• Investigation •

Factors influencing willingness to participate in ophthalmic clinical trials and strategies for effective recruitment

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Abstract

• **AIM:** To explore the factors influencing individuals' willingness to participate in ophthalmic clinical trials.

• **METHODS:** A questionnaire survey was conducted from January to April 2021 among patients and their family members at Zhongshan Ophthalmic Center, Sun Yat-sen University, in Guangzhou, China. The survey gathered data on respondents' willingness, demographic and socioeconomic profiles, as well as their reasons and concerns regarding engagement in clinical trials.

• **RESULTS:** Of the 1078 residents surveyed (mean age 31.2±13.1y; 65.8% females) in Guangzhou, 749 (69.5%) expressed a willingness to participate in future ophthalmic clinical trials. Specific characteristics associated with greater willingness included a younger age, lower annual income, higher education, prior participation experience, previous ophthalmic treatment, and a better understanding of clinical trials. With the exception of age, these characteristics were significantly linked to a higher willingness. The primary barrier to participation, expressed by 64.8% of those willing and 54.4% of those unwilling, was "Uncertain efficacy". In terms of motivations, the willing group ranked "Better therapeutic benefits" (35.0%), "Professional monitoring" (34.3%), and "Trust in healthcare professionals" (33.1%) as their top three reasons, whereas the unwilling participants indicated "Full comprehension of the protocol" (46.2%) as the key facilitator.

• **CONCLUSION:** This study reveals a substantial willingness to participate in ophthalmic clinical trials and demonstrates the predictive role of demographic and socioeconomic factors. Variations in motivators and concerns between willing and unwilling participants highlight the significance of tailored recruitment strategies. Importantly, the need for and trust in healthcare professionals stand out as powerful motivations, underscoring the importance of enhancing physician-patient relationships, adopting patient-centered communication approaches, and addressing individualized needs to improve accrual rates.

• **KEYWORDS:** participation willingness; recruitment strategy; ophthalmic clinical trial

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INTRODUCTION

Clinical trials in China have faced significant challenges[1-4], with only 29.2% of the 500 trials registered on ClinicalTrials.gov over the past decade reaching completion. Effective participant recruitment is a pivotal stage in the planning and conduct of clinical trials, and poor recruitment is a common bottleneck in this process[5-7]. Ophthalmic clinical trials, in particular, have raised concerns due to low willingness among potential participants. In a study involving 54 patients with retinitis pigmentosa, merely 21% expressed a

willingness to participate in a trial related to retinal implant[8]. Similarly, among 462 patients with keratoconus, only 37.2% expressed motivation to take part[9], while just 50% of the 40 cataract patients were open to engaging in a trial related to cataract surgery[10]. This lack of willingness not only obstructs recruitment efforts but also disrupts the progress of trials, potentially leading to invalid results. Furthermore, the existing research has been constrained to specific population subgroups, making it inadequate for reflecting the current public perspectives. In response to this challenge, our study employed a questionnaire survey to investigate the willingness of individuals to participate in ophthalmic clinical trials. We aimed to identify socio-economic characteristics as predictors of participation and compare perspectives on clinical trials between those who are willing and those who are not. This research provides valuable insights to aid in the development of patient-centered recruitment strategies.

SUBJECTS AND METHODS

Ethical Approval This study received approval from the Ethics Committee of Zhongshan Ophthalmic Center, Sun Yat-sen University, Guangzhou, China (Approval number: 2019KYPJ131). Written informed consent was obtained from each participant prior to their enrollment in the study to ensure voluntary participation and protection of their rights.

Questionnaire Design The questionnaire was developed by incorporating insights from existing literature[11-13] and consulting experts in the field. To ensure its validity and clarity, a beta version of the questionnaire was pilot-tested with 50 volunteers, and their feedback was used to refine the questionnaire. The final version consisted of single-choice, multiple-choice, and free-text items, covering the following key aspects: 1) demographic information (*e.g.*, gender, age, disease status, medical history, knowledge and experience of clinical trials); 2) sociodemographic variables (*e.g.*, educational level and annual income); 3) barriers and facilitators influencing participation in ophthalmic clinical trials.

