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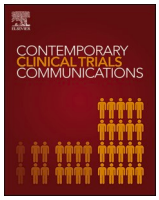

Improving community participation in clinical trials in Ghana; factors to consider

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ABSTRACT

Introduction: Clinical trials are an essential part of drug and vaccine development, as well as the development of new biomedical devices, and medical procedures. Successful enrolment of human volunteers is important to the success of any clinical trial anywhere around the globe. Enrolment is however affected by a number of factors including knowledge, attitudes, and perceptions (KAPs). We aimed to determine factors that are deemed important in improving participation in clinical trials within a Ghanaian community.

Method: This was a cross-sectional study that employed a structured questionnaire within the New Juaben South Municipal Assembly (NJSMA). Participants who were 18 years and above were included in this study. There were a total of 639 participants in this study. Participants' demographics were collected and various questions were asked to assess their KAP towards participation in clinical trials.

Results: The mean age of participants was 29.03 ± 8.95 years, there were more males (51.96%) than females, 42.35% had tertiary education, 38.03% were artisans, 74.80% were Christians and 14.40% had previously participated in a clinical trial. Participants had average knowledge about clinical trials (CT) with a mean score of 7.56 ± 1.76 (63%). A significant association between knowledge levels and education was observed ($\chi 2 = 100.3$, $p < 0.0001$). Helping in advancing the medical knowledge was the key reason for participation in CT while mistrust of the medical system was the key setback in participation in CT. There was a generally positive attitude and a neutral perception towards participation in CTs.

Conclusion: Groups intending to conduct CT should highlight the benefits of CT and address the perception of mistrust in the conduct of CTs in their education and sensitization programs before initiation of CTs in Ghana.

1. Introduction

According to the U.S. National Institutes of Health (NIH), clinical trial is " a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioural outcomes" [1]. Clinical trials (CTs) are essential in the development of new biomedical devices, new medical or surgical procedures and the development of new drugs or vaccines [2]. CTs are highly regulated by specially appointed regulatory bodies in various jurisdictions including the U.S. Food and Drug Administration (US-FDA) for trials being conducted in the US, European Medicines Agency (EMA) for trials being conducted with the European Union, and in Ghana, the Ghana Food and Drugs Authority (GH-FDA). CT takes place in four phases; phase I, II, III and IV [3].

In an era of high antimicrobial resistance, the need for less toxic cancer drugs and a surge in the cases of emerging and re-emerging infectious diseases like the Ebola epidemic in 2014 in West Africa [4] and

Abbreviations: NJSMA, New Juaben South Municipal Assembly.

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currently SARS-CoV-2, there will always be the need for the development of new drugs and vaccines to combat such diseases. The success of any clinical trials can be affected by factors other than biomedical factors which may include; race, ethnicity, age, and sex [5]. Knowledge of the risk, attitudes and perceptions towards participation in clinical trials may all impact the success of a clinical trial [6–8].

Earliest reported clinical trials in Ghana dates back to 1970s in which the efficacy of diethylcarbamazine (DEC) was evaluated for treatment of onchocerciasis [9]. Since then, a number of clinical trials covering different infectious disease conditions including malaria, tuberculosis and human immunodeficiency virus (HIV) have been carried out in Ghana [10]. However, not much trials have been carried out with respect to non-communicable conditions such as hypertension, cardiovascular diseases, and mental health disorders [10]. Among the successful clinical trials that have taken place in Ghana is the RTS,S/AS01 malaria vaccine which has been adopted by the World Health Organization (WHO). Some part of phase II and phase III trials were carried out in some communities in Ghana [11]. Although there has been some successes with roll out of clinical trials in Ghana in the past, the rise in the use of social media and in some situations the traditional media is fuelling misinformation about clinical trials around the world including Ghana [12,13].

Indeed, in the wake of the Ebola epidemic in 2015, a proposed Ebola vaccine trial was suspended by the Ministry of Health of Ghana due to concerns raised by some parliamentarians and some members of the public [14]. Some cultural, biomedical and historical factors were identified as some of the factors leading to the unsuccessful clinical trial in one study [14]. Other perceptions that forced the suspension of the trial included the fear that the vaccine will cause an outbreak in the country as well as allegations of improper incentives for the participants [15]. In light of this failed Ebola vaccine trial in Ghana, we examined the knowledge, attitudes and perceptions (KAPs) towards participation in clinical trials in a Ghanaian community in order to determine which factors are considered key to improving participation in future clinical trials in the country.

2. Materials & method

2.1. Study site and study design

This study was conducted in the New Juaben South Municipal Assembly (NJSMA) in the Eastern Region of Ghana between July and August 2021. Koforidua is the capital of the municipality and covers a land area of 60 square kilometres. NJSMA is situated 6° 5′ 38.4″ N, 0° 15′ 32.4″ W and it borders on the North with New Juaben North Municipal Assembly, on the South-East with Akuapem North Municipal and on the East with the Yilo Krobo Municipal Assembly [16].

