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Call-to-entry rate and recruitment barriers in clinical trials for low-income populations

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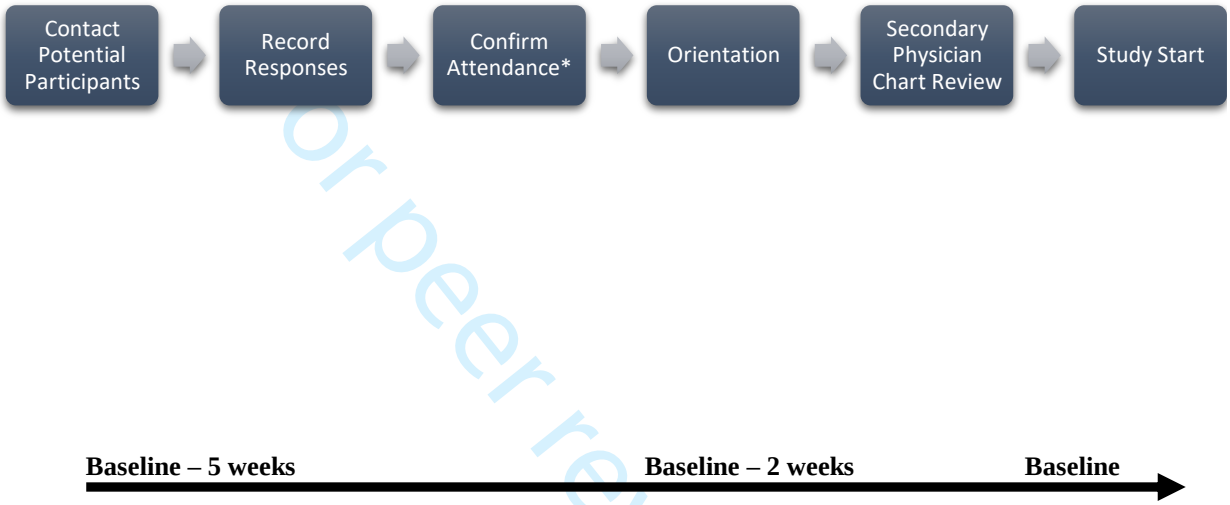
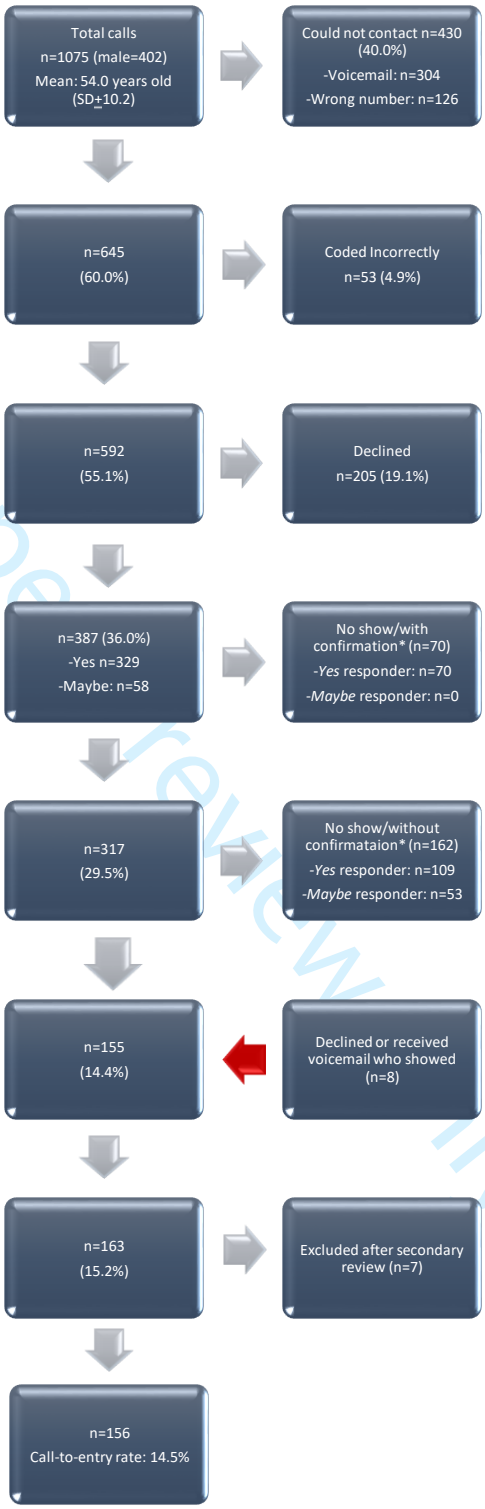
Figure 1. Steps involved in the recruitment process, from contacting potential participants to study enrollment