Data Collection Participants included Guangzhou residents aged 18y or older who were capable of independently completing the questionnaire or effectively communicating with the interviewer. Trained research nurses or clinical research coordinators from Zhongshan Ophthalmic Center, Sun Yat-sen University, Guangzhou, China were responsible for distributing the questionnaires and ensuring the data collection process. Data collection was conducted from January 2021 to April 2021.

Statistical Analysis The independent *t*-test was utilized to compare continuous variables between two groups: those willing and unwilling to participate in clinical trials. The Chi-square test was used for other comparisons. Univariate and multivariate logistic regression analyses were conducted to identify the factors associated with willingness to participate. All statistical tests were performed at a 95% confidence level, and statistical significance was defined as a *P*-value of less than 0.05 (two-sided).

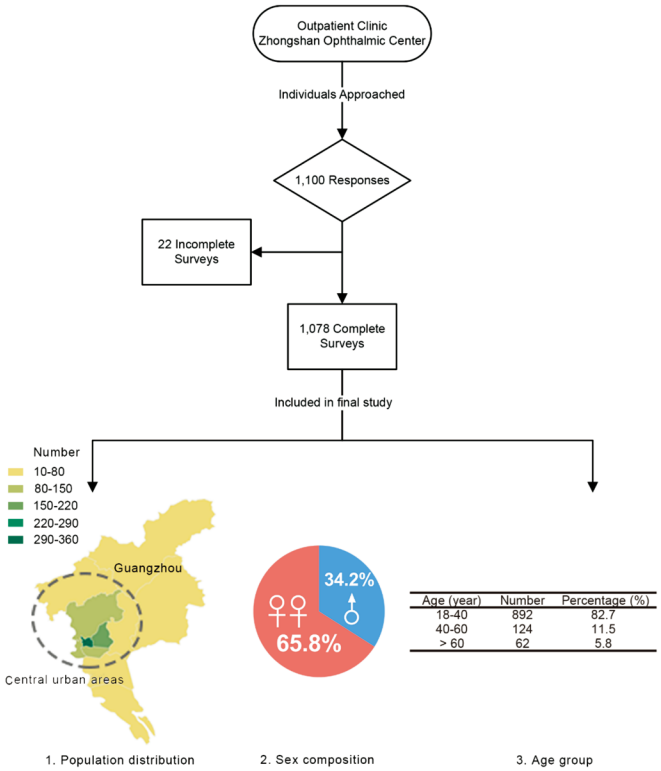

Figure 1 Flow chart of the study population.

RESULTS

Demographic and Socioeconomic Characteristics Associated with Willingness to Participate From January to April 2021, a survey was conducted among 1100 residents of Guangzhou, aged 18 to 85. After excluding incomplete questionnaires, a total of 1078 valid responses were analyzed (Figure 1). The survey participants primarily consisted of ophthalmic outpatients and their family members, with a substantial majority residing in central urban areas (92.7%) and holding a university education or higher (84.9%). The respondents had an average age of 31.2y, and 65.8% of them were female. Out of all respondents, 749 (69.5%) expressed their willingness to participate in ophthalmic clinical trials, while 329 (30.5%) declined.

The demographic and clinical characteristics of the respondents, stratified by their willingness to participate in ophthalmic clinical trials, are presented in Table 1. Significant differences were observed between the two groups in terms of age, annual income, education, prior participation in trials, ophthalmic clinical treatments, and clinical trial comprehension. Specifically, the willing group tended to be slightly younger (average age: 31.4±12.7y) compared to the unwilling group (average age: 33.2±14.0y). Respondents with financial constraints exhibited a higher tendency to volunteer

Table 1 General characteristics of participants *n* (%)

