

REVIEW ARTICLE

# Factors affecting the recruitment of Hispanic/Latinx American older adults in clinical trials in the United States: A scoping review

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**Abstract**

**Objective:** Participation of Hispanic/Latinx American older adults (HLAOA) in clinical trials is fundamental to health equity in aging research. However, information on strategies for the successful recruitment of this population in clinical trials is limited.

**Design:** This scoping review aims to identify hindering and facilitating factors that impact the recruitment of HLAOA in clinical trials in the United States.

**Methods:** Two databases (PubMed, EMBASE) were searched for original research articles from inception until March 2022 reporting on factors that engaged HLAOA ( $\geq 65$ ) in clinical trials. One thousand and thirteen studies were scrutinized to identify 31 eligible articles.

**Results:** Most articles were from cancer clinical trials (14 studies). Hindering factors that impacted the recruitment of HLAOA in clinical trials were related to (i) study design and logistics challenges, (ii) challenges imposed by social determinants of health, (iii) communication barriers, and (iv) patients' mistrust, and (v) family issues. Facilitating factors include (i) effective modes of outreach, (ii) strategic clinical trial design, (iii) incorporating culturally-respectful approaches that are tailored to the participants' sociocultural background, and (iv) bridging language barriers.

**Conclusions:** Successful recruitment of HLAOA into clinical trials requires identifying the study question, co-designing the trial design, implementation, and evaluation in respectful collaboration with the Hispanic/Latinx community with careful attention to their needs and minimizing the study burden on this vulnerable population. Factors identified here may guide researchers to better understand the needs of HLAOA and successfully recruit them into clinical trials, leading to more equitable research that increases their representation in clinical research.

**KEYWORDS**

clinical trials, diversity, ethnogeriatrics, Latinx Hispanic, older adults, recruitment

## INTRODUCTION

Inclusive representation of diverse populations in clinical trials is essential to ensure that the results are robust and representative of real-world demographics.<sup>1</sup> Less than 10% of patients in the United States participate in clinical trials, and only 5%–15% are non-White patients.<sup>2,3</sup> Consequently, the results of studies with poor representation are less applicable to critical groups of interest and can lead to disproportionately adverse health outcomes.<sup>4,5</sup> Very recent examples include studies<sup>6–8</sup> of the COVID-19 pandemic. Many minority populations, including African Americans, and Hispanic/Latinx, experienced more adverse COVID-19 outcomes than their White counterparts<sup>6</sup>; older adults reported far worse disease severity.<sup>7</sup> However, participation among racial and ethnic minoritized persons and older adults were markedly low in the US COVID-19 vaccine clinical trials.<sup>8</sup>

Hispanic/Latinx ethnicity is the largest minority population in the United States.<sup>9,10</sup> It is imperative to ensure high quality health care and adequate participation in clinical research for Hispanic/Latinx American older adults (HLAOA)<sup>10,11</sup>; as they experience many health disparities.<sup>10</sup> To address structural inequities, the National Institutes of Health (NIH) encourages the inclusion of women and minoritized groups, as well as older adults, in clinical research.<sup>1,12–16</sup> Despite this, ethnogeriatric populations ( $\geq 65$  years old) are still grossly underrepresented in clinical trial (CT) research.<sup>17–20</sup> One study stressed that only 3.95% of minoritized populations were included in randomized control trials published in the United States during the last 25 years. An important reason for the poor participation of older adults is unconscious bias and ageism, with most clinical trials excluding participants based on their age even when studying health conditions that are particularly common in older adults.<sup>12</sup>

Though some research has addressed the low participation of older adults<sup>19,21,22</sup> or minority groups independently, to the best of our knowledge, there are no scoping reviews explicitly focused on the factors affecting HLAOA recruitment into clinical research studies. Through this scoping review, we seek to fill this existing gap in the aging research literature.

## METHODS

We used the Arksey and O'Malley<sup>23</sup> framework, enhanced by Levac et al.,<sup>24</sup> to guide this scoping review. The database search was conducted in PubMed and EMBASE (via Ovid) in March 2022 using search keywords were “Older,” “Clinical trials,” and “Hispanic,”

### Key points

- Inclusion criteria for most clinical trials are narrow and a primary barrier in recruiting HLAOA in clinical research.
- Recruitment strategies that are developed in conjunction with Hispanic/Latinx Americans patients and families and informed by their social and cultural aspects and their beliefs and behaviors are most likely to be successful.

### Why does this paper matter?

Increasing diversity in clinical trials is a top national research priority. Hispanic/Latinx Americans are the largest and growing minority group in the United States but are extremely underrepresented in clinical trials in the United States of America. This work examines the underlying factors that serve as facilitators and barriers for Hispanic/Latinx American older adults (HLAOA) including in clinical trials.

including their various MESH terms and synonyms. Search strings were established following the SPIDER<sup>25</sup> (Sample, Phenomenon of Interest, Design, Evaluation, Research type), a search strategy tool used for quantitative, qualitative, and mixed methods research. The SPIDER tool guided the research strategy to identify: the sample—Hispanic/Latinx Americans who are 65 years or older; the phenomenon of interest—Clinical Trials; the design—any; the evaluation—the factors affecting the recruitment process; and the Research type—qualitative, quantitative, and mixed methods. Search strings were adapted to the search algorithm of each database, as can be found in the supplementary material, Text S1. Search outcomes were imported into Mendeley reference management software.<sup>26</sup>

## Inclusion and exclusion criteria

Our eligibility criteria included English-language original research conducted in the United States; studies that aimed to recruit or were able to recruit older adults (defined as 65 years or older) and Hispanic/Latinx American race or ethnicity; and reporting factors related to clinical trial recruitment. We included articles published since the inception of each database and study designs, including quantitative, qualitative, mixed-