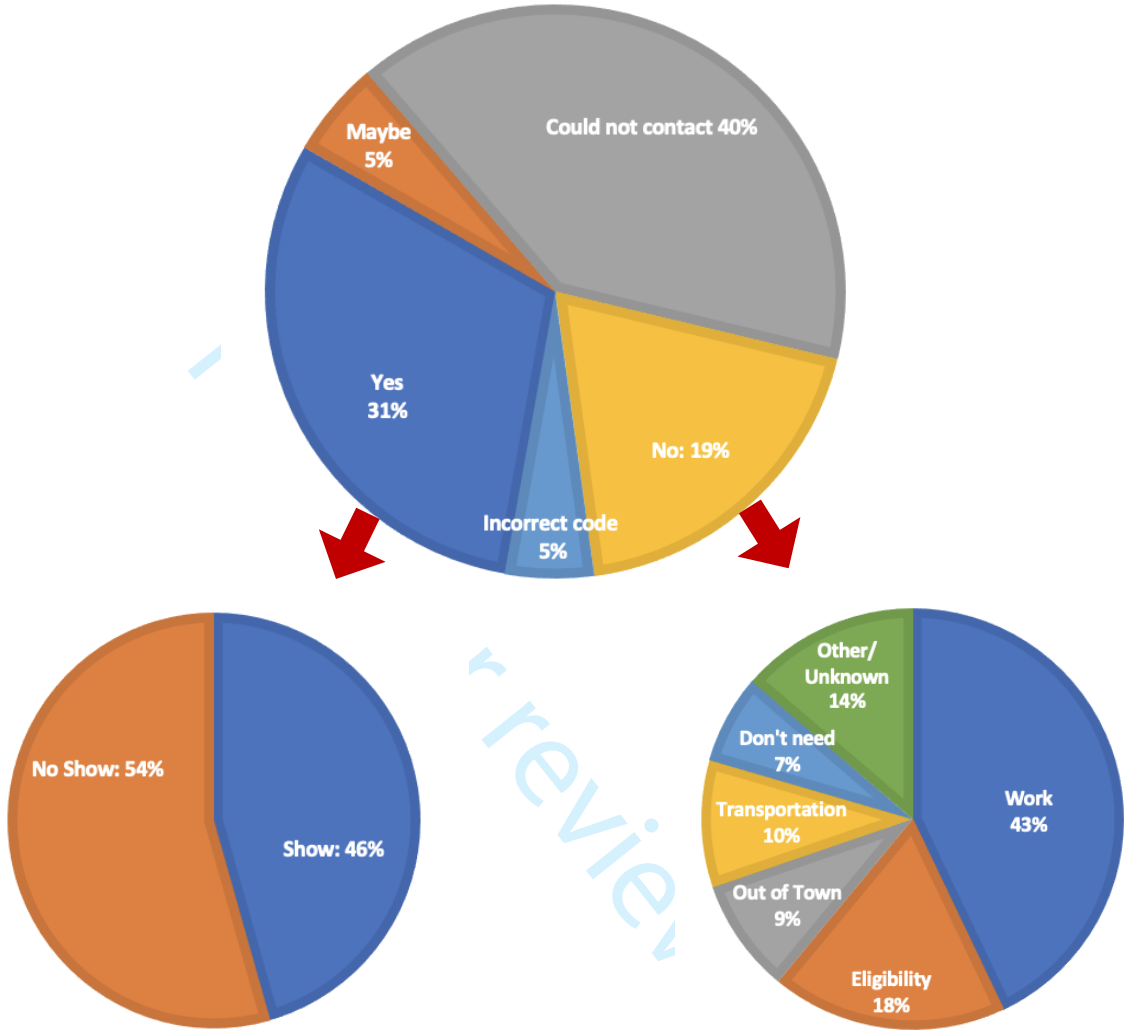
**Staff called potential participants who responded yes and maybe one day prior to orientation*

Figure 2. Flowchart illustrating potential participants called to study entry to achieve call-to-entry rate in a low-income population (n=1075)



**No show to study orientation. Yes and maybe responders received a reminder call the day prior*

Figure 3. Responses of potential participants (top) delineated into show rates of individuals who responded *yes** with show rates (bottom left) and *no* with the reasons to decline (bottom right)



*Show rate of maybe responders was low (n=5 of 58, 91.4%) and therefore not included in the figure

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Determining call-to-entry rate and recruitment barriers in clinical studies for community clinics serving low-income populations: A cohort study

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Original Research

Title. Determining call-to-entry rate and recruitment barriers in clinical studies for community clinics serving low-income populations: A cohort study

Running title. Addressing low-income recruitment barriers

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ABSTRACT

Background. Recruitment for clinical studies is challenging. To overcome barriers, investigators have previously established call-to-entry rates to assist in planning. However, rates specific to low-income minority populations are needed to account for additional barriers to enrollment these individuals face.

