

Factors contributing to community participation in malaria clinical drug trials among adults in Kicukiro district, Kigali City, Rwanda

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Abstract

Malaria continues to pose a major public health challenge in Rwanda, with over 4.2 million cases reported in 2023 despite ongoing prevention and control efforts. Urban districts such as Kicukiro are increasingly affected due to rapid urbanization, population movement, environmental changes, and poor drainage systems. As malaria burden and emerging drug resistance increase, clinical drug trials remain important for developing effective treatments, although their success depends on community participation. This study assessed factors influencing community participation in malaria clinical drug trials among adults in Kicukiro District, Kigali City, Rwanda, using a mixed-methods analytical cross-sectional design. Quantitative data were collected through multistage sampling and analyzed using descriptive and regression analyses, while qualitative data from in-depth interviews were analyzed thematically, with findings integrated through. The findings showed that awareness of clinical trials, perceived risk, previous participation in research, family support, and trust in healthcare providers significantly influenced participation in malaria clinical drug trials. In multivariable analysis, respondents aged 26–35 years were more likely to participate compared to those aged 18–25 years (AOR = 1.72; 95% CI: 1.01–2.93; $p = 0.046$). Respondents with higher education were also more likely to participate (AOR = 2.11; 95% CI: 1.24–3.58; $p = 0.006$). Awareness of clinical trials significantly increased the likelihood of participation (AOR = 2.63; 95% CI: 1.55–4.45; $p < 0.001$), while respondents with low perceived risk were more likely to participate (AOR = 2.07; 95% CI: 1.24–3.45; $p = 0.005$). Previous participation in research (AOR = 3.08; 95% CI: 1.70–5.60; $p < 0.001$), family support (AOR = 2.36; 95% CI: 1.37–4.05; $p = 0.002$), and trust in healthcare providers (AOR = 2.61; 95% CI: 1.52–4.47; $p < 0.001$) were also significant predictors of participation. Qualitative findings supported the quantitative results by revealing that fear of side effects, misinformation, limited understanding of clinical trials, and mistrust in research processes discouraged participation. Participants emphasized that clear communication, continuous community sensitization, involvement of trusted local leaders, and strong relationships with healthcare providers could improve participation in malaria clinical drug trials. The study concluded that participation in malaria clinical drug trials is influenced by a combination of socio-demographic, individual-level, and interpersonal factors. Strengthening community awareness, improving trust in healthcare providers, promoting family and community support, and addressing misconceptions through effective communication and community engagement strategies are essential to improve participation in malaria clinical drug trials in Rwanda.

Keywords: Community participation, Malaria clinical trial, Participation determinants, Kicukiro district, Rwanda

1. Introduction

Malaria is one of the most persistent infectious diseases globally, with significant implications for health and development. Even with progress in prevention and treatment, malaria is still a major cause of morbidity and mortality, especially in tropical and subtropical regions (WHO, 2024). In Africa, malaria continues to pose a major public health challenge, straining health systems, slowing down economic growth, and hurting the health of the most vulnerable groups, like children and pregnant women (WHO, 2024). Rwanda has achieved remarkable progress in malaria control over the past two decades. By increasing the use of interventions like insecticide-treated nets, indoor spraying, community health workers, and improved case management, the country saw a big drop in malaria cases and deaths between 2005 and 2015 (RBC, 2024). However, recent reports indicate a resurgence in malaria transmission. In 2023 alone, Rwanda reported more than 4.2 million malaria cases, representing a 12% increase compared to the previous year (WHO, 2024; Malaria World, 2025). This resurgence signals emerging challenges and the need for continuous innovation to sustain progress.

Clinical drug trials play a pivotal role in the global fight against malaria, especially in the development of new drugs to combat resistance to existing antimalarial medicines (Malaria Journal, 2025). Clinical trials provide critical data on the efficacy, safety, and tolerability of new therapies, ensuring that populations at risk have access to effective treatments. For malaria clinical drug trials to succeed, active community participation is essential. The ethical principle of community engagement ensures that participants are fully informed, voluntarily consent, and contribute to research outcomes that will ultimately benefit them (Späth et al., 2024). Moreover, participation helps strengthen the representativeness of findings, facilitates recruitment, and fosters trust between researchers and communities. Without adequate participation, clinical trials risk delays, incomplete data, and limited applicability of findings (RBC, 2024). However, participation in clinical trials is not automatic; it is shaped by multiple determinants, including socio-demographic factors such as age, gender, and education, as well as cultural beliefs, perceptions of risk, and trust in the healthcare system (Späth et al., 2024). In sub-Saharan Africa, studies have shown that misconceptions about clinical research, fear of side effects, and mistrust in researchers often discourage participation (RBM Partnership to End Malaria, 2024). Conversely, health education campaigns, previous positive experiences with healthcare programs, and perceived community benefits can enhance participation (Malaria Journal, 2025). Despite the growing importance of clinical trials in malaria control, evidence from Rwanda remains limited regarding what drives or hinders community participation in such studies. Most existing studies have focused on malaria prevention and treatment uptake, with little emphasis on perceptions and engagement in clinical research (RBC, 2024). Given the resurgence of malaria in Rwanda and the urgent need for new drug therapies, it is critical to understand the determinants of participation in malaria clinical drug trials. Such insights are necessary to strengthen community engagement strategies, build trust, and ensure successful implementation of malaria research in Kicukiro District and beyond

2.0 Material and Methods

2.1.0 Material

2.1.1 Individual-level factors influencing participation in malaria clinical drug trials

Empirical evidence shows that individual-level factors play a central role in determining participation in clinical trials. These factors include knowledge of the disease, awareness of clinical trials, perceived risk,

and previous participation in research. Studies consistently show that individuals who understand the purpose and procedures of clinical trials are more likely to participate compared to those with limited knowledge. Rodríguez-Torres et al. (2021) found that awareness of clinical trials, perceived benefits, and prior experience are key facilitators of participation, while fear of side effects, uncertainty, and lack of understanding act as major barriers. Similarly, Bodicoat et al. (2021) reported that limited knowledge and poor communication about clinical research significantly reduce participation, particularly among populations with limited exposure to research activities. Recent evidence from sub-Saharan Africa also highlights the importance of research literacy. Späth and Schmidt (2024) observed that inadequate explanation of study procedures and weak communication between researchers and communities contribute to misunderstandings and low participation. Their findings emphasize that individuals need not only awareness but also clear and meaningful understanding of clinical trials to make informed decisions. These findings are relevant to the present study, as they indicate that awareness of clinical trials, perceived safety, and prior exposure to research are critical factors that shape individual willingness to participate.