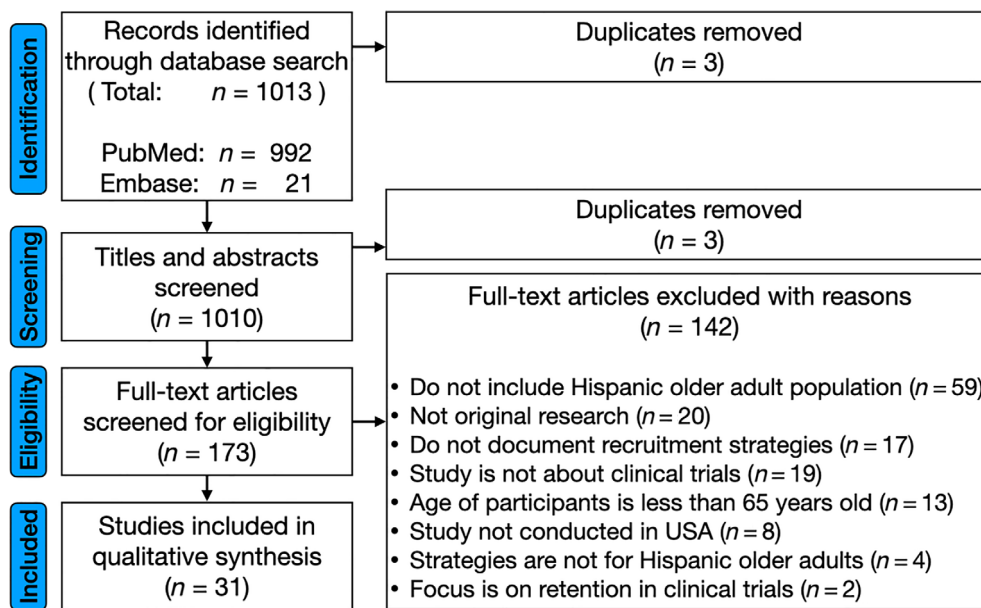


FIGURE 1 PRISMA flow chart of articles eligible and included in the review.

methods, and randomized control trials. Systematic reviews, meta-analysis, commentary articles, and narrative reviews were excluded. As this was a scoping review and not a systematic review, the study protocol was not eligible to be registered with PROSPERO, the international register of prospective reviews (<https://www.crd.york.ac.uk/prospero/#aboutpage>).

## Screening and data extraction

Coauthors identified the relevant studies and removed duplicates. All study titles and abstracts were scrutinized. Relevant articles pertaining to this study were identified, and full-text screening was completed to select the articles included in the final analysis using the predetermined inclusion criteria described above. Figure 1 depicts the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) flow chart of all the articles screened and included in the review.

The software Microsoft 365 Excel<sup>27</sup> was used to extract, manage, and analyze the data relevant to the scoping review question. We used a standardized template and included the article details: author and year of publication; study sites; design; disease focus; research strategy/aim; methodology; study population characteristics, Hispanic and HLAOA participation, and factors affecting HLAOA recruitment. Two authors (DR and SAH) independently reviewed all the papers and extracted data blinded to each other. After completing independent work, they audited each other's data extraction table and noted that the concordance was over 90%. The two authors had significantly different opinions about two papers, which were resolved by further discussion. Any questions that remained were

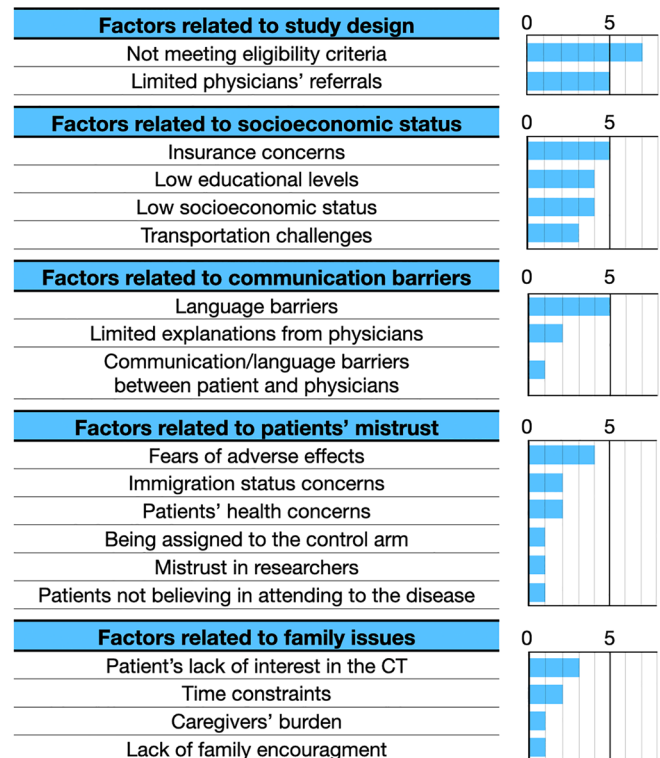


FIGURE 2 Factors associated with hindering recruitment of HLAOA into clinical trials.

brought to the last author (VSP), who moderated the discussions until consensus was achieved.

## Data analysis

To analyze the data, two authors (DR and SAH) independently reviewed each of the 31 papers and made a list of all the items or actionable information related to hindering

TABLE 1 Summary of factors associated with facilitating the recruitment of HLAOA.

Factors associated with hindering the recruitment of HLAOA	Supporting studies	Reference number	Study design	Disease focus
Not meeting the eligibility criteria	Raman et al.	29	A cross sectional study	Alzheimer's disease
	Unson et al.	32	Clinical trial	Osteoporosis
	Borno et al.	35	Nonrandomized, single-arm feasibility study/two-step recruitment intervention study	Prostate cancer
	Brooks et al.	36	Prospective multi-institutional observational study/cross-sectional quantitative survey	Gynecological cancers
	Gelman	42	Qualitative face-to-face interviews	Alzheimer's disease
	Ramsey et al.	54	The Systolic Blood Pressure Intervention multicenter randomized clinical trial	Hypertension
	Sisk et al.	56	A randomized controlled trial	Heart failure patients
Limited physicians' referrals	Nacif de Brey et al.	50	A multi-strategy recruitment intervention comparison study	Arthritis
	Veit et al.	57	Mathematical decision model study	Breast cancer and coronary heart disease
	Brooks et al.; Ramsey et al.; Sisk et al.	36,54,56	a	
Low socioeconomic status	Gross et al.	28	A population-based case-control study	Breast cancer
	Borno et al.	35	a	
	Langford et al.	45	A secondary analysis of the Health Information National Trends Survey (HINTS) 2007 data	Any cancer
	Lara et al.	46	A cross-sectional survey and telephone interview study	Any cancer
Transportation challenges	Duda et al.	39	Sub study of the National Lung Screening Trial (NLST)—Randomized multicenter study/multi-strategy recruitment intervention study	Lung cancer
	Brooks et al.; Gelman	36,42	a	
Low educational levels	Gelman; Langford et al.	42,45	a	
	Leiter et al.	48	A secondary analysis of the Health Information National Trends Survey (HINTS) data from 2008 and 2012	Any cancer
	Palmer et al.	51	A cross-sectional telephone interview study	Prostate Cancer