Objective. To obtain a call-to-entry rate in a low-income uninsured Hispanic population with chronic disease.

Methods. We used data from four of our randomized clinical studies to determine the call-to-entry rate for individuals (n=1075) with or at risk for type 2 diabetes: Participants needed / Potential participants contacted = Recruitment rate (yield). Research staff contacted potential participants to enroll in a study that evaluated six-month diabetes programs at community clinics from 2015 to 2020. We recorded call-to-entry rates, reasons for declining the study, show rates, and attrition.

Results. The call-to-entry rate was 14.5%. Forty percent of potential participants could not be contacted, and 30.6%, 19.1%, and 5.4% responded *yes*, *no*, and *maybe*, respectively. No show percentages were 54% for *yes* and 91.4% for *maybe* responders. The majority (61.6%) declined due to inability to attend; reasons to decline included work (43%), eligibility (18%), transportation (10%), out of town (9%), did not think they needed the program (7%), and other/unknown (14%). Being a physician predicted inability to reach participants [Adjusted Odds Ratio 2.91, 95% confidence interval 1.73, 4.90]. Attrition was 6.8%.

Conclusions. We described a call-to-entry rate and detailed recruitment data, including reasons to decline the study. This valuable information can assist investigators in study planning and overcoming enrollment barriers in low-income populations. Telehealth-based or strategies that limit transportation needs may increase participant involvement.

Keywords. diabetes, community health workers, recruitment, telehealth, low-income, clinical trial

Strengths and limitations of this study

- Investigators analyzed recruitment data from four randomized clinical trials.
- All participants (n=1075) were from an understudied minority and resource-limited population.
- Investigators collected detailed information, including reasons for declining the study, show rates, and attrition.
- Investigators explored a potential value of incorporating Community Health Workers in recruitment processes.
- The study is limited by lack of generalizability as it includes a low-income Hispanic population with or at risk for diabetes.

INTRODUCTION

Recruitment is a known challenge in clinical studies, particularly in low-income communities.(1, 2) Data from a recent clinical study revealed an underrepresentation of uninsured participants (n=24,332) and of those living in geographic areas with lower socioeconomic levels.(3) Low-income populations face higher levels of mistrust in the health system, language and cultural concerns, transportation challenges, limited health literacy, and medical record deficiencies.(1, 4-7) Investigators have found that socioeconomic issues are a major reason individuals decline study participation.(8) Specifically, clinical studies often lack key facilitators such as community participation and cultural appropriateness, including incorporating Community Health Workers (CHWs).(1, 4-6, 9, 10) Consequently, fewer disadvantaged individuals are represented in clinical studies despite having higher rates of chronic disease.(11) This raises concerns for implicit bias, fairness, and objectivity in evidence-based guidelines and interventions.(12)

CHWs or *promotores* traditionally are educators, which has encouraged recent efforts to incorporate them into research teams.(13) CHWs are of particular interest for Hispanic communities to address cultural and linguistic barriers and obtain sensitive data that may be pivotal to overcome recruitment barriers.(14-16) National samples have noted potential CHW roles in research.(13) However, the majority of interventions that incorporate CHWs in research involve data collection, and there is a paucity of literature describing their involvement in recruitment for clinical trials.(14-16)

Estimating the number of individuals that research staff will need to contact to achieve recruitment goals is vital in the recruitment process.(1, 4) It allows investigators to plan effective real-world studies by communicating database needs with clinic stakeholders, hiring staff, obtaining retention plans, and forecasting training needs.(17) Previous investigators have established call-to-entry rates, N/C=R, where N=participants needed, C=potential participants

contacted, and R=recruitment rate (yield), to aid in clinical study planning.(18, 19) However, recruitment data from low-income populations remain under recorded.

Nearly three decades ago, the National Institutes of Health provided recommendations to increase the representation of people with low socioeconomic status. Yet, investigators still struggle to provide diversity in research.(1, 20) Unmet recruitment goals lead to underpowered studies with inconclusive or skewed results, further contributing to an ongoing cycle of disparities for low-income populations in clinical studies.(17)

In the current study, we aimed to analyze our recruitment data from four randomized clinical trials that evaluated a diabetes program for resource-limited Hispanics.(7, 21, 22) We outlined methodological approaches to gather a call-to-entry rate in this population and explored the value of incorporating CHWs into recruitment processes.