Characteristics	Total (*n*=1078)	Willing (*n*=749)	Unwilling (*n*=329)	*P*
Age (y), mean±SD	31.2±13.1	31.4±12.7	33.2±14.0	0.036
Age groups (y)				
18-40	892 (82.7)	628 (83.9)	264 (80.2)	
41-60	124 (11.5)	81 (10.8)	43 (13.1)	
>60	62 (5.8)	40 (5.3)	22 (6.7)	
Sex				0.740
Male	369 (34.2)	254 (33.9)	115 (35.0)	
Female	709 (65.8)	495 (66.1)	214 (65.0)	
Urban region	999 (92.7)	699 (93.3)	300 (91.2)	0.215
Self-rating of eye health	4.58±2.42	4.67±2.40	4.35±2.48	0.201
Annual income[a] (US dollar)				<0.010
Less than 14053	686 (63.6)	495 (66.1)	191 (58.1)	
14053-28106	276 (25.6)	188 (25.1)	88 (26.7)	
More than 28106	116 (10.8)	66 (8.8)	50 (15.2)	
Education				<0.001
High school or less	163 (15.1)	94 (12.6)	69 (21.0)	
University or higher	915 (84.9)	655 (87.4)	260 (79.0)	
Prior participation in clinical trials				<0.010
Yes	374 (34.7)	323 (43.1)	51 (15.5)	
No	704 (65.3)	426 (56.9)	278 (84.5)	
Previous ophthalmic treatment				<0.050
Yes	580 (53.8)	423 (56.5)	157 (47.7)	
No	498 (46.2)	326 (43.5)	172 (52.3)	
Knowledge of clinical trials				<0.010
A little or less	367 (34.0)	200 (26.7)	167 (50.8)	
Some	625 (58.0)	469 (62.6)	156 (47.4)	
Comprehensive	86 (8.0)	80 (10.7)	6 (1.8)	

SD: Standard deviation. [a]The exchange rate is 1.00 China's yuan to 0.14 US dollar.

for clinical trials, as 66.1% of willing group respondents had an annual income of less than 14 053 US dollars, compared to 58.1% in the unwilling group. A significant difference in education level was noted, with 87.4% of the willing group having completed a university education or higher, in contrast to 79.0% in the unwilling group. Furthermore, 43.1% of the willing group had prior experience with clinical trials, which was significantly higher than the 15.5% reported by the unwilling group. Additionally, a larger proportion of the willing group (56.5%) had previously received eye-related medical care compared to the unwilling group (47.7%). Concerning clinical trial comprehension, the majority of willing participants (73.3%) possessed a fundamental or in-depth understanding of clinical trials, including 10.7% exhibiting comprehensive knowledge. In contrast, among the unwilling participants, over half (50.8%) had limited knowledge of clinical trials.

Except for age, all variables displayed significant associations with the willingness to participate in the study (Table 2). Individuals with an annual income of 14 053 US dollars or less exhibited a stronger inclination to participate, with an odds ratio (OR) of 1.76 [95% confidence interval (CI): 1.15, 2.77, *P*=0.010]. Likewise, individuals with a university education or higher expressed a more pronounced desire to enroll in the study, yielding an OR of 2.89 (95%CI: 1.56, 5.37, *P*<0.010). Those with prior experience in clinical trials demonstrated a significantly greater tendency to participate again, with an OR of 3.01 (95%CI: 2.09, 4.32, *P*<0.001). In addition, individuals who had sought ophthalmic consultation were more inclined to participate, with an OR of 1.37 (95%CI: 1.03, 1.83, *P*=0.030). Significantly, a better understanding of clinical trials was associated with a higher willingness to participate. Specifically, those with some understanding had an odds ratio of 1.68 (95%CI: 1.24, 2.26, *P*<0.001), while those with a comprehensive understanding had a substantially higher odds ratio of 7.77 (95%CI: 3.24, 18.60, *P*<0.001).