2.1.2 Interpersonal factors influencing participation in malaria clinical drug trials

Interpersonal relationships have been widely identified as important determinants of participation in clinical research. Family support, peer influence, and trust in healthcare providers play a key role in shaping how individuals perceive clinical trials and make decisions about participation. Bodicoat et al. (2021) found that social support and interpersonal communication significantly influence participation, particularly when information is provided through trusted individuals. In many settings, individuals rely on family members and peers when making health-related decisions, and their opinions can either encourage or discourage participation. In African contexts, Kaehler et al. (2022) emphasized the importance of community engagement and trust-building in malaria research. Their findings showed that individuals are more likely to participate when they trust healthcare providers and when research activities are communicated through familiar and respected community structures. Similarly, Späth and Schmidt (2024) highlighted that weak community engagement and lack of trust can reduce participation in clinical trials. Their study showed that trust is built through consistent communication, transparency, and respectful interaction with participants. For the current study, these findings suggest that interpersonal factors act as a bridge between knowledge and behaviour. Even when individuals are aware of clinical trials, their decisions are influenced by family dynamics, peer interactions, and their level of trust in healthcare providers.

2.1.3 Factors associated with participation in malaria clinical drug trials

Participation in clinical trials is influenced by a combination of individual, interpersonal, and contextual factors. Empirical studies show that these factors interact in complex ways rather than acting independently. Rodríguez-Torres et al. (2021) reported that participation is shaped by a combination of knowledge, perceived risk, trust, social support, and practical considerations such as accessibility. Similarly, Bodicoat et al. (2021) identified barriers including lack of awareness, mistrust, logistical challenges, and negative attitudes toward research. The World Health Organization (2024) emphasizes that clinical trials should be designed in a way that is participant-centered, transparent, and responsive to community needs. This includes addressing both individual concerns and broader social and structural barriers that may affect participation. Awash et al. (2024) further demonstrated that community engagement strategies, such as health education, involvement of local leaders, and use of community-based health workers, can significantly improve participation in malaria-related research. Their findings highlight the importance of integrating social and contextual factors into research design.

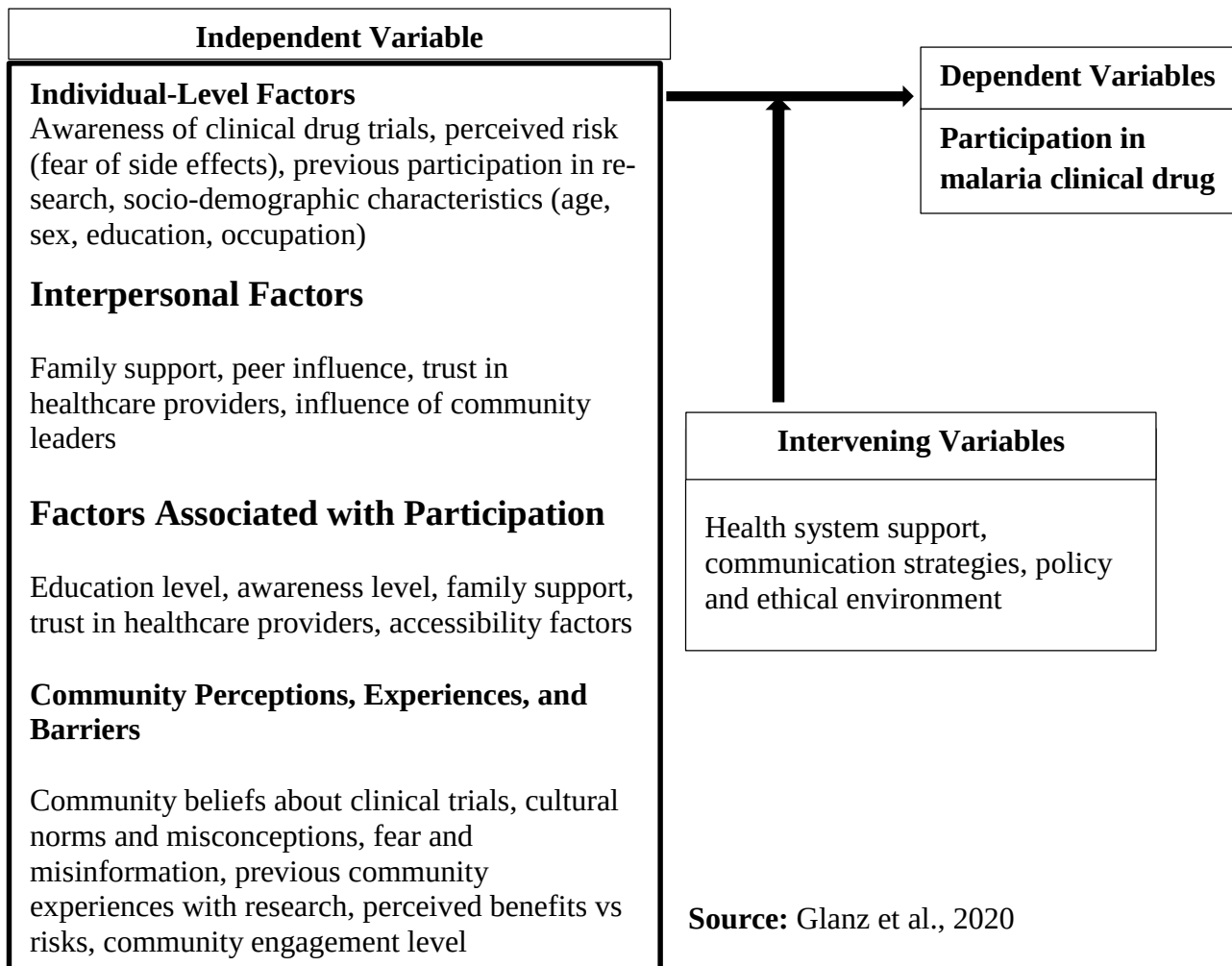
These studies support the approach used in the present research, which examines multiple factors simultaneously to identify those most strongly associated with participation. This approach allows for a more comprehensive understanding of participation in malaria clinical drug trials.

2.1.4 Community perceptions, experiences, and barriers influencing participation in malaria clinical drug trials

Community perceptions and experiences are critical in shaping participation in clinical trials. Empirical evidence shows that beliefs, attitudes, and past experiences influence how individuals respond to research opportunities. Späth and Schmidt (2024) found that communities may develop negative perceptions when they feel excluded from research processes or when communication is unclear. Their study highlighted that misconceptions, lack of trust, and limited engagement contribute to low participation.