METHODS

In this cohort study, we analyzed our recruitment data from four randomized clinical trials that evaluated a multidimensional program for low-income, uninsured Hispanics with or at risk for type 2 diabetes.(7, 21, 22) Specifically, we describe the methods used to obtain a call-to-entry rate in this population, including reasons to decline the study, show rates, and attrition. Detailed methodologies of the parent studies were previously described(7, 21, 22); the studies occurred at community clinics in greater Houston, Texas from 2015 to 2020. Recruitment occurred five weeks before study baseline; follow-up occurred for a minimum of one month (Cohort 1) and up to 24 months (Cohorts 2-4) after study termination pending study protocols.(23) Data were collected from recruitment to follow-up.(7, 21, 22)

Potential participants were identified through a clinic database. Participants met inclusion criterion if they were Latino(a)/Hispanic adults with type 2 diabetes or prediabetes (International Classification of Disease (ICD)-10 E11.X; R73.09).(7, 21, 22) Exclusion criteria included type 1 diabetes, not appropriate for group care (e.g., require >1 diabetes-related appointments per month), inability to understand Spanish, pregnancy, and any condition that could alter Hemoglobin (Hb) A1c levels (e.g., varying chronic steroid doses of >10mg and blood transfusion in the last three months). Measures to reduce bias included participant randomization, blinded data collection, standardized recruitment processes, and independent analysis of the results by other researchers.(7, 21, 22)

Figure 1 provides the steps involved in the five-week recruitment process, from contacting potential participants to study start. From the clinic database, research staff contacted participants telephonically to explain the study and invite them to a study orientation that occurred an average of two weeks after the initial call. Staff recorded responses as *yes*, *no*, or *maybe*. For those who declined, staff recorded the reason. If individuals informed the staff that they were ineligible, i.e., not Hispanic or did not have diabetes, they were recorded as *coded incorrectly*. If individuals could not be reached, staff made four additional attempts at

various times and on weekdays and weekends. If voicemail was available, staff left a message with nonidentifying patient and program information and a callback number. If the phone number was not correct or disconnected, alternative numbers were sought in the electronic medical record (EMR). If no alternatives were present, staff recorded *wrong number*.

Staff called potential participants who responded *yes* or *maybe* the day prior to orientation to confirm attendance. At orientation, staff gathered baseline data and informed consent. During a two-week period from orientation to study start, a physician conducted a secondary chart review to ensure all participants met eligibility criteria.

Recruitment staff for the four cohorts were bilingual (English/Spanish) and consisted of seven CHWs, one clinic administrator, and one physician. CHWs received three hours of training that included instructions on reading a script in Spanish to participants.

Measures

In addition to recording potential participant responses, the research team recorded the number who showed at orientation and who were excluded after secondary physician chart review. These data were used to obtain a call-to-entry rate. Other measures included study retention. We also explored CHW versus physician recruitment data.

Statistical Analysis

We conducted the statistical analysis in Stata version 17.1, StataCorp (College Station, Texas). Continuous variables were presented as mean (standard deviation) and categorical variables as count (percentage), and results were totaled for the four cohorts. We classified participants' responses when contacted by research personnel, whether participants showed to orientation, and reasons for declining to participate using counts (percentages). We then calculated the call-to-entry rate: N/C=R. We explored determinants of inability to contact participants using logistic regression models adjusted for age, sex, and if contacted by a CHW or physician.

In the primary studies, loss to follow-up and missing data was managed by each trial independently, e.g., employed multiple imputation procedures for missing clinical values. In the current study, researchers were assigned patients to call and recorded responses on an online, secure spreadsheet. During the recruitment process, investigators reviewed the spreadsheet routinely to ensure data were recorded appropriately and in the case of missing data, e.g., reason for declining not present, contacted the researcher directly to input the data. This resulted in obtaining 100% of calling data for the current study. We did not gather the contact person for the first cohort and, thus, did not include in this portion in the analysis.

Patient and Public Involvement Statement

Involvement included design, conduct, and dissemination of information. Specifically, CHWs were involved to provide informed decisions regarding patients' priorities, experiences, and references. Through qualitative and quantitative surveys, CHWs gathered patient information to guide practices, i.e., study design, conduct, any burden of the intervention, and recruitment. Patients received ongoing communication with providers regarding their clinical outcomes, i.e., HbA1c, blood pressure, and weight. CHWs were certified by the state of Texas, bilingual or Spanish-speaking, and self-identified as Hispanic. Texas CHW certification requires 160 hours of coursework or 1000 hours of community service in the last three years and 20 biennial continuing education hours.

RESULTS

Figure 2 illustrates 1,075 (male=402 [37.4%]) potential participants and loss at each step of the recruitment process with attendant numbers and percentages. Forty percent (n=430) could not be contacted (received voicemail, n=304; wrong number, n=126), and 4.9% (n=53) informed staff that they were not Hispanic or did not have type 2 diabetes, resulting in 592 (55.1%) individuals who staff successfully contacted. After a total of 19.1% (n=205) declined the study, 36.0% (n=387) remained, of which 239 responded *yes* and 58 responded *maybe.* Individuals averaged 54.0 years old (SD±10.2).