Motivations and Barriers to Trial Participation Among individuals willing to participate, the top three motivations

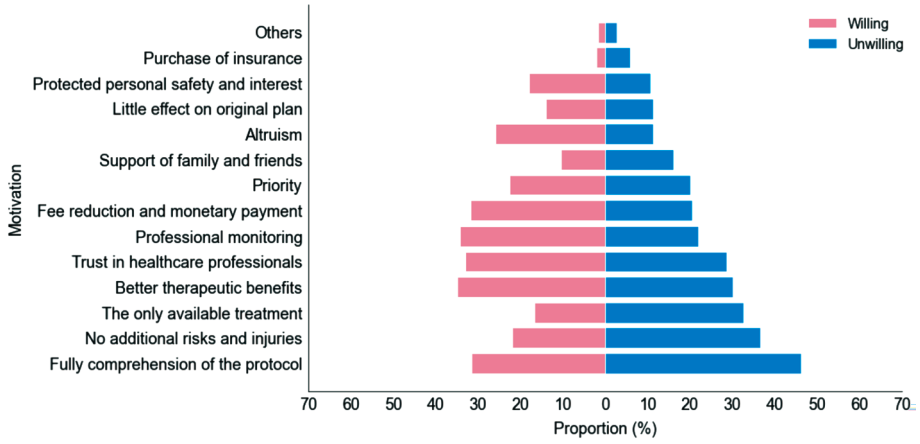

Figure 2 Motivations to participation in ophthalmic clinical trials.

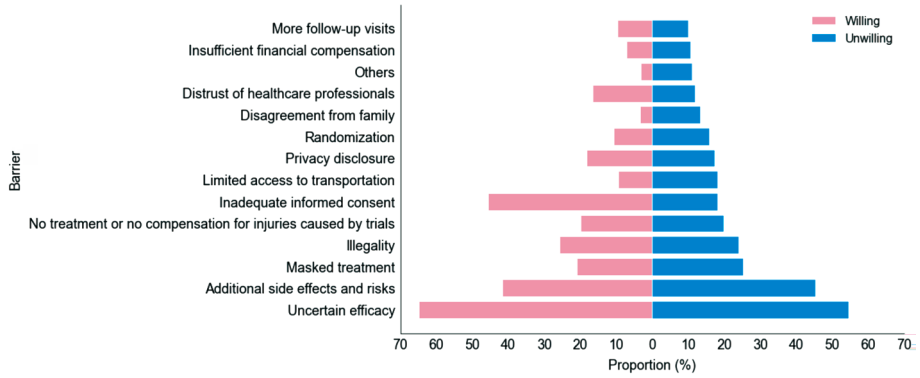

Figure 3 Barriers to participation in ophthalmic clinical trials.

were "Better therapeutic benefits" (35.0%), "Professional monitoring" (34.3%), and "Trust in healthcare professionals" (33.1%), as illustrated in Figure 2. In contrast, respondents who declined participation cited "Full comprehension of the protocol" (46.2%), "No additional risks and injuries" (36.5%), and "The only available treatment" (32.5%) as their primary reasons. Figure 3 reveals two distinct response patterns regarding concerns about clinical trial participation. Among those willing to participate, the top three concerns were "Uncertain efficacy" (64.8%), "Inadequate informed consent" (45.7%), and "Additional side effects and risks" (41.7%). Conversely, those who declined participation cited "Uncertain efficacy" (54.4%) as the primary obstacle, followed by "Additional side effects and risks" (45.3%) and "Masked treatment" (25.2%).

DISCUSSION

Open and Positive Attitudes Towards Participation in Ophthalmic Clinical Trials Previous investigations have often focused on specific population groups or particular clinical trials, reporting a willingness to participate in ophthalmic clinical trials within a range of 21% to 50%[8-10]. With advancements in science and technology, ophthalmic clinical research encompasses a broad range of ocular conditions, including common issues like refractive errors, cataracts, and glaucoma, as well as rare and severe conditions

Table 2 Multivariable logistic regression of factors associated with willingness to participate in clinical trials (*n*=1078)[a]