(Continues)

TABLE 1 (Continued)

Factors associated with hindering the recruitment of HLAoa	Supporting studies	Reference number	Study design	Disease focus
Insurance concerns	Byrne et al.	37	Cross-sectional quantitative survey	Breast, lung, colorectal, or prostate cancer
	Ford et al.	40	Qualitative focus group discussions	Clinical trial participation of any disease
	Gansler et al.	41	Secondary data analysis of Clinical Trials Matching Service	Any cancer
	Duda et al.; Lara et al.	39,46	a	
Language barriers	Unson et al.; Gelman; Leiter et al.; McHenry et al.; Palmer et al.	32,42,48,49,51	a	
Patient–physician language barriers	Byrne et al.	37	a	
Time physicians spend with patients	Ford et al.; Gansler et al.	40,41	a	
Fears of adverse effects	Karlawish et al.	43	Qualitative face-to-face interviews	Alzheimer's disease
	Byrne et al.; Ford et al.; Veit et al.	37,40,57	a	
Being assigned to the control arm	Ford et al.	40	a	
Immigration status concerns	Ford et al.; Gelman	40,42	a	
Mistrust in researchers	Saadi et al.	30	A randomized controlled trial	Hypertension
Patients nor believing in attending to the disease	Gelman et al.	42	a	
Health concerns	Borno et al.; Sisk et al.	35,56	a	
Time constraints	Brooks et al.; McHenry et al.	36,49	a	
Caregivers' burden	Gelman	42	a	
Lack of family encouragement	Hinton et al.	47	A community-based cohort study/multi-strategy recruitment intervention study	Alzheimer's disease
Patient's lack of interest in the CT	Unson et al.; Borno et al.; McHenry et al.	32,35,49	a	

<sup>a</sup>Study details have been described previously.

and facilitating the recruitment of HLAOA in clinical trials, which were labeled as strategies or factors. Then, both authors met and worked on clustering the items to form primary themes and sub-themes, which are presented below.

## RESULTS

The study team identified 1013 articles from database search results. Thirty-one articles were noted to be

eligible based on our inclusion criteria for this scoping review (Figure 1). Table S1 provides descriptive details of the study strategy and included studies. Most articles reported factors related to CT recruitment in cancer (14 studies). Other disease focuses were Alzheimer's and other related dementias (5 studies), Hypertension (2), Osteoporosis (2), Parkinson's (1), Arthritis (1), Diabetes (1), Stroke (1), Heart disease (1), and three studies reported results of CT recruitment in general.



Most importantly, no study focused specifically on recruitment strategies/factors related to HLAOA. However, six studies explicitly included information about the factors impacting the recruitment of HLAOA.<sup>28–33</sup> In contrast, the information mentioned in the other 25 studies was used to infer factors affecting the recruitment of HLAOA.<sup>34–58</sup>

Fourteen studies reported aspects impacting the CT participation of mix-age ( $\geq 18$  years old) diverse ethnic minority cohorts.<sup>31,34,35,37–40,42,43,45,50–53</sup> In comparison, 11 studies studied factors associated with older adults ( $\geq 65$  years old) of diverse ethnic minorities.<sup>28–30,32,33,47,54–58</sup> Five studies focused on discussing factors related to improving or hindering any patient enrollment in CTs.<sup>36,41,44,46,48</sup> One study examined barriers and facilitators to recruiting older adults to clinical trials.<sup>49</sup>

## Factors hindering the recruitment of HLAOA in clinical trials

Figure 2 depicts the five common factors that hinder the participation of HLAOA in CTs: (A.1) factors related to study design; (A.2) factors related to socioeconomic status; (A.3) factors related to communication barriers; (A.4) factors related to patients' mistrust; (A.5) factors related to family issues. Table 1 summarizes the factors hindering the recruitment of HLAOA, respective supporting studies, and study design.

### Factors related to study design

In seven studies, patients not meeting the clinical trials' eligibility criteria were mentioned as a hindering factor.<sup>29,32,35,36,42,54,56</sup> Reasons may vary; for instance, one study stated that after noticing that Hispanic/Latinx Americans and other ethnic minority groups were more frequently excluded due to their Logical Memory Scores, they adjusted the criteria in an effort to prevent differential exclusion by race and ethnicity.<sup>29</sup> Another study stated that CTs were available for only 7% of Hispanic/Latina women, compared with 43% for non-Hispanic women.<sup>36</sup> The same study stressed that patients over the age of 71 were less likely to have trials available compared to patients under 41 years old.<sup>36</sup> An Alzheimer's Disease and Related Dementias (ADRD) study reported that HLAOA they screened failed to meet criteria stipulating an existing Alzheimer's disease diagnosis.<sup>42</sup> They also found that HLAOA patients struggled to get evaluated and obtain a diagnosis as they encountered structural barriers to accessing care. Other CT studies excluded patients as the patients had comorbidities or

because patients had cognitive impairments.<sup>56</sup> Additionally, limited referrals from physicians were noted to hinder participation in CTs.<sup>36,50,54,56,57</sup>