Staff called potential participants who responded *yes* or *maybe* the day before orientation. Seventy individuals who confirmed did not show to orientation (*yes*: 70, *maybe*: 0). Of those who did not confirm, 162 did not show (*yes*: 109, *maybe*: 53), leaving 155 (14.4%). An additional eight individuals who initially declined or received voicemail showed, resulting in 15.2% (n=163). Secondary chart review excluded seven individuals. The final study n for the four cohorts was 156. All individuals were Hispanic, low-income, and uninsured. The majority (>50%) were undocumented immigrants.

These data resulted in a call-to-entry rate of 14.5%, where:

$$\text{Call-to-entry rate (yield) (R)} = \frac{\text{Participants Needed (N)}}{\text{Potential Participants to Contact (C)}}$$

$$1075 = \frac{156}{14.5\%}$$

This equation may be altered to assist in project planning to estimate the number of potential participants needed to contact (C), where:

$$\text{Potential Participants to Contact (C)} = \frac{\text{Participants Needed (N)}}{\text{Call-to-entry rate/yield (R)}}$$

For example, for a desired cohort of 80 participants (N) and a yield of 14.5% (R), a total of 552 potential participants are needed to contact (C) to meet study goals:

$$552 = \frac{80}{14.5\%}$$

Figure 3 (top) illustrates the flowchart in Figure 2 and further stratifies the *yes* responders to show and no show (Figure 3, bottom left) and the reasons individuals declined (Figure 3, bottom right). More than half (54%) of *yes* responders did not show. Fifty-eight individuals responded *maybe*, but the vast majority (n=53/58, 91.4%) did not show to orientation and were, therefore, not included in the figure. Of the *yes* responders who confirmed attendance the day prior to orientation (n=171), 100 (58.5%) showed, and of the *maybe* (n=1), 1 (100%) showed. The most common reason to decline was due to work (43%). The least common reason was that they did not think they needed the program (7%). Other reasons to decline included eligibility (18%), transportation (10%), out of town (9%), other/unknown (14%). The majority (61.6%) of individuals declined the study due to inability to attend: work, transportation, and out of town.

Participants were less likely to respond *no* to the physician than a CHW (physician: 4.3%, CHWs: 18.6%; p<0.0001). More individuals responding *yes* to CHWs showed compared to the physician, though this was not significant (CHW: 41.5%, physician: 33.3%; p=0.44). An adjusted logistic regression analysis revealed that the physician was a significant predictor of an inability to reach participants compared to CHW (Adjusted Odds Ratio [AOR] 2.91, 95% confidence interval 1.73, 4.90).

Attrition was low at the study end (six months, 6.8%).

DISCUSSION

This study demonstrated the methodologies in recruitment for low-income, uninsured Hispanics. Study findings included identifying a call-to-entry rate of 14.5%. In addition, many (40%) could not be contacted at all and most (61.6%) declined the study due to inability to come to the study site. Obtaining these recruitment data in a low-income setting is a valuable step to strategize clinical research studies, communicate database needs with study sites, and achieve recruitment goals. This is essential to appropriately power studies, provide accurate results, and reduce discrimination in resource-poor settings, thereby reducing a cycle of disparities in clinical studies.(17)

There are important considerations for sources of potential variations in call-to-entry rates among differing sites and populations. Nearly half (40%) of our potential participants could not be contacted; the degree to which EMRs are updated will affect the call-to-entry rates. Additionally, due to transportation and work barriers in low-income populations, investigations with several opportunities for study entry, such as multiple orientation days, and those located near to participants' homes are more likely to receive a *yes* response. Furthermore, we observed that potential participants provided more detailed information to CHWs than the provider or administrator, including reasons to decline the study, which provided helpful information for planning subsequent investigations. Participants were also more likely to decline the study when contacted by a CHW. While this finding may be interpreted as CHWs being less successful at recruitment, participants may have been more comfortable giving frank answers to CHWs when unable to participate. Consistent with this interpretation, exploratory data showed that more potential participants showed when recruited by a CHW than by a physician.

Other investigators who evaluated similar populations demonstrated the potential variation of data. A randomized clinical trial evaluating low-income Hispanics with type 2 diabetes at five community health centers and had screening processes that included primary care physician oversight started with an initial pool of 1176 patients but, after screening, had

487 potential participants.(24) Of the 487 eligible patients, 56.6% responded *yes*, and the remaining 43.4% declined or could not be contacted. Retention rates averaged 85% at study end (12-months). Investigators emphasized the importance of addressing patient-related challenges for successful recruitment.(24) On the other hand, in a 24-month investigation of 2,631 potentially eligible individuals, of whom the majority had annual household incomes <$35,000, the majority (81.2%) were not eligible or did not complete their baseline assessment, 4.9% declined, and 13.9% met entry criteria and responded *yes*.(25) Study retention was 86% at 24-months. Investigators noted the value of taxi vouchers, after-hours appointments, and community engagement to enhance retention.(25)