Similarly, Bodicoat et al. (2021) identified mistrust, misinformation, and practical barriers such as time constraints and transportation challenges as key obstacles to participation. These barriers are particularly relevant in resource-constrained settings, where individuals must balance participation with daily responsibilities. Awasthi et al. (2024) showed that effective community engagement can improve participation by addressing misconceptions and building trust. Their findings emphasized the importance of involving local leaders, providing continuous education, and ensuring that communities are actively engaged in research processes. The World Health Organization (2024) also highlights the importance of participant and community engagement in improving the acceptability and feasibility of clinical trials

2.1.5 Conceptual framework



3.0 Methods

3.1 Study Design

The quantitative component adopted an analytical cross-sectional study design. This design involved collecting data from adult community members at one point in time to assess the relationship between independent variables and participation in malaria clinical drug trials. An analytical cross-sectional design was considered suitable because it allowed the researcher to determine the prevalence of factors influencing participation and examine associations between variables without requiring long-term follow-up. It is commonly used in public health research when studying determinants of health-related behaviors and participation (Setia, 2016). The qualitative study involved in-depth interviews with purposively selected participants, including healthcare providers, community leaders, and adult community members. These participants were selected because they had direct experience or relevant knowledge regarding malaria and clinical research within the community. The exploratory design helped to explore issues such as fear of side effects, trust in researchers, misconceptions about clinical trials, and the influence of family and community on participation decisions. According to Creswell and Poth (2018), phenomenology is useful when the goal is to understand how people experience and interpret a particular phenomenon. The integration of the analytical cross-sectional design and phenomenological design strengthened the study by ensuring that both measurable outcomes and personal experiences were adequately captured.

3.2 Study Area

This study was conducted in Kicukiro District, one of the three districts that make up Kigali City, the capital of Rwanda. Kicukiro is located in the southern part of Kigali and is characterized by a mix of residential, commercial, and institutional areas. The district is administratively divided into several sectors, cells, and villages, and is served by a network of public and private health facilities that provide a range of healthcare services, including malaria diagnosis and treatment. According to the Fifth Rwanda Population and Housing Census, Kicukiro District had an estimated population of approximately 491,731 residents as of 2022 (NISR, 2022). This relatively large and diverse population reflects a typical urban setting with varying socio-economic conditions, levels of education, and access to health information. Kicukiro District was selected as the study area because it represents an urban context where patterns of health behaviour and exposure to clinical research may differ from rural settings. Urban populations are often characterized by higher population density, increased mobility, and greater interaction with healthcare systems, which may influence awareness of and participation in clinical trials. Although malaria transmission in Kigali City is generally lower than in rural endemic areas, the disease remains a public health concern, particularly in peri-urban and densely populated zones. Ongoing malaria prevention and control programs, as well as access to healthcare services, make the district a relevant setting for studying participation in malaria clinical drug trials.

3.3 Target Population

The target population for this study consisted of adult community members residing in Kicukiro District, Kigali City, Rwanda, as well as selected key informants involved health care providers from Gatenga medicalized health center and community leaders.

3.4 Sampling techniques and sample size

3.4.1 Sample Size Determination

The sample size was determined using Cochran's formula for estimating a single population proportion. This formula is widely used in public health research to calculate sample sizes where the population is large (Cochran, 1977).

$$n_0 = \frac{Z^2 \times p(1 - p)}{d^2}$$

Where:

$$n^0 = \frac{Z^2 pq}{e^2} = \frac{(1.96)^2 \times 0.5 \times (1 - 0.5)}{(0.05)^2} = 384$$

$Z=1.96$ $Z = 1.96$ corresponds to a 95% confidence level.

$p=0.5$ $p = 0.5$ represents the estimated proportion of adults aware of malaria clinical trials.

$e=0.05$ $e = 0.05$ is the margin of error.

Adjusting for 10% non-response, the final sample size will be approximately 423 adults

3.4.2 Sampling Techniques

For the quantitative component, a multistage sampling technique was used. Cells and villages were systematically selected across all sectors of Kicukiro District to ensure adequate representation of the study population. Selected households were then approached systematically, and one eligible adult was selected from each household. Where multiple eligible adults were available, one participant was randomly selected. This approach enhanced representativeness and minimized selection bias (Creswell & Creswell, 2017). For the qualitative component, purposive sampling was used to select participants who could provide rich and relevant information. These included community members, healthcare providers, and local leaders who had experience or knowledge related to malaria and clinical trials. Convenience sampling ensured that important stakeholder groups relevant to the study's goals were represented while recruiting participants based on their availability and desire to participate. (Creswell & Poth, 2018).

3.5 Research Tools and Instruments

This study used both quantitative and qualitative data collection instruments to ensure a comprehensive understanding of the factors influencing participation in malaria clinical drug trials. Quantitative data were collected using a structured questionnaire administered to adult community members and health care providers.

Most of the items were close-ended to facilitate coding and statistical analysis, although a few open-ended questions were included to allow respondents to provide additional clarification where necessary. The use of structured questionnaires supports consistency in data collection and allows for efficient analysis of quantitative data (Creswell & Creswell, 2017). Qualitative data were collected using an interview guide designed for in-depth interviews. The guide consisted of open-ended questions that allowed participants to share their experiences, views, and perceptions regarding malaria clinical drug trials. The use of an interview guide ensured that all relevant topics were covered while allowing flexibility for participants to discuss issues that were important to them. This approach is appropriate for capturing detailed and context-specific information in qualitative research (Creswell & Poth, 2018).

3.6 Piloting of Research Instruments

Before the main data collection was carried out, a pilot study was conducted in Gasabo District, Kigali City, Rwanda, to test the suitability of the research instruments. Gasabo District was intentionally selected because it shares similar urban and socio-demographic characteristics with Kicukiro District, where the actual study was conducted. The pilot study involved 42 adult respondents, representing approximately 10 % of the quantitative sample size. In addition, two participants were involved in testing the qualitative interview guide, including one healthcare provider and one community leader. The piloting process aimed to

determine whether the questions were clear, understandable, relevant to the study objectives, and appropriate for the target population.

During the pilot exercise, participants were encouraged to give feedback on the wording, clarity, and flow of the questions. Most respondents reported that the questionnaire was easy to understand and relevant to the topic. However, some participants experienced difficulty understanding a few technical terms related to clinical trials and research procedures. Based on the feedback received, some questions were revised, simplified, and restructured to improve clarity and make them easier for respondents to understand. To assess the reliability of the quantitative questionnaire, Cronbach's Alpha was calculated for the Likert-scale items related to awareness, perceived risk, family support, and trust in healthcare providers. The overall Cronbach's Alpha coefficient obtained was 0.81, indicating that the instrument had good internal consistency and was reliable for data collection. According to Polit and Beck (2021), a reliability coefficient of 0.70 or above is considered acceptable in social science and public health research.