### Factors related to socioeconomic status

The socioeconomic status of a person is determined by combining diverse social and economic aspects such as income, education, place of residence, among others.<sup>59</sup> In relation to this, four studies stated low socioeconomic status affected patient enrollment in CTs.<sup>28,35,45,46</sup> For instance, Hispanic/Latinx Americans at lower income levels were associated with being poorly informed about the potential clinical trials and their effects.<sup>45,46</sup> Similarly, a lack of possession or usage of devices, steady internet access, and low-technical literacy were more likely to exclude patients from CTs recruited using online methods.<sup>35</sup> Three studies highlighted transportation challenges as hindering aspects.<sup>36,39,42</sup> Four studies report that low education levels could limit Hispanic/Latinx Americans and particularly HLAOA participation in CTs.<sup>42,45,48,51</sup> Hispanic/Latinx Americans reporting lower levels of education were less informed about CTs, thus, were less likely to participate.<sup>45,48,51</sup> Similarly, poor knowledge of the Alzheimer's disease characteristics precluded HLAOA from participating in research mainly because patients' families did not understand the relevance of their trial participation.<sup>42</sup>

Five articles stressed that insurance challenges could hinder Hispanic/Latinx Americans and especially HLAOA's participation in clinical research.<sup>37,39–41,46</sup> Another study reported patients with Medicaid or uninsured were less likely to participate in CTs.<sup>41</sup> Additionally, another study highlighted the knowledge level of CTs reimbursement was associated with willingness to participate.<sup>46</sup> When the CT cost was insufficiently covered<sup>37,40</sup> or partly covered, such as screening examinations, but not subsequent testing,<sup>39</sup> the HLAOA participation was poor.

### Factors related to communication barriers

Five studies noted language barriers hindered HLAOA recruitment.<sup>32,42,48,49,51</sup> In two studies, Spanish-speaking participants reported low CT awareness and poor participation.<sup>48,51</sup> It is important to note that patients with very limited literacy may be excluded<sup>49</sup> when the study procedures require the participants to read in English or Spanish at a basic level. For example, the National Alzheimer's Coordinating Center (NACC) Uniform Dataset (UDS)<sup>60</sup> has very specific assessments that all participants must complete in order to be eligible to participate in the Alzheimer's

Disease Research Center (ADRC). These assessments require a fifth-grade level of ability to read in Spanish and thereby eliminate persons who have very limited literacy. One study that used mass media in the CT, mentioned it was ineffective in encouraging high enrollment levels. The authors discussed that it was due to the message complexity or failure to devise persuasive messages that resonated with HLAOA.<sup>32</sup> Another study reported that patient–physician language barriers prevented Hispanic-Latinx persons from participating in research studies.<sup>37</sup> Also, two studies found the length of the patient–physician meetings could have impacted HLAOA recruitment.<sup>40,41</sup> Physicians spent less time with participants to explain CTs better or clarify patients' doubts<sup>40,61–63</sup> or information overload due to lack of time, where patients missed the suggestion to participate in CTs.<sup>41</sup>

### Factors related to patients' mistrust

Four studies reported that the fear of adverse effects and “experimentation” could limit the research participation of HLAOA.<sup>37,40,43,57</sup> One article identified group assignment—assigned to the control arm—was discouraging for some HLAOA.<sup>40</sup> Other factors related to mistrust were patients' concerns about immigration status, which was stressed in two studies,<sup>40,42</sup> and mistrust toward researchers.<sup>30</sup> Similarly, patients not believing in the importance of attending to the disease<sup>42</sup> and patients' health concerns<sup>35,56</sup> were also factors that negatively impacted the participation of Hispanic/Latinx and HLAOA in CTs and research.

### Factors related to family issues

Two studies stressed that time constraint was a factor limiting HLAOA enrolment related to caregiver assistance.<sup>36,49</sup> For instance, patients being caregivers to their family members.<sup>49</sup> One study pointed out that the high burdens of Hispanic/Latinx American caregivers hindered family members' support of HLAOA from participating in CTs.<sup>42</sup> One study stressed that a lack of family encouragement hindered older adults in CT participation.<sup>47</sup> Additionally, patients' lack of interest in CT was stressed in three studies.<sup>32,35,49</sup>

## Factors associated with facilitating the participation of HLAOA in clinical trials

Figure 3 summarizes the three primary factors identified in the eligible studies as having a positive impact on the recruitment of HLAOA in CTs: (B.1) Factors related to

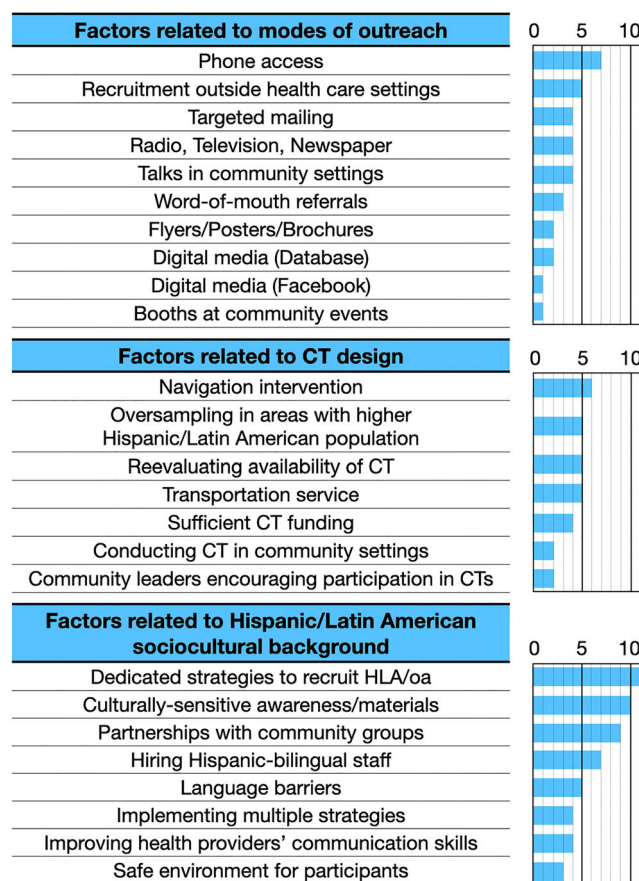


FIGURE 3 Factors facilitating HLAOA recruitment into clinical trials.

modes of outreach of HLAOA; (B.2) Factors related to clinical trial design; (B.3) Factors related to Hispanic/Latin American sociocultural background. Table 2 summarizes the factors associated with facilitating the recruitment of HLAOA, respective supporting studies, and study design.