There is a call in health intervention research to partner with community members, but there is a dearth of information detailing strategies.(15) Facilitators of participation, including culturally appropriate methods, community involvement, and language sensitivity, are vital to overcome barriers.(1, 4-6, 9, 10) CHWs are well-positioned to overcome cultural and linguistic barriers, obtain sensitive data, address social determinants of health that providers often cannot, and have the potential to play key roles in research teams.(13-16, 26)

Strengths of the study are providing information to assist in study planning and overcoming recruitment barriers in low-income communities.(1, 2) For example, our data demonstrated that it is unlikely (91.4%) for those who responded *maybe* to show, suggesting that when resources are limited, investing in these individuals may not be the best strategy. Additionally, we found that the most common reason to decline was due to an inability to attend; alternative intervention modalities (e.g., telehealth/telephonic) may enhance the reach of the target population. We also explored incorporating CHWs in the recruitment process to gather data and involve communities. Limitations of the study include lack of information on why individuals who confirmed attendance did not show to orientation. Generalizability is also limited, as the study includes a low-income Hispanic population with a diabetes, which could result in a selection bias; however, it is unlikely that one call-to-entry rate can generalize across all

populations and diseases. Finally, larger investigations that incorporate CHWs in recruitment processes are needed to gain a better understanding of their value in recruitment.

Conclusions

This study provides valuable information to assist in recruitment planning in low-income populations. Call-to-entry rates, reasons to decline the study, and show rates are crucial for successful clinical research study implementation. Improving the ability to recruit low-income populations increases the ability to meet study goals and provide valuable data, thereby lessening health disparities among vulnerable populations. Future studies are warranted to explore recruitment data for diseases, conditions, and ethnicities.

Competing interests. The authors declare that they have no competing interests.

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Data Availability Statement. The data that support the findings of this study are available from the corresponding author upon reasonable request. Clinicaltrials.gov ID NCT03394456

Contributorship statement. EV, CJ, VC, and AD contributed to the study conception, design, data collection; MAR to the study analysis and interpretation of results, and EV, SV, MAR, LP, ZSD, SS, AD, and VS to the manuscript preparation. EV is responsible for the overall content as guarantor, accepting full responsibility for the finished work and the conduct of the study, had access to the data, and controlled the decision to publish.

Research Ethics Approval for Human Participants. This study involved human participants and was approved by Baylor College of Medicine Institutional Review Board (# H-40322).

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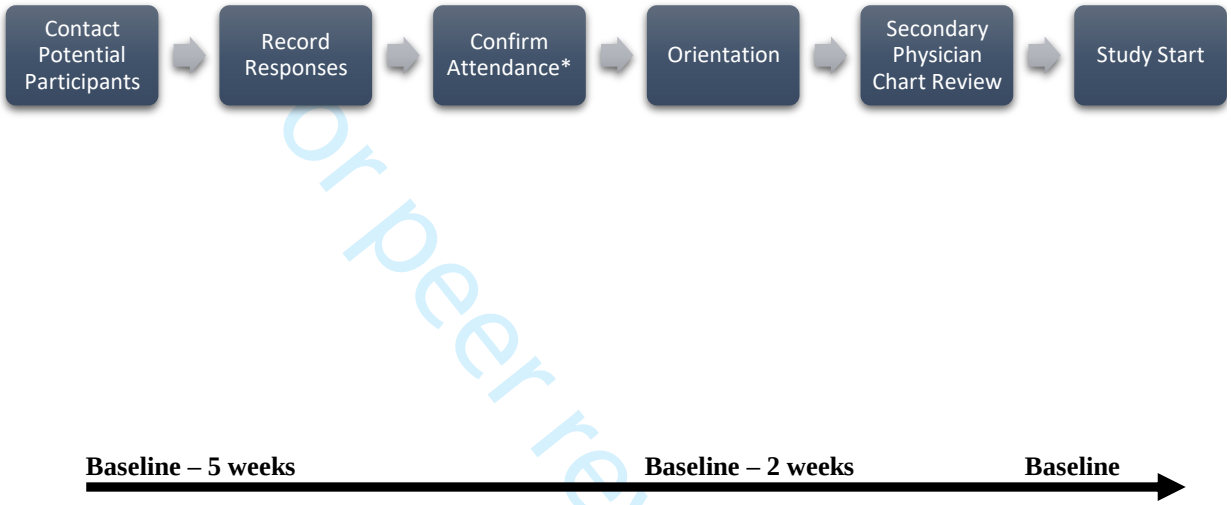
FIGURE CAPTIONS

Figure 1. Steps involved in the recruitment process, from contacting potential participants to study enrollment