3.7 Testing for validity, reliability and establishment of trustworthiness

3.7.1 Validity

Validity refers to the extent to which a research instrument measures what it is intended to measure. In this study, content validity was ensured by developing the questionnaire based on the study objectives and variables identified in the literature. The draft questionnaire was reviewed by the research supervisor and other experts in public health to assess its relevance, clarity, and coverage of key concepts. In addition, the piloting of the questionnaire in Gasabo District helped to identify unclear or ambiguous questions

3.7.2 Reliability

Reliability refers to the consistency of a research instrument in measuring a concept. In this study, internal consistency of the questionnaire was assessed using Cronbach's alpha coefficient after the pilot study. The results indicated that the instrument had acceptable reliability. The overall Cronbach's alpha coefficient was 0.81, which is considered good for social science research. Specifically, the subscales showed the following results: Individual-level factors: $\alpha = 0.78$, Interpersonal factors: $\alpha = 0.82$ and Perception-related items: $\alpha = 0.80$. These values indicate that the items used in the questionnaire were consistent in measuring the intended constructs. A Cronbach's alpha value of 0.70 and above is generally considered acceptable for reliability (Taber, 2018).

3.8. Ethical Consideration

Ethical principles were carefully observed throughout the study to ensure the protection, dignity, and rights of all participants. Prior to data collection, ethical approval was obtained from Mount Kigali University. This approval confirmed that the study met the required ethical standards and was suitable for implementation. In addition, permission to conduct the study was sought from City of Kigali and Gatenga medicalized health center

4. RESULTS and findings

4.1 Socio-demographic profile.

Table 1. Socio-demographic Characteristics of Respondents (N = 411)

Variable	Category	Frequency (n)	Percentage (%)
Age (years)	18–25	89	21.7
	26–35	145	35.3

	36–45	131	31.9
	46–55	36	8.8
	≥56	10	2.4
Sex	Male	208	50.6
	Female	203	49.4
Education level	Primary	82	19.9
	Secondary	133	32.4
	Technical/Vocational	15	3.6
	University/Higher	181	44.0
Occupation	Formal employment	71	17.3
	Informal employment	174	42.3
	Small-scale business	71	17.3
	Student	46	11.2
	Farmer/Others	49	11.9

Table 1 presents the socio-demographic profile of respondents for quantitative components, which provides an important foundation for understanding participation in malaria clinical drug trials. The findings show that the largest proportion of respondents were aged 26–35 years (35.3%), followed by those aged 36–45 years (31.9%), while participants aged 18–25 years accounted for 21.7%. Only a small proportion of respondents were aged 46 years and above (11.2%). The mean age of the respondents was 33.8 years with a standard deviation of 9.6 years, indicating that the study population was largely composed of young to middle-aged adults. This age pattern suggests that most participants were within an economically active group, which is more likely to engage with healthcare services and be exposed to information related to clinical trials.

The distribution by sex was almost equal, with males representing 50.6% and females 49.4% of the respondents. This balance enhances the credibility of the findings by ensuring that perspectives from both genders are adequately represented and reduces the likelihood of gender bias in the analysis.

In terms of education, a substantial proportion of respondents had attained university or higher education (44.0%), followed by those with secondary education (32.4%), while 19.9% had primary education and only 3.6% had technical or vocational training. This indicates that the study population was relatively well-educated, which may positively influence understanding of clinical trial concepts, including perceived risks and benefits. However, the presence of respondents with lower levels of education suggests that variations in comprehension may still exist, requiring tailored communication approaches. Regarding occupation, the largest proportion of respondents were engaged in informal employment (42.3%), followed by those in formal employment (17.3%) and small-scale business activities (17.3%). Students accounted for 11.2%, while those categorized as farmer or others represented 11.9%. This distribution reflects the economic structure of the study area, where informal employment is common. Such employment patterns may influence participation in clinical trials, particularly where time availability and economic priorities affect individuals' ability to engage in research activities. The socio-demographic

characteristics indicate that the study population is predominantly composed of relatively young, economically active, and moderately educated individuals. These attributes are likely to shape awareness, perceptions, and decisions regarding participation in malaria clinical drug trials, and therefore provide an essential context for interpreting subsequent findings.

Table 2. Socio-demographic characteristics of qualitative respondents (n = 12)

Variable	Category	Frequency (n)	Percentage (%)
Sex	Male	7	58.3
	Female	5	41.7
Age group (years)	20–34	6	50.0
	35–44	3	25.0
	45 years and above	3	25.0
	Married/Cohabiting	10	83.3
Marital status	Single	1	8.3
	Not specified	1	8.3
	Primary	4	33.3
Education level	Secondary	2	16.7
	Diploma (A1)	2	16.7
	Bachelor's degree and above	4	33.3
Category of respondent	Community members	4	33.3
	Healthcare providers	4	33.3
	Local leaders	4	33.3
	Formal employment	5	41.7
	Informal employment	3	25.0
Occupation	Small-scale business	1	8.3
	Other community roles	3	25.0

Table 2 presents the socio-demographic characteristics of the 12 respondents who participated in the qualitative component of the study. The findings show that the majority of respondents were male (58.3%), while females accounted for 41.7%. This gender distribution provided perspectives from both men and women regarding participation in malaria clinical trials, particularly on issues of family decision-making, trust, and perceptions of risk. Some female participants emphasized the importance of consulting spouses before participation, while some male respondents described greater individual autonomy in making health decisions. Regarding age, half of the respondents (50.0%) were aged between 20 and 34 years, while 25.0% were aged between 35 and 44 years and another 25.0% were aged 45 years and above. The age range was 27 to 56 years, with a mean age of approximately 37.1 years. This indicates that most participants were within the active and productive age group, which is important because individuals in this category are more likely to be involved in household healthcare decisions and community mobilization activities. In terms of marital status, the majority of respondents (83.3%) were married or cohabiting, while only 8.3% were single. One respondent had no marital status specified. This finding is important because marital relationships strongly influenced decision-making regarding participation in clinical trials. Several respondents reported that they would first consult their spouse before deciding to participate, especially when the study involved repeated visits or perceived health risks. Concerning education level, one-third of respondents (33.3%) had primary education, while another 33.3% had bachelor's degree or higher qualifications. Respondents with diploma-level education accounted for

16.7%, and those with secondary education also represented 16.7%. Higher education levels were mainly observed among healthcare providers and local leaders, while most community members had primary or secondary education. This variation helped explain differences in awareness of clinical trials, understanding of informed consent, and perceptions toward participation.

Equal representation was maintained across respondent categories, with community members, healthcare providers, and local leaders each contributing 33.3% of the total sample. This balanced representation strengthened the study by incorporating views from service users, service providers, and individuals involved in community mobilization and governance.

Regarding occupation, 41.7% of respondents were in formal employment, mainly healthcare providers and some administrative leaders. Informal employment accounted for 25.0%, particularly among community members engaged in casual work or non-structured income-generating activities. Small-scale business owners represented 8.3%, while 25.0% were categorized under other community roles, mainly village and cell leadership responsibilities. This occupational diversity enriched the findings by capturing experiences from both institutional and community perspectives.