## Recommended modes of outreach to HLAOA

### Phone access

Out of strategies for outreach participants, seven studies pointed out that using a toll-free phone line was useful to outreach participants.<sup>29,31,39,49,50,53,55</sup> With a toll-free number participants could contact a project staff for CT information,<sup>29,39,55</sup> refer to other community resources,<sup>50</sup> and follow up with appointments.<sup>49,53</sup> One study used a Spanish line as an enrollment system for a pre-hospital stroke clinical trial allowing potential participants to complete the consent-taking process in their primary language.<sup>31</sup>

### Mail advertisement

The targeted mailing was an important contact source discussed in four studies.<sup>33,39,54,55</sup> Older adults were more

TABLE 2 Summary of factors associated with facilitating the recruitment of HLAOA.

Factors associated with facilitating the recruitment of HLAoa	Supporting studies	Reference number	Study design	Disease/study focus
Phone access	Sanossian et al.	31	Field Administration of Stroke Therapy-Magnesium (FAST-MAG) Trial/a randomized placebo-controlled clinical trial	Stroke
	Pelto et al.	53	An intervention designed study	Any cancer
	Rubin et al.	55	The Diabetes Prevention Program (DPP), a multicenter randomized controlled trial	Diabetes
	Raman et al.; Duda et al.; McHenry et al.; Nacif de Brey et al.	29,39,49,50	a	
Targeted mailing	Unson et al. (B)	33	Osteoporosis	To examine whether ethnicity or socioeconomic status influenced a group's ability to meet eligibility criteria and willingness to enroll
	Duda et al.; Ramsey et al.; Rubin et al.	39,54,55	a	
Radio, television, newspaper	Langford et al.; Raman et al.; Duda et al.; Nacif de Brey et al.; Gelman	29,39,42,45,50	a	
Flyers/posters/brochures	Nacif de Brey et al.; Pelto et al.	50,53	a	
Digital media (Facebook)	Dobkin et al.	38	Fox Insight web-based longitudinal study/multi-strategy recruitment intervention study	Parkinson's disease
Digital media (Database)	Palacio et al.	52	An experimental machine learning study	Clinical trial participation of any disease
	Gansler et al.	41	a	
Recruitment outside healthcare settings	Unson et al. (B); Ford et al.; Hinton et al.; Pelto et al.; Ramsey et al.	33,40,47,53,54	a	
Talks in community settings	Vicini et al.	58	A secondary analysis of a minority outreach program (MOP)	Any cancer

(Continues)



TABLE 2 (Continued)

<b>Factors associated with facilitating the recruitment of HLAoa</b>				
<b>HLAoa</b>	<b>Supporting studies</b>	<b>Reference number</b>	<b>Study design</b>	<b>Disease/study focus</b>
	Duda et al.; Karlawish et al.; Nacif de Brey et al.	39,43,50	a	
Word-of-mouth referrals	Ford et al.; Hinton et al.; Nacif de Brey et al.	40,47,50	a	
Booths at community events	Bishop et al.	34	Single-strategy recruitment intervention study	Clinical trial participation of any disease
Reevaluating availability of CT	Kehl et al.	44	A large, population- and health-system-based, multiregional Cancer Care Outcomes Research and Surveillance (CanCORS)	Lung or Colorectal cancer
	Raman et al.; Brooks et al.; Duda et al.; Ford et al.	29,36,39,40	a	
Oversampling in areas with higher Hispanic/Latin American population	Unson et al.; Borno et al.; Kehl et al.; Palmer et al.; Palacio et al.	33,35,44,51,52	a	
Community leaders encouraging participation in CTs	Duda et al.; Nacif de Brey et al.	39,50	a	
Conducting CT in community settings	Brooks et al.; Hinton et al.	36,47	a	
Navigation intervention	Brooks et al.; Ford et al.; Hinton et al.; McHenry et al.; Rubin et al.; Vicini et al.	36,40,47,49,55,58	a	
Transportation service	Gross et al.; Duda et al.; Karlawish et al.; McHenry et al.; Rubin et al.	28,39,43,49,55	a	
Sufficient CT funding	Duda et al.; Pelto et al.; Ramsey et al.; Vicini et al.	39,53,54,58	a	
Dedicated strategies to recruit HLA/oa	Unson et al.; Duda et al.; Langford et al.; Lara et al.; Hinton et al.; McHenry et al.; Palmer et al.; Ramsey et al.; Rubin et al.; Sisk et al.; Vicini et al.	32,39,45–47,49,51,54–56,58	a	

TABLE 2 (Continued)

<b>Factors associated with facilitating the recruitment of HLAoa</b>				
<b>HLAoa</b>	<b>Supporting studies</b>	<b>Reference number</b>	<b>Study design</b>	<b>Disease/study focus</b>
Implementing multiple strategies	Raman et al.; Nacif de Brey et al.; Sisk et al.; Vicini et al.	29,50,56,58	a	
Culturally-sensitive awareness/materials	Saadi et al.; Unson et al.; Unson et al. (B); Brooks et al.; Gelman; Karlawish et al.; Lara et al.; Pelto et al.; Sisk et al.; Vicini et al.	30,32,33,36,42,43,45,53,56,58	a	
Safe environment for participants	Raman et al.; Hinton et al.; McHenry et al.	29,47,49	a	
Partnerships with community groups	Raman et al.; Saadi et al.; Duda et al.; Gelman; Langford et al.; McHenry et al.; Nacif de Brey et al.; Rubin et al.; Vicini et al.	29,30,39,42,45,49,50,55,58	a	
Language barriers	Sanossian et al.; Borno et al.; Byrne et al.; Palmer et al.; Palacio et al.	31,35,37,51,52	a	
Hiring Hispanic-bilingual staff	Unson et al.; Brooks et al.; Duda et al.; Ford et al.; Hinton et al.; Nacif de Brey et al.; Ramsey et al.	32,36,39,40,47,50,54	a	
Improving health providers' communication skills	Byrne et al.; Ford et al.; Kehl et al.; McHenry et al.	37,40,44,49	a	