Figure 2. Flowchart illustrating potential participants contacted to achieve a call-to-entry rate in a low-income Hispanic population (n=1075)

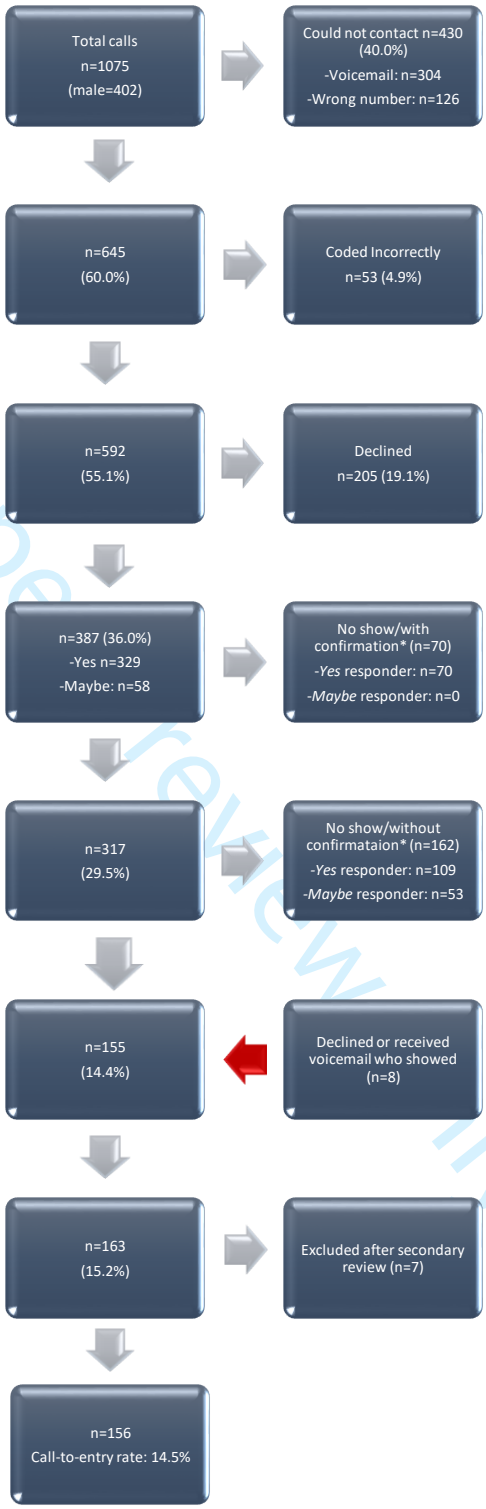
Figure 3. Responses of potential participants (top) delineated into show rates of individuals who responded *yes* with show rates (bottom left) and *no* with the reasons to decline (bottom right)

Figure 1. Steps involved in the recruitment process, from contacting potential participants to study enrollment