The socio-demographic diversity of the qualitative respondents enhanced the richness of the data and provided deeper understanding of how education, trust, leadership influence, and family dynamics shaped participation in malaria clinical drug trials. These characteristics also strengthened the interpretation of the quantitative findings by providing contextual explanations of the observed statistical relationships.

4.2 Individual-level factors influencing participation in malaria clinical drug trials

Table 3. Individual-level factors among respondents (N = 411)

Variable	Category	Frequency (n)	Percentage (%)
Awareness of clinical trials	Yes	238	57.9
	No	173	42.1
Perceived susceptibility to malaria	High	256	62.3
	Low	155	37.7
Perceived severity of malaria	High	289	70.3
	Low	122	29.7
Perceived risk of clinical trials	High	167	40.6
	Low	244	59.4
Previous participation in research	Yes	96	23.4
	No	315	76.6

Table 3 provides insight into individual-level factors that may shape participation in malaria clinical drug trials, particularly, awareness, perceived risk, and prior exposure to research. Taken together, these variables offer a useful lens for understanding how individuals make decisions about engaging in clinical studies.

The findings indicate that a substantial proportion of respondents demonstrated good knowledge of malaria (63.7%), suggesting that awareness of the disease is relatively well established within the study population. This reflects the impact of ongoing malaria control programs and health education efforts. However, this level of awareness does not appear to extend equally to clinical research, as only 57.9% of respondents reported being aware of malaria clinical drug trials, while 42.1% had no awareness. This gap

highlights a disconnect between disease knowledge and understanding of research participation, which may limit community engagement in clinical trials.

The findings further showed that perceived susceptibility to malaria was high among the majority of respondents. More than half of the respondents, 256 (62.3%), reported high perceived susceptibility to malaria, while 155 (37.7%) reported low perceived susceptibility. This finding suggests that most respondents considered themselves at risk of contracting malaria, which may be influenced by continued malaria transmission within the community and previous experiences with the disease. High perceived susceptibility may positively influence willingness to participate in malaria clinical drug trials because individuals who feel vulnerable to malaria are more likely to appreciate the importance of research aimed at improving malaria prevention and treatment strategies.

Perceived risk was also an important factor. While 59.4% of respondents considered clinical trials to have low risk, a notable proportion (40.6%) perceived them as high risk. This indicates that concerns and uncertainties remain significant among a considerable segment of the population. Such perceptions may arise from limited information, misconceptions, or lack of direct experience with clinical research, and can influence individuals' willingness to participate.

In addition, only 23.4% of respondents reported previous participation in research, while a large majority (76.6%) had never been involved in any research activity. This limited exposure suggests that most individuals lack firsthand experience with clinical trials, which may affect their confidence and trust in research processes. Individuals without prior experience are more likely to rely on perceptions or external influences when making decisions about participation.

When these findings are considered collectively, a clear pattern emerges. Although knowledge of malaria is relatively high, awareness of clinical trials remains moderate, perceived risk is still present among a substantial proportion of respondents, and prior exposure to research is low. These combined factors suggest that participation in malaria clinical drug trials is influenced not only by knowledge but also by awareness, perceptions of risk, and familiarity with research processes.

4.3 Interpersonal factors influencing participation in malaria clinical drug trials

Table 4. Interpersonal factors among respondents (N = 411)

Variable	Category	Frequency (n)	Percentage (%)
Family support	Yes	247	60.1
	No	164	39.9
Peer influence	Positive	226	55.0
	Negative	185	45.0
Trust in healthcare providers	High	267	65.0
	Low	144	35.0
Influence of community leaders/CHWs	Positive	259	63.0
	Negative	152	37.0

Table 3 presents the distribution of interpersonal factors among respondents. The findings show that a majority of respondents reported having family support (60.1%), suggesting that social networks within households play an important role in shaping health-related decisions. However, a notable proportion

(39.9%) indicated lack of such support, highlighting that not all individuals benefit from positive household influence. This variation suggests that decisions regarding participation in clinical trials may not be entirely individual but are often influenced by family dynamics and approval.

Peer influence also appears to play a meaningful role, with 55.0% of respondents reporting positive influence from peers, while 45.0% experienced negative influence. This near balance indicates that community-level interactions can either encourage or discourage participation in clinical trials. From an analytical perspective, this suggests that misinformation, shared experiences, or community perceptions may significantly shape attitudes toward research participation.

Trust in healthcare providers emerged as one of the strongest interpersonal factors, with 65.0% of respondents reporting high levels of trust, compared to 35.0% who expressed low trust. This finding is particularly important, as healthcare providers often serve as the primary source of information and guidance regarding clinical trials. High trust levels may facilitate acceptance and participation, while low trust may act as a barrier, especially in contexts where clinical research is not well understood.

The findings also revealed that influence from community leaders and Community Health Workers (CHWs) played an important role in shaping respondents' perceptions toward participation in malaria clinical drug trials. More than half of the respondents, 259 (63.0%), reported positive influence from community leaders and CHWs, while 152 (37.0%) reported negative influence. This finding suggests that community leaders and CHWs are trusted sources of health information within the community and may significantly influence community attitudes and decisions regarding participation in clinical research. Positive engagement and sensitization by these community actors may therefore help improve awareness, build trust, address misconceptions, and encourage participation in malaria clinical drug trials.

When these findings are considered together, it becomes evident that interpersonal relationships play a significant role in influencing participation in malaria clinical drug trials. Family support provides a foundation for decision-making, peer influence shapes perceptions through social interaction, and trust in healthcare providers affects confidence in the research process. The interplay of these factors suggests that participation is not solely determined by individual knowledge but is also strongly shaped by social context.

4.4 Factors associated with participation in malaria clinical drug trials

Table 5. Bivariate analysis of factors associated with participation in malaria clinical drug trials

Variable	Category	Participate (%)	Not Participate (%)	p-value
Age group	18–25	34 (38.2)	55 (61.8)	0.041
	26–35	72 (49.7)	73 (50.3)	
	36–45	62 (47.3)	69 (52.7)	
	≥46	17 (36.2)	30 (63.8)	
Sex	Male	96 (46.2)	112 (53.8)	0.621
	Female	89 (43.8)	114 (56.2)	
Education level	Primary	28 (34.1)	54 (65.9)	0.003
	Secondary	58 (43.6)	75 (56.4)	
	Higher	99 (54.7)	82 (45.3)	
Occupation	Informal	70 (40.2)	104 (59.8)	0.027
	Formal	38 (53.5)	33 (46.5)	

	Others	77 (47.0)	89 (53.0)	
Awareness of clinical trials	No	52 (30.1)	121 (69.9)	<0.001
	Yes	133 (55.9)	105 (44.1)	
Perceived risk	High	54 (32.3)	113 (67.7)	0.001
	Low	131 (53.7)	113 (46.3)	
Previous participation	No	120 (38.1)	195 (61.9)	<0.001
	Yes	65 (67.7)	31 (32.3)	
Family support	No	48 (29.3)	116 (70.7)	<0.001
	Yes	137 (55.5)	110 (44.5)	
Trust in healthcare providers	Low	42 (29.2)	102 (70.8)	<0.001
	High	143 (53.6)	124 (46.4)	
Accessibility to trial sites	Difficult	51 (31.9)	109 (68.1)	0.002
	Easy	134 (53.4)	117 (46.6)	

Table 5 presents the bivariate analysis of factors associated with participation in malaria clinical drug trials among adults in Kicukiro District. The findings showed that several socio-demographic, individual-level, and interpersonal factors were significantly associated with participation in malaria clinical drug trials.

