cultural values by making family members feel included in the research process and providing family-oriented scenarios during the intervention sessions. Additionally, the research team engaged with participants remotely via phone check-ins, individualized text messages, video, mailings (eg, holiday cards, birthday cards, and quarterly newsletter), and in group chats where participants in the intervention group share their experiences. These strategies have enabled us to maintain personal connections with our participants during COVID-19, which has been a socially isolating period.

CONCLUSION

Although Latinos comprise the fastest-growing minority group in the U.S.,[1] Latinas remain underrepresented in the clinical research of midlife women's health, particularly during the menopause transition. The novel COVID-19 pandemic posed many unprecedented challenges for the research community, which had the potential to further limit the representation of Latinos in clinical research. We report several key strategies we adopted in our work with midlife Latinas to enhance recruitment and enrollment. A diverse research team that is relatable and understands the cultural values of potential participants is important to clinical research. Flexible modalities of recruitment, data collection, and intervention delivery that address these key cultural values are also necessary. Linking participants to community resources and providing personalized health information is key to build trust and rapport. Collaborating with community-based organizations and Latino-owned businesses can also increase outreach. Future studies of midlife women's health should invest in these strategies to increase recruitment and enrollment of Latinas in clinical research.

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