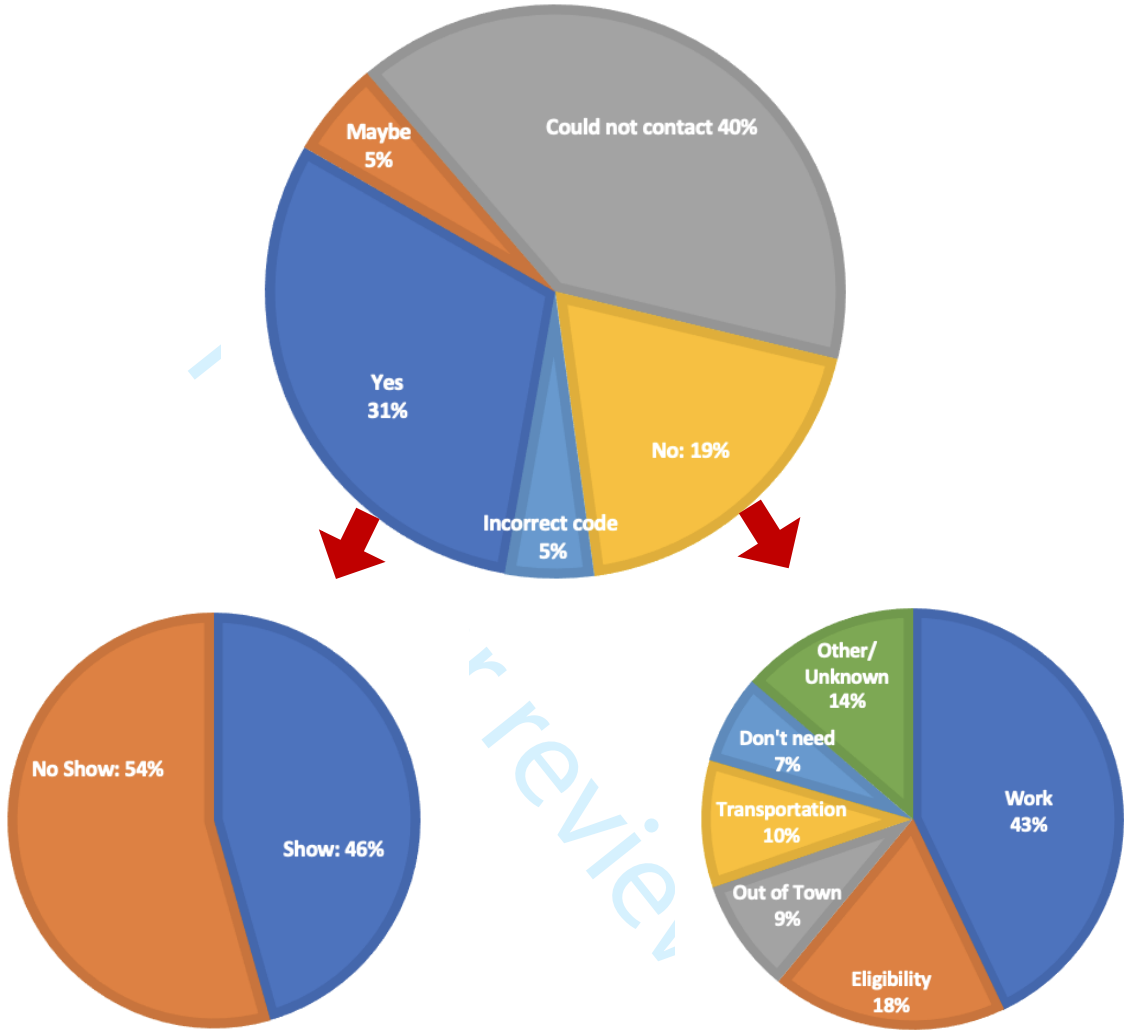
**Staff called potential participants who responded yes and maybe one day prior to orientation*

Figure 2. Flowchart illustrating potential participants contacted to achieve a call-to-entry rate in a low-income Hispanic population (n=1075)



**No show to study orientation. Yes and maybe responders received a reminder call the day prior*

Figure 3. Responses of potential participants (top) delineated into show rates of individuals who responded *yes** with show rates (bottom left) and *no* with the reasons to decline (bottom right)



*Show rate of maybe responders was low (n=5 of 58, 91.4%) and therefore not included in the figure

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation	Location
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	Title
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	Abstract -Methods -Results
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	p. 5, para. 103
Objectives	3	State specific objectives, including any prespecified hypotheses	p. 6, para. 3
Methods			
Study design	4	Present key elements of study design early in the paper	p. 7, para. 1
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	p. 7, para. 1-3 p. 8, para. 1-3
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	p. 7, para. 1-3 p. 8, para. 1, 2
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	n/a
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	p. 7, para. 3 p. 8, para. 4
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	p. 7, para. 3 p. 8, para. 1-4
Bias	9	Describe any efforts to address potential sources of bias	p. 7, para. 2
Study size	10	Explain how the study size was arrived at	p. 7, para 3
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	p. 7, para 3
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	p. 8, para 5
		(*b*) Describe any methods used to examine subgroups and interactions	n/a
		(*c*) Explain how missing data were addressed	p. 9, para 1
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy	p. 9, para 1
		(*e*) Describe any sensitivity analyses	n/a

Continued on next page

Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—e.g., numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	p. 10, para. 1, 2
		(b) Give reasons for non-participation at each stage	p. 10, para. 1, 2 p. 11, para. 2
		(c) Consider use of a flow diagram	Figure 2
Descriptive data	14*	(a) Give characteristics of study participants (e.g., demographic, clinical, social) and information on exposures and potential confounders	p. 10, para 2
		(b) Indicate number of participants with missing data for each variable of interest	n/a
		(c) *Cohort study*—Summarise follow-up time (e.g., average and total amount)	p. 10, para 2
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	p. 10, para 1, 2 p. 11, para 2
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	
		Cross-sectional study—Report numbers of outcome events or summary measures	
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (e.g., 95% confidence interval). Make clear which confounders were adjusted for and why they were included	p. 10, para 1-3 p. 11, para 2
		(*b*) Report category boundaries when continuous variables were categorized	Not relevant
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	Not relevant
Other analyses	17	Report other analyses done—e.g., analyses of subgroups and interactions, and sensitivity analyses	Pg. 11, para 3
Discussion			
Key results	18	Summarise key results with reference to study objectives	p. 12, para 1
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	p. 13, para 3
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	p. 12, para 1 p. 14, para 2
Generalisability	21	Discuss the generalisability (external validity) of the study results	p. 14, para 1
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	p. 15, para. 3

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.