The analysis revealed that age group was significantly associated with participation ($p = 0.041$). Respondents aged 26–35 years had the highest participation rate (49.7%), followed by those aged 36–45 years (47.3%). In comparison, lower participation was observed among respondents aged 18–25 years (38.2%) and those aged 46 years and above (36.2%). This may suggest that adults within the active working-age groups are more exposed to health information and may be more willing to participate in research activities.

Sex was not significantly associated with participation ($p = 0.621$). Participation rates were relatively similar among males (46.2%) and females (43.8%), indicating that gender may not strongly influence participation in malaria clinical drug trials within the study population.

Education level showed a statistically significant association with participation ($p = 0.003$). Respondents with higher education reported the highest participation rate (54.7%) compared to those with secondary education (43.6%) and primary education (34.1%). This finding suggests that higher levels of education may improve understanding of clinical research and increase willingness to participate.

Occupation was also significantly associated with participation ($p = 0.027$). Respondents in formal employment reported higher participation (53.5%) compared to those in informal employment (40.2%) and those in other occupations (47.0%). This could be related to better access to health information and increased awareness among formally employed individuals.

Awareness of clinical trials had a strong association with participation ($p < 0.001$). More than half of respondents who were aware of clinical trials participated (55.9%), while participation was much lower among those who lacked awareness (30.1%). This finding highlights the importance of awareness and health education in promoting participation in malaria clinical drug trials.

Perceived risk was significantly associated with participation ($p = 0.001$). Respondents with low perceived risk were more likely to participate (53.7%) compared to those with high perceived risk (32.3%). This

suggests that fear of side effects and concerns about safety may discourage participation in clinical trials. Previous participation in research also showed a strong association with participation ($p < 0.001$). Respondents who had previously participated in research reported higher participation (67.7%) compared to those without previous research experience (38.1%). This finding indicates that previous exposure to research activities may improve familiarity and confidence in clinical trials.

Family support was another important factor significantly associated with participation ($p < 0.001$). Respondents who received family support had higher participation (55.5%) compared to those who lacked family support (29.3%). This demonstrates the important role family members play in influencing decisions related to participation in clinical research.

Finally, trust in healthcare providers was significantly associated with participation ($p < 0.001$). Respondents with high trust in healthcare providers reported greater participation (53.6%) compared to those with low trust (29.2%). This finding suggests that trust in healthcare professionals and researchers is essential for improving community participation in malaria clinical drug trials.

The findings further showed that accessibility to trial sites was significantly associated with participation in malaria clinical drug trials ($p = 0.002$). Respondents who reported easy access to trial sites had higher participation (53.4%) compared to those who experienced difficulty accessing trial sites (31.9%). On the other hand, respondents who reported difficult access were less likely to participate, with the majority (68.1%) indicating non-participation. This finding suggests that practical and logistical factors such as distance to health facilities, transportation challenges, travel costs, and time required to reach trial sites may influence willingness and ability to participate in malaria clinical drug trials. Easier access to research sites may therefore improve community participation by reducing logistical barriers and increasing convenience for potential participants.

4.5 Multivariate analysis of factors associated with participation in malaria clinical drug trials

Table 6. Multivariate analysis of actors associated with participation in malaria clinical drug trials

Variable	Category	COR	AOR	95% CI	P-value
Age group	18–25	1	1	Ref	
	26–35	1.60	1.72	1.01–2.93	0.046
	36–45	1.45	1.58	0.92–2.71	0.098
	≥46	0.92	0.94	0.48–1.86	0.860
Education level	Primary	1	1	Ref	
	Secondary	1.49	1.43	0.79–2.60	0.235
	Higher	2.33	2.11	1.24–3.58	0.006
Occupation	Informal employment	1	1	Ref	
	Formal employment	1.71	1.61	0.92–2.82	0.093
	Others	1.29	1.28	0.78–2.10	0.320
Awareness of clinical trials	No	1	1	Ref	
	Yes	2.95	2.63	1.55–4.45	<0.001
Perceived risk	High	1	1	Ref	

Previous participation	Low	2.42	2.07	1.24–3.45	0.005
	No	1	1	Ref	
Family support	Yes	3.41	3.08	1.70–5.60	<0.001
	No	1	1	Ref	
Trust in healthcare providers	Yes	3.01	2.36	1.37–4.05	0.002
	Low	1	1	Ref	
Accessibility to trial sites	High	2.80	2.61	1.52–4.47	<0.001
	Difficult	1	1	Ref	
	Easy	2.45	2.18	1.29–3.69	0.004

Key: COR = Crude Odds Ratio, AOR = Adjusted Odds Ratio, CI = Confidence Interval, Ref = Reference Category

Table 6 presents the multivariate logistic regression analysis of factors associated with participation in malaria clinical drug trials among adults in Kicukiro District. Both crude odds ratios (COR) and adjusted odds ratios (AOR) were used to assess the relationship between independent variables and participation in malaria clinical drug trials. The adjusted analysis helped identify factors that independently influenced participation after controlling for the effects of other variables included in the model. The findings showed that respondents aged 26–35 years were significantly more likely to participate in malaria clinical drug trials compared to respondents aged 18–25 years ($COR = 1.60$; $AOR = 1.72$; 95% $CI: 1.01–2.93$; $p = 0.046$). This may suggest that individuals within this age group are more actively engaged in health-related activities and may have greater exposure to information about clinical research. Respondents aged 36–45 years also showed increased odds of participation ($COR = 1.45$; $AOR = 1.58$; 95% $CI: 0.92–2.71$), although the association was not statistically significant ($p = 0.098$). Meanwhile, respondents aged 46 years and above were slightly less likely to participate compared to those aged 18–25 years ($COR = 0.92$; $AOR = 0.94$; 95% $CI: 0.48–1.86$; $p = 0.860$), indicating no significant association between older age and participation in malaria clinical drug trials. Education level was also associated with participation. Respondents with secondary education showed slightly higher odds of participation compared to those with primary education ($COR = 1.49$; $AOR = 1.43$; 95% $CI: 0.79–2.60$), although the association was not statistically significant ($p = 0.235$). However, respondents with higher education were significantly more likely to participate in malaria clinical drug trials compared to those with primary education ($COR = 2.33$; $AOR = 2.11$; 95% $CI: 1.24–3.58$; $p = 0.006$). This finding may indicate that higher educational attainment improves understanding of clinical trials and increases confidence in participating in research activities. Regarding occupation, respondents in formal employment showed higher odds of participation compared to those in informal employment ($COR = 1.71$; $AOR = 1.61$; 95% $CI: 0.92–2.82$), but the association did not reach statistical significance ($p = 0.093$). Respondents categorized under other occupations also showed slightly increased odds of participation ($COR = 1.29$; $AOR = 1.28$; 95% $CI: 0.78–2.10$), although this association was not statistically significant ($p = 0.320$). These findings suggest that occupation alone may not independently predict participation after adjustment for other factors. Awareness of clinical trials remained one of the strongest predictors of participation. Respondents who were aware of clinical trials were nearly three times more likely to participate compared to those who lacked awareness ($COR = 2.95$;