Variable	OR	95%CI	*P*
Age, y	1.00	0.99, 1.01	0.912
Annual income[b], US dollar			
Less than 14053	1.76	1.15, 2.77	0.010
14053-28106	1.48	0.93, 2.38	0.100
More than 28106	Ref		
Education			
High school or lower	Ref		
University or higher	2.89	1.56, 5.37	<0.010
Prior participation in clinical trials			
No	Ref		
Yes	3.01	2.09, 4.32	<0.001
Previous ophthalmic treatment			
No	Ref		
Yes	1.37	1.03, 1.83	0.030
Knowledge about clinical trials			
A little or less	Ref		
Some	1.68	1.24, 2.26	<0.001
Comprehensive	7.77	3.24, 18.60	<0.001

OR: Odds ratio; CI: Confidence interval. [a]All variables with *P*<0.05 in the Table 1 were included in the multivariable regression model; [b]The exchange rate is 1.00 China's yuan to 0.14 US dollar.

such as retinal dystrophies and ocular tumors. Moreover, ophthalmic studies encompass various study designs, from observational studies without intervention to randomized controlled trials, and they require a spectrum of follow-up frequencies. This diversity sets ophthalmic clinical research apart from many other clinical studies. As a result, ophthalmic clinical research is not confined to a specific or limited population; it now provides opportunities for the general population, regardless of whether they have pre-existing eye conditions, to potentially participate in multiple trials. Therefore, it has become essential to explore the broader public's perception of ophthalmic clinical trials. To the best of our knowledge, this survey is the first to reveal a high level of public acceptance, with 69.5% of respondents expressing their willingness to engage in ophthalmic clinical trials. This finding challenges preconceived notions that clinical trial participation is primarily inclined toward major illnesses and cancer[14-15]. This inclusivity of ophthalmic clinical research is an important concept that should be communicated to the public and healthcare professionals. Given the high overall public acceptance demonstrated in this study, healthcare professionals can optimize patient recruitment by referring individuals who decline participation in a particular ophthalmic clinical trial to other particular trials. Given the high overall public acceptance demonstrated in this study, healthcare professionals can optimize patient recruitment by referring individuals who decline participation in a specific ophthalmic clinical trial to other relevant trials.

Demographic and Socioeconomic Factors as Predictors of Recruitment Demographic and socioeconomic characteristics have emerged as influential predictors of willingness to participate in ophthalmic clinical trials[16-17]. Our study identified attributes associated with an increased willingness to participate, including a comprehensive understanding of clinical trials, prior exposure to ophthalmic healthcare, previous engagement in clinical trials, higher educational attainment, and lower socioeconomic status. In practical terms, the adoption of recruitment strategies that capitalize on these demographic and socioeconomic characteristics enables the creation of tailored willingness profiles for prospective participants. Prioritizing individuals with high-participation-willingness traits streamlines recruitment, reduces costs, saves time, and minimizes logistical challenges. This approach proves particularly valuable in time-sensitive and high-pressure recruitment scenarios.

Discrepancies in the influence of annual income on willingness exist between domestic and foreign studies. Our investigation revealed a higher propensity for participation among individuals with lower annual income, aligning with a domestic study[18-19]. This observation contrasts with surveys from Western countries, where individuals with higher incomes exhibit greater willingness[9,12,20]. Diverse national contexts and socio-cultural backgrounds likely underlie this disparity. A comparative study disclosed that Chinese patients, particularly those residing in rural areas, prioritize personal benefits more prominently than American patients[12]. The availability of cost-free medical care and financial incentives exerts a more significant influence on their decision to participate. In China, patients with financial constraints often confront restricted access to medical services due to economic disparities and inadequate health insurance coverage. Participation in clinical trials offers them not only free medical treatment but also additional reimbursement, rendering it an irresistibly attractive option[18-19]. In contrast, low-income individuals in Western countries often encounter marginal financial costs, such as co-payments and co-insurance when participating in clinical trials, owing to the terms outlined in their health plans. This financial burden can diminish their motivation to participate. At present, numerous international sponsors and organizations possess limited knowledge of the cultural context, behavioral patterns, and physiological traits of Chinese clinical trial volunteers. This knowledge gap has, to some extent, affected the effectiveness of trial recruitment and execution. Therefore, addressing cultural sensitivity is an issue that warrants attention in the implementation of clinical trials.