<sup>a</sup>Study details have been described previously.

likely to get information via direct mail than through community events or poster displays.<sup>55</sup> The framing of the mailing message was found to be necessary for effective communication; using more graphics than words in these messages was critical for participants with reading difficulties.<sup>33</sup>

#### *Advertising in radio, television, and newspaper*

Hispanic respondents placed greater trust in information from these sources.<sup>45</sup> Also, these media were more effective when employed simultaneously as message saturation,<sup>29,39</sup> and continued exposure over time increased awareness about specific research trials.<sup>50</sup> Using a high-profile and trusted Latinx television personality to convey CT information had a positive effect on recruitment.<sup>42</sup>

#### *Flyers/posters/brochures*

Two studies mentioned positive effects of flyers/posters/brochures on the recruitment process,<sup>50,53</sup> especially when these were made available through trusted venues like a hospital or clinic, or a healthcare facility.<sup>53</sup> Such materials were particularly effective when used with other recruitment strategies, such as providing flyers prior to a talk/event.<sup>50</sup>

#### *Digital media*

The use of digital media to outreach participants is in the early stages of exploration. However, one study identified that using digital marketing campaigns on Facebook attracted large numbers of HLAOA, as well as participants (including HLAOA) who were lower-income, less educated, and in worse physical health.<sup>38</sup> Also related to

using technology to outreach participants, two papers pointed out the use of databases as a strategy to identify potential participants. First, the use of CT matching services,<sup>41</sup> and second, to identify Hispanic surnames in a health claim database.<sup>52</sup>

#### *Community contexts or contexts outside the healthcare systems*

Five articles discussed community contexts or contexts outside the healthcare systems as central to outreach HLAOA.<sup>33,40,47,53,54</sup> For instance, churches, ethnic gathering places, and support groups,<sup>40</sup> or satellite clinics.<sup>47</sup> In addition to community outreach recognized as productive for HLAOA recruitment, strategies to recruit HLAOA in the community setting helped improve recruitment. Four studies suggested educational talks or healthcare services in the community encouraged potential participants to enroll in CT<sup>39,43,50,58</sup> by increasing trial awareness and building community trust.<sup>39</sup> Providing educational talks in the community is also a form of community service in the shape of information, demonstrating a willingness to give something back to the community.<sup>50</sup> Also, educational outreach and information delivery were reported to be helpful to vulnerable populations to break down barriers and empower patients in the healthcare decision process.<sup>58</sup> One Alzheimer's disease trial suggested educating the Hispanic/Latinx American community, in general, could positively influence the cultural perceptions of the disease.<sup>43</sup> Face-to-face contact combined with community service elements, such as blood pressure checks,<sup>49</sup> was mentioned to improve recruitment.<sup>58</sup> As identified in three studies, word-of-mouth referrals were identified to have positive effects on recruiting Hispanic/Latinx and HLAOA<sup>40,47,50</sup>; personal recommendations increased trust and credibility in the community about participating in the CT.<sup>40,50</sup> Though it was not mentioned as effective in recruiting high numbers of HLAOA to CTs, one study reported booths at community fairs/events could help mainly outreach potential participants and increase the visibility of academic medical centers among minority groups.<sup>34</sup>

### Strategies related to clinical trial design

#### *Using Community Based Participatory Research (CBPR) techniques*

Nine studies stressed partnering with community-based agencies/groups that already have earned the trust of the Hispanic population as a method that benefits recruitment.<sup>29,30,39,42,45,49,50,55,58</sup> Two papers suggested framing the study specifically following community-based participatory research principles,

such as researchers working with community leaders to design the recruitment program,<sup>30,58</sup> and working toward establishing a solid relationship with these organizations.<sup>49</sup> These groups could advise researchers in using/designing tailored materials relevant to the unique needs of their community members appeared to improve recruitment.<sup>42</sup> Similarly, creating partnerships increased the future attempts to recruit minority groups successfully.<sup>50</sup> One study found collaboration with charitable organizations was a useful channel to recruit participants since the Hispanic/Latinx American population viewed such institutions as trustworthy and placed greater trust in health information from these organizations.<sup>45</sup>

#### *Trial accessibility strategies*

Five studies stressed the importance of being flexible in reevaluating all aspects associated with the availability of clinical trials.<sup>29,36,39,40,44</sup> For instance, making clinical trials more available and accessible,<sup>36,44</sup> such as having longer opening hours—nights or weekends—to facilitate the populations' needs could facilitate recruitment.<sup>39,40</sup> Five studies suggested oversampling health facilities or areas with more Hispanic patient populations to increase the recruitment numbers.<sup>33,35,44,51,52</sup> Also, two studies discussed community leaders to encourage minority groups, including Hispanic/Latinx and HLAOA, CT participation.<sup>39,50</sup> Another two studies suggested evaluating the possibility of conducting study consenting and screening questionnaires and evaluations in the community or a community setting (instead of hospitals or academic institutions) promoted trust and alleviated fear, thereby increasing recruitment rates.<sup>36,47</sup>

#### *Use of health navigators (“Promotorxs de Salud”)*

One study pointed to navigation as a strategy to improve recruiting minoritized groups<sup>40</sup>; Navigation is a barrier-focus approach where a staff member works with patients to understand their multilevel barriers and find ways to overcome them.<sup>40</sup> Six studies identified a navigation intervention that highly favored the recruitment of HLAOA.<sup>36,40,47,49,55,58</sup>

#### *Utilizing financial incentives*

Transportation or transportation reimbursement encourage participation in CTs.<sup>28,39,43,49,55</sup> Economic stipends were an encouraging factor<sup>39,57</sup> and help offset losses incurred due to taking time off from work in recruiting this population. In addition to financial assistance to participants, allocating sufficient CT funding to improve recruiting HLAOA to CTs was highlighted as vital in four studies.<sup>39,53,54,58</sup>