AOR = 2.63; 95% CI: 1.55–4.45; $p < 0.001$). This finding highlights the important role of awareness and access to information in improving community participation in malaria clinical drug trials. Perceived risk was significantly associated with participation. Respondents who reported low perceived risk were more likely to participate compared to those with high perceived risk ($COR = 2.42$; AOR = 2.07; 95% CI: 1.24–3.45; $p = 0.005$). This suggests that fear of side effects, concerns about safety, and uncertainty about clinical trials may discourage individuals from participating in research activities.

Previous participation in research showed a strong positive association with participation in malaria clinical drug trials. Respondents who had previously participated in research activities were approximately three times more likely to participate compared to those without previous research experience ($COR = 3.41$; AOR = 3.08; 95% CI: 1.70–5.60; $p < 0.001$). This finding may indicate that previous exposure to research helps build familiarity, trust, and confidence in the clinical trial process. Family support also remained significantly associated with participation. Respondents who received support from family members were more than twice as likely to participate in malaria clinical drug trials compared to those without family support ($COR = 3.01$; AOR = 2.36; 95% CI: 1.37–4.05; $p = 0.002$). This demonstrates the important influence of family relationships and social support in shaping decisions related to participation in clinical research. Trust in healthcare providers was another significant predictor of participation. Respondents with high trust in healthcare providers were more likely to participate in malaria clinical drug trials compared to those with low trust ($COR = 2.80$; AOR = 2.61; 95% CI: 1.52–4.47; $p < 0.001$). This finding suggests that confidence in healthcare professionals and researchers plays a critical role in encouraging community participation in clinical drug trials. Accessibility to trial sites was also significantly associated with participation in malaria clinical drug trials. Respondents who reported easy access to trial sites were more likely to participate compared to those who experienced difficulty accessing the sites ($COR = 2.45$; AOR = 2.18; 95% CI: 1.29–3.69; $p = 0.004$). This finding suggests that respondents with easier access to clinical trial locations were about two times more likely to participate in malaria clinical drug trials than those facing accessibility challenges. Factors such as shorter distance to health facilities, availability of transportation, reduced travel costs, and convenience in reaching trial sites may therefore positively influence participation. On the other hand, transportation difficulties, long travel distances, and time constraints may discourage individuals from taking part in clinical research activities. These findings highlight the importance of improving accessibility and reducing logistical barriers in order to enhance community participation in malaria clinical drug trials.

The multivariate analysis demonstrated that awareness of clinical trials, low perceived risk, previous participation in research, family support, trust in healthcare providers, higher education level, and being aged 26–35 years were important factors influencing participation in malaria clinical drug trials among adults in Kicukiro District.

4.6 Qualitative findings on perception experiences and barriers of participants regarding the participation in malaria clinical drug trials

Table 7. Perceptions and experience of participants and healthcare provider

Themes	Sub-themes	Definitions
Understanding of clinical Trials	General	Refers Participants' general
	awareness and interpretation	comprehension and personal interpretation of malaria clinical drug trials
	Limited	Refers to insufficient community

Motivations for Participation	understanding in community.	knowledge about clinical trials and their processes.
	Access to treatment and benefits	Refers to perceived opportunity to obtain healthcare services and related benefits through participation.
	Personal health benefits	Refers to expectation of improved individual health outcomes from participation
	Contribution to community health	Belief that participation supports better community health and malaria control
Perceived risks and fears	Fear of side effects	Concern about possible adverse effects and uncertain treatment outcomes.
	Concerns about procedures (e.g., blood samples)	Discomfort or fear related to research procedures involved in the trial.
	Rumors and misinformation	Refers to incorrect information that influencing attitudes toward participation
Perceptions and community attitudes	Negative perceptions and mistrust	Refers to unfavorable beliefs and lack of confidence in clinical research.
	Positive perceptions from experience	Refers to favorable attitudes developed through prior research experiences
	Mixed perceptions based on knowledge	Refers to varied opinions shaped by individual levels of understanding.
Influence of social networks	Family influence in decision-making	Refers to the effect of family opinions on participation decisions.
	Peer and community influence	This refers to the influence of social networks and community views on participation.
Role of leaders and health	Influence of local leaders	It refers to the impact of local authority figures on community participation

workers		decisions.
	Role of community health workers	Refers to the contribution of health workers in informing and mobilizing participants.
Trust in health system and researchers	Trust based on professionalism	Refers to confidence resulting from researchers' competence and ethical conduct.
	Conditional trust influenced by transparency	Refer to trust determined by openness and clear communication from researchers.
	Time constraints and workload	Limited participation due to competing responsibilities and lack of time.
Barriers to participation	Lack of information and poor sensitization	Refers to reduced participation caused by inadequate awareness and education.
	Economic and logistical challenges	This refers to financial and practical barriers affecting participation.
	Community education and sensitization	Refers to activities aimed at improving knowledge on malaria clinical trial and encourage participation.
Strategies to improve participation	Use of local leaders and media	This refers to the engagement of trusted channels to promote awareness and participation.
	Transparency and feedback to participants	Sharing clear information and study outcome to strengthen trust.

The qualitative findings provide deeper insight into the factors influencing participation in malaria clinical drug trials and help explain patterns observed in the quantitative results. Overall, the findings reveal that participation is shaped by a complex interaction of knowledge, perceptions, social influence, and structural conditions.

Understanding of clinical trials

This theme refers to the extent of knowledge, understanding, and interpretation that individuals possess about clinical trials. A key theme emerging from the qualitative data is the variation in understanding of clinical trials within the community. While some respondents demonstrated a clear understanding, others showed limited knowledge. For example, one participant explained that *"a clinical trial is a process where*

a new drug is tested on people to determine whether it works effectively before it is made available to the general population” (IDI 001 Participant). In contrast, a community leader emphasized that *“most people in the community do not clearly understand what clinical trials are; some even think participation is mainly for financial gain rather than for improving health”* (IDI 012 Leader). These findings directly support the quantitative result where only 57.9% of respondents were aware of clinical trials, highlighting a significant knowledge gap. This suggests that awareness campaigns must go beyond general health education and focus specifically on research literacy.