Tailoring Recruitment Strategies for Personalized Perspectives Standardized recruitment approaches come with inherent limitations when addressing individual unique needs. Given the increasing prevalence of patient-centered clinical trials, it is imperative to explore novel recruitment strategies that focus on delivering personalized information. In our study, willing participants emphasized three key motivations: "Better therapeutic benefits", "Professional monitoring", and "Trust in healthcare professionals". In contrast, reluctant participants predominantly prioritized "Full comprehension of the protocol" as a major driver, suggesting a more cautious attitude toward clinical trials. Uncertainty about treatment efficacy emerged as a common obstacle for all respondents. The varying perspectives among groups with different willingness levels underscore the necessity of tailoring information during the recruitment process. For individuals with high willingness, it is essential to emphasize crucial aspects such as potential benefits, treatment details, follow-up procedures, and relevant particulars. A comprehensive understanding of healthcare activities plays a pivotal role in enhancing willingness[20-21], a concept supported by our study. To persuade reluctant individuals to participate, effective communication of necessary information is crucial. This includes discussing the scientific design of the clinical trial, subject safety oversight, and protective measures. By adopting a more individualized

and targeted approach, recruitment strategies can be refined to cater to the unique perspectives and needs of potential participants. This not only improves recruitment efficiency but also enhances the overall experience for trial participants.

In addition to the information itself, the method of delivery plays a crucial role in shaping effective recruitment strategies. Both disseminating educational materials such as booklets, videos, or audiovisual patient information tools, and employing simplified consent statements, have yielded mixed results in terms of their impact on recruitment outcomes[22-23]. In contrast, health education programs have proven effective in reducing anxiety[24], and oral education[25] has emerged as a potential method for enhancing recruitment efficiency. The variability in results suggests that education conducted by healthcare professionals offers a more positive approach, capable of providing accurate, comprehensive, and easily understandable information. Encouraging flexible communication between potential participants and trial staff can offset the relative rigidity of formal information resources[7,26]. Moreover, consistent with prior research reporting physicians and nurses as trusted sources of information[9,19,26], our study emphasizes the influence of patients' trust in healthcare professionals as a key motivator in decision-making process. Therefore, when engaging with potential subjects, healthcare professionals should take a leadership role in communication, exhibit professionalism, and actively engage in recruitment activities. The current lack of compelling evidence regarding the effectiveness of healthcare professionals' education may result from methodological limitations and inadequate standardized training. Future research should focus on striking the right balance between accommodating commonalities and respecting variations in the communication process. This will help refine recruitment strategies and ultimately improve clinical trial participation rates.

Limitations and Future Directions This study presents two primary limitations. First, the study sample was drawn exclusively from individuals in Guangzhou, which may limit the applicability of the findings to cities in South China that share similarities with Guangzhou. The generalizability of these findings to other regions across China remains uncertain, given the significant geographical diversity within the country. To enhance the external validity of the results, future studies should encompass participants from diverse regions throughout China. Second, this study employed a hypothetical approach to assess individuals' willingness to participate in ophthalmic clinical trials. Hypothetical scenarios can elicit different responses compared to real-life situations, potentially leading individuals to be less concerned or inclined to respond as they would in actual clinical trial scenarios. To gain deeper insights into the psychological aspects of potential participants, conducting a follow-up study involving individuals who have either participated in or declined participation in real clinical trials is valuable. Combining questionnaires with qualitative research methods can provide a more comprehensive understanding of individuals' experiences and the psychological changes associated with clinical trial participation or refusal. This mixed-methods approach will offer a deeper insight into the multifaceted factors that influence individuals' decision-making processes.

In conclusion, this study provides a comprehensive perspective on recruitment strategies, serving as a cornerstone for patient-centric approaches that address the diverse needs and preferences of potential participants, ultimately enhancing recruitment inclusivity and effectiveness to advance clinical trials in ophthalmology in advancing ophthalmology clinical trials.

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