## Factors related to participants' sociocultural background

Of all the encouraging factors identified here that could affect recruiting HLAOA in clinical trials, the most mentioned were related to the older adults' sociocultural background. Eleven studies suggested to careful planning and designing strategies dedicated to recruiting the Hispanic/Latinx American population.<sup>32,39,45–47,49,51,54–56,58</sup> The effects of these strategies were mentioned to significantly improve with established recruitment goals.<sup>39,47</sup> Culturally tailored recruitment strategies may enhance CT awareness and willingness to participate.<sup>45,46,49</sup> In addition to planning strategies intentionally, four studies mentioned the benefits of applying different strategies at different time points of the trial and continuously monitoring them for their effectiveness.<sup>29,50,56,58</sup> Most importantly, all recruitment strategies must consider the available resources, including the local experience and expertise, and the cost-effective of these strategies.<sup>55</sup>

Ten studies highlighted the vital importance of using culturally-sensitive material in recruiting HLAOA.<sup>30,32,33,36,42,43,45,53,56,58</sup> Formalizing training processes to improve cultural competency among the research staff, including relevant multicultural knowledge, health, and demographic information important to the study population<sup>36</sup> is key. Culturally tuned accessibility and suitable materials tailored to unique community members were also suggested.<sup>42,43</sup> The materials such as flyers, brochures, or posters,<sup>53</sup> educational booklets,<sup>58</sup> and slide presentations,<sup>53</sup> among others, were mentioned as effective. One article highlighted the importance of personal beliefs that might serve as barriers affecting their participation.<sup>32</sup> Three studies suggested creating a safe environment of respect and trust to encourage potential participants.<sup>29,47,49</sup> Factors discussed in three studies were being attentive to address participants' anxiety about the new experience at the recruitment stage as well as all CT stages, and providing them with comfort and security whenever possible<sup>49</sup> and overall, ensuring a friendly and positive experience for participants.<sup>29,47</sup>

## Strategies to bridge language barriers

Five studies explicitly stated that when recruiting the Hispanic/Latinx American population, bridging language barriers was key.<sup>31,35,37,51,52</sup> The authors of two studies found that providing educational materials written in Spanish and easily explained for participants with low literacy levels was helpful.<sup>40,42</sup> Another seven studies stressed hiring Hispanic-bilingual staff in the research team had a positive effect on the recruitment

process<sup>32,36,39,40,47,50,54</sup>; involving Hispanic physicians in the research team was highlighted.<sup>36</sup> Furthermore, four studies identified that improving health providers/physicians' skills to explain and offer CTs to patients had a positive impact.<sup>37,40,44,49</sup>

## DISCUSSION

We conducted this scoping review to better understand the factors related to enrolling HLAOA into clinical trials. The findings of this scoping review suggest, predominantly, planning and developing recruitment strategies should pay careful attention to the social and cultural aspects of Hispanic/Latinx Americans. The focus on sociocultural characteristics is shown to be critical and applies universally across other minoritized groups, too, such as in the case of African American population<sup>64</sup> and Chinese American population.<sup>65,66</sup> We note that the three most suggested strategies include: (1) developing dedicated strategies to recruit HLAOA before starting the clinical trial; (2) making sure that all strategies, planning, and used materials are culturally sensitive to the Hispanic/Latinx American population; (3) partnering with community groups trusted by HLAOA.

Strategies were mentioned as helpful or improved Hispanic and HLAOA recruitment and developed as a part of the research protocol<sup>19,20</sup> The highlighted strategies are built on the constructs of cultural competence theories<sup>67</sup>; such aspects help build trusting relationships with the Hispanic population that is critical to their recruitment.<sup>68,69</sup> Understanding participants' sociocultural background is central because it enables the researchers to have a two-way communication channel with the potential participants for two reasons. First, it provides researchers with tools to meaningfully communicate and connect with the Hispanic/Latinx American population. A key influencing factor for recruitment is that the clinical trial matches the health priorities of the targeted population.<sup>70</sup> Thus, engaging HLAOA in clinical trials goes beyond using the Spanish language to translate CT's informational materials. Building respectful, collaborative partnerships with patients and families at every step of the research process is vital, and structuring study-related messages that acknowledge HLAOA's lived experiences is critical.<sup>17,71</sup> In other words, it is fundamental to use HLAOA's sociocultural communication codes, dynamics, and life experiences (who they are/how they live), in general, to build effective health messages that inform participants in such a way that it aligns with their health and cultural priorities.<sup>72,73</sup> Second, understanding HLAOA's sociocultural background enables researchers to "listen" to what participants expect to communicate,

as well as to “see” what limits HLAOA from participating in CTs, thus, determining measures to overcome them. Many other authors have highlighted that partnering with community groups for research appears to recruit minoritized populations effectively.<sup>71–73</sup> Community groups that have built long-term relationships with the Hispanic/Latinx Americans could provide valuable insights, such as their sociocultural communication codes, needs, and priorities to researchers to implement effective recruitment strategies. By working with, and being part, of the Hispanic/Latinx American population for a long period of time, community groups deeply understand the sociocultural communication codes, needs, and priorities of this population and, thus, they have the tools to help researchers to make visible specific health priorities to the HLAOA population, opening the door to recruit participants.