Motivation for participation

This theme outlines the elements that motivate people to take part in clinical trials. Participants described participation as an opportunity to access treatment early, with one respondent noting that *“one of the main reasons I agreed to participate was the opportunity to receive the medication early, especially since it might later become expensive or difficult to access”* (IDI 001 Participant). Others were motivated by personal health needs, as reflected in the statement *“I chose to participate because I frequently suffered from malaria, and I believed that being part of the study could help improve my health”* (IDI 003 Participant). These insights help explain why previous participation was the strongest predictor in the quantitative analysis (AOR = 3.08, $p < 0.001$). The implication is that exposure and positive experiences can significantly enhance future participation.

Perceived risks and fear

This theme examines the worries, apprehensions, and fears that participants have concerning clinical trials. Perceived risk emerged as a major barrier across both data sources. Participants expressed concerns about safety and uncertainty, with one respondent stating *“many people are afraid to participate because the medicine is new and could have harmful or unknown side effects”* (IDI 009 Leader). Another participant highlighted procedural concerns, noting *“I sometimes worry when blood samples are taken repeatedly because I fear it could weaken the body”* (IDI 004 Participant). In addition, misinformation plays a role, as captured in the quote *“there are many rumours in the community, with some people saying participants are injected with unknown substances”* (IDI 001 Participant). These findings reinforce the quantitative result where 40.6% of respondents perceived high risk, and those perceiving lower risk were significantly more likely to participate (AOR = 2.07, $p = 0.005$). This indicates that addressing fear and misinformation is critical for improving participation.

Perception and Community attitudes

This theme explores how participants and community members perceive clinical trials. Community perceptions were found to be mixed, shaped largely by experience and information exposure. Some participants reported negative attitudes, stating *“many community members have negative perceptions about clinical trials, believing that participants may be harmed”* (IDI 004 Participant). However, others shared positive perspectives based on experience, such as *“people who have already participated often share positive experiences, explaining that they did not face any problems”* (IDI 003 Participant). This variation aligns with the quantitative finding that awareness significantly influences participation ($p < 0.001$). It suggests that community narratives and shared experiences play a powerful role in shaping attitudes.

Influence of social networks

This theme concerns the role of social relationships and interactions in shaping decisions about participation in clinical trials. Interpersonal influences were strongly evident in the qualitative findings and support quantitative results. Decision-making was often described as a shared process within families,

with one respondent explaining *“before participating, I would need to consult my spouse because any risks or outcomes could affect both of us”* (IDI 012, a Leader). This aligns with the quantitative finding that family support significantly increases participation (AOR = 2.36, $p = 0.002$). Additionally, peer influence was noted, as *“information about the study often spreads through friends and community members, and their opinions can either encourage or discourage participation”* (IDI 001 Participant). These findings highlight that participation decisions are socially influenced rather than purely individual.

Role of leaders and health workers

This theme outlines the influence of local leaders, community leaders, healthcare providers, and community health workers in promoting awareness, providing information, building trust, and encouraging participation in clinical trials. The role of local leaders and community health workers was also emphasized. Participants indicated that *“when local leaders understand and support the research, they can effectively reassure community members and encourage them to participate”* (IDI 011 Leader). Similarly, *“community health workers play an important role because they are trusted and directly inform people”* (IDI 003 Participant). These insights explain why trust in healthcare providers was a strong predictor in the quantitative analysis (AOR = 2.61, $p < 0.001$). It also suggests that leveraging trusted community structures is essential for improving participation.

Trust in health system and researchers

This theme investigates the extent to which participants trust healthcare systems, researchers, and research institutions. Trust in healthcare providers and research institutions was generally high but dependent on communication and transparency. As one participant noted, *“we trust healthcare providers because they are trained professionals who understand what they are doing”* (IDI 004 Participant). However, another respondent emphasized that *“trust is built when researchers provide clear explanations, answer questions honestly, and remain available to support participants”* (IDI 005 HCP). This confirms the quantitative finding that trust significantly influences participation and highlights the importance of maintaining trust through ongoing engagement.

Barriers to participation

This theme highlights the challenges and obstacles that limit or discourage participation in clinical trials. Barriers related to time, logistics, and economic constraints were also identified. Participants explained that *“participating in a study that requires frequent visits can be difficult because people have work responsibilities”* (IDI 005 HCP), and that *“regular visits can interfere with daily income and responsibilities”* (IDI 011 Leader). These findings reflect the socio-economic context observed in the quantitative data, where many respondents were engaged in informal employment. This suggests that practical barriers must be addressed alongside attitudinal factors.

Strategies to Improve Participation

This theme emphasizes recommended methods and actions that could boost participation in clinical trials. Participants proposed several strategies to improve participation. Continuous education was strongly emphasized, with one respondent stating *“health workers should continuously educate the community about research, not only when a study is being conducted”* (IDI 001 Participant). Others recommended broader communication approaches, such as *“using local leaders, community meetings, radio, and other media to improve understanding”* (IDI 009 Leader). Additionally, transparency was highlighted, as *“researchers should share test results and clearly explain participants’ health status”* (IDI 001 Participant). These suggestions directly address gaps identified in both qualitative and quantitative findings.

5. Conclusion

The study shows that awareness is important, but it must be accompanied by clear understanding. Similarly, trust plays a central role, but it needs to be built through transparent communication and consistent engagement. Social relationships, particularly family influence, shape decision-making, while practical challenges affect individuals' ability to participate. In the context of Rwanda, the presence of a strong health system and established community structures provides a solid foundation for improving participation. However, these structures need to be more actively used to support clinical trial awareness and engagement. In general, improving participation requires a comprehensive approach that combines community education, trust-building, involvement of families and local leaders, and practical support to address logistical barriers. By addressing these factors together, it is possible to enhance participation and strengthen the effectiveness of clinical research in similar settings. Further research is needed to explore effective strategies for improving community understanding of clinical trials and addressing misconceptions. Studies should examine how interpersonal relationships influence participation across different settings and populations. In addition, intervention-based research should be conducted to assess the effectiveness of community engagement approaches, communication strategies, and trust-building initiatives in increasing participation in clinical trials.

7. Acknowledgement

I am profoundly grateful to my research supervisor, Dr. Clemence NISHIMWE for her invaluable guidance, insightful feedback, and consistent encouragement throughout the research process. Her expertise and mentorship greatly enriched this work. Finally, my sincere appreciation goes to all those who offered help in any form be it emotional, spiritual, or practical. Their kindness and support played an essential role in bring this project to life.

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