Regarding the factors deterring HLAOA participation, our results show that the most frequently highlighted factor is patients failing to meet the clinical trial's eligibility criteria. This echoes with other authors stressing that study design features may hinder the recruitment of minority groups of older adults when they are limited to participants who speak English and are healthy.<sup>19,22,74,75</sup> As explained before, language/communication is a cultural component; thus, restrictions in language affect HLAOA since an important percentage of this population are mainly Spanish-only speakers.<sup>76</sup> Similar findings were reported among other minoritized groups, such as Chinese American patients who are also affected by English-only participation restrictions.<sup>66,77,78</sup> Prevalence of comorbidities, such as diabetes and hypertension, is higher in many minority populations than White population; Hispanic/Latinx report a greater risk than other minority groups in the United States.<sup>79–82</sup> These diseases have been identified in other studies as the main causes for excluding older adults from CT.<sup>19</sup> Two reasons for study designs to consider excluding adults with comorbidities can be the lack of patients' willingness and their physicians' approval due to potential adverse risks posed by the clinical trial intervention. The study design protocol decision to exclude older people with comorbidities is likely higher among minoritized groups, including Hispanic/Latinx, because they are at increased risk of developing such conditions compared to non-Hispanic White population.<sup>83</sup> Flexible research design to accommodate the needs of older adults,<sup>21,74</sup> with adequate details to implement them can help to include. For instance, using in-depth geriatric assessments to elucidate relevant characteristics of older adults could guide and potentially increase the selection of frail patients instead of only including healthy older adults, which is common practice.<sup>22,84</sup> The argument is to provide a scientific rationale

for exclusion criteria regarding older adults' health instead of assuming they are too frail to participate.<sup>85</sup> Another reason for older adults not meeting eligibility criteria is when some research protocols impose an unjustified upper-age limit.<sup>19,20</sup> The incidence of trial eligibility criteria that exclude older adults due to age is unclear; however, studies with the age limit as an inclusion criterion have decreased over time.<sup>86</sup> Therefore, there is the potential to overcome this issue by addressing the study design.

Systemic issues, such as structural racism,<sup>87</sup> can cause discrimination against HLAOA leading to health inequality.<sup>88,89</sup> Discrimination at a systemic level may distort scientific knowledge,<sup>87,89</sup> causing researchers to consciously or unconsciously replicate systemic discriminatory practices in the study design. Therefore, incorporating a more conscious evaluation of the study design could help minimize discriminatory practices. Another issue that hinders older adult participation is patients' mistrust that arises from discriminatory practices, as past publications of Hispanic/Latin Americans reported their perceived discrimination from healthcare providers.<sup>90</sup> Mistrust in research can result in fear of unknown adverse effects or being assigned to the control arm in CTs, as noted in our findings. Additionally, prevalent folk beliefs among the Hispanic/Latin American community can alter understanding of healthcare practices,<sup>91,92</sup> or of certain diseases—Alzheimer's disease is viewed as part of aging rather than a serious health condition.<sup>93</sup> Therefore, clinical trials with critical outcomes for older adults can be negatively impacted by such misconception. Future interventions may focus on understanding cultural misconceptions affecting clinical trial participation and overcoming them.

Other factors identified as hindering the participation of HLAOA in CT were related to socioeconomic status, particularly education and income, which have been reported in previous publications.<sup>94,95</sup> The lack of or limited education in the Hispanic/Latin American population can affect CT participation in two ways. First, the inability to understand specific diseases can encourage cultural misconceptions or beliefs.<sup>96</sup> Second, they may have difficulties processing information given by researchers about the disease and/or the implications of participating in a clinical trial.<sup>97</sup> Patients' income is also an important aspect hindering participation in CT, regardless of ethnic background. Studies have shown that financial concerns among patients with low income are often related travel challenges, no time off from work, and insurance coverage.<sup>98</sup> These observations are in line with our findings, as many of the US Hispanic/Latin American population have low income<sup>99</sup> and low educational levels<sup>100</sup> when compared with other ethnic groups. In this context, it can be said that researchers should



consider these socioeconomic factors when designing CTs for HLAOA participants.

Nápoles and Chadiha arrived at the conclusion that there was a lack of evidence on the successful recruitment of ethnic minorities in clinical research.<sup>101</sup> In this scoping review, we further extended their findings that drawing a comprehensive understanding of HLAOA recruitment methods is vastly limited by the existing medical literature. We concur with previous work that unique sociocultural factors pertaining to the Hispanic population coupled with particular needs for older adults call for custom-made study designs.<sup>49</sup> As other researchers have concluded, there is not one single recommended approach for successfully recruiting older participants, particularly when attempting to recruit minoritized groups.<sup>75,102–104</sup>

## LIMITATIONS

There are a few limitations of this scoping review worth discussing. First, the articles included in this scoping review did not specifically focus on clinical recruitment. However, we have included these articles as (a) they provide valuable information about our focused population, (b) they recruited HLAOA as one of many minority groups relevant to their study aims, and (c) the data of HLAOA that were included in their analysis was collected as part of the ethnic composition of the general US population recruited for their studies. Another limitation of our scoping review is that we only searched articles in PubMed and Embase; thus, other studies could be published in different databases that might not have been considered in this review. However, these databases are the primary stem of research studies from biomedicine, health fields, and related disciplines. A third limitation is that our study did not aim to assess the effectiveness of the factors identified as improvers or hinderers, but it is suggested that future research focuses on such evaluations.

## CONCLUSIONS

The HLAOA population is growing rapidly and is projected to grow to 19.9 million by 2060, with the number of persons 85 years and older becoming as high as 3.4 million Americans. It is imperative that all researchers focused on adults and older adults make sincere attempts to recruit HLAOA in their clinical trials. In this scoping review, we have summarized factors that facilitate and impede the participation of HLAOA in clinical trials. Researchers might use this information

to mitigate unconscious biases and improve the participation of HLAOA in clinical trials, leading to more equitable research that does not exclude communities of color.

## AUTHOR CONTRIBUTIONS

*Conception and idea:* Vyjeyanthi S. Periyakoil. *Search strategy:* Dulce K. Rodriguez and Vyjeyanthi S. Periyakoil. *Study selection and data extraction:* Dulce K. Rodriguez, Vyjeyanthi S. Periyakoil, and Sumali A. Hewage. *Data analysis and interpretation:* Dulce K. Rodriguez and Sumali A. Hewage. *First draft of the manuscript and critical revision:* Dulce K. Rodriguez, Sumali A. Hewage, and Vyjeyanthi S. Periyakoil. *Approval of the submitted manuscript:* All authors.

## CONFLICT OF INTEREST

The authors declare no conflicts of interest.

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None.

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## SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

**Text S1.** Search Algorithms for PubMed and EMBASE.

**Figure S1.** All concepts Search.

**Figure S2.** Results published in English language.

**Table S1.** Descriptive details of the included studies.

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