A cross-sectional study was employed using a structured questionnaire. The participants were randomly selected and interviewed while some self-administered the questionnaire. This survey was carried out between 15th October and November 19, 2021. Participants who were 18 years and above were recruited.

2.2. Sample size estimate

The Raosoft online sample size calculator [17] was used to estimate the minimum number of participants required. Using the 2020 projected population of NJSMA of 232776 [16], with a 95% confidence level and a 5% margin of error, minimum sample size was estimated to be 384. A total of 639 respondents were included in this study.

2.3. Statistical analysis

All analysis was conducted using GraphPad Prism version 9.0.0 (GraphPad Software, San Diego, CA). Quantitative variables are presented as mean (M) ± standard deviation (SD), or frequency (percentage %) while categorical variables are presented as frequencies with corresponding percentages. Chi-square analysis was done to determine the association between independent variables (gender, educational level, occupation and previous participation in clinical trials) and the level of knowledge. To boost the power of our chi-square analysis, traders and unemployed were collapsed into artisans while health care workers were collapsed into civil/public servants under the occupation variable. Religion was also collapsed into Christianity and Islam as collapsing the numbers for traditional and other religious affiliations did not significantly affect the analyses.

2.4. Measurement tool

A structured questionnaire adopted and modified from Ref. [18] was used to carry out this survey. A total of 12 questions were asked to test the knowledge of respondents on clinical trials. To assess the attitudes of participants towards participating in clinical trials, factors associated with their willingness, elements enhancing participation and clinical conditions that motivate participation in clinical trials were evaluated. To assess the perception towards participation in clinical trials, reasons to participate or not to participate in clinical trials and their general opinion about clinical trials were evaluated.

2.5. Ethical consideration

Adequate information concerning the study was provided to enable participants to make an informed consent. Only consenting participants were recruited for this study. This study posed minimum risk to participants and no personal identifiers were collected and stored.

3. Results

3.1. Demographics of participant

There were a total of 639 respondents with a mean age of 29.03 years and comprised of more males (51.96%) than females. As much as 42.35% had a tertiary level education. Artisans together with students formed the majority (72.77%). Occupations that were classified as artisans in this work included carpenters, barbers, hairdressers, caterers, fashion designers (tailors and seamstress), cleaners and drivers. Majority of the respondents were of Christian religious affiliation and only 92 (14.40%) had previously participated in clinical trials. Table 1 is a summary of the demographics of participants.

3.2. Knowledge about clinical trials

All the questions and participants' responses are summarized in Table 2a below. Each question was assigned 1 mark for a correct or positive response, 0.5 for a partially answered question where a participant was required to select more than one correct response but answered the question partially. A zero (0) was assigned to a wrong answer or a negative response. On the definition of clinical trials, participants who selected these two options "Studies to test new drugs or procedures on humans" and "Testing new device" were scored 1 while respondents who selected at least one correct response were assigned 0.5 mark. Similarly, on the question of the "Potential benefits of clinical trials", respondents who selected all of "Improve medical knowledge", "Improve patient care", and "Improve community well-being" scored 1 mark while those who selected at least one of the correct responses were assigned 0.5(partial) mark. A summary of all the questions and responses are shown in Table 2a below.

A percentage of the total marks scored by each participant was computed and summarized in Table 2b below. More than half of the respondents 350(54.77%) scored between 60 and 79% and classified as having an average knowledge about clinical trials while 61(9.55%) scored ≥80% and were classified as having a high knowledge about

Table 1
Demographics of participants.

Sociodemographic	Classification	Number (%)
Gender	Male	332(51.96)
	Female	307(48.04)
Age (years)	Minimum	18
	Maximum	68
	Mean ± SD	29.03 ± 8.95
Educational level	Basic	144(22.54)
	Secondary	145(22.69)
	Tertiary	270(42.35)
	Post Graduate	21 (3.29)
	No formal education	59 (9.23)
Occupation	Student	222(34.74)
	Artisan	243(38.03)
	Health Worker	94(14.71)
	Civil/Public servant	72(11.27)
	Trader	5(0.78)
	Unemployed	3(0.47)
Religious affiliation	Christian	478(74.80)
	Islam	144(22.54)
	Traditional	2(0.31)
	I do not wish to disclose	12(1.88)
	Others	3(0.47)
Previous participation in clinical Trials	Yes	92(14.40)
	No	543(85.00)
	Was requested, but didn't participate	4(0.63)

clinical trials. The overall mean score for knowledge level was 63% which is an average classification.

3.3. Relationship between knowledge levels and gender, education, occupation, religion and previous participation

There was a significant association between previous participation and knowledge level ($\chi^2 = 13.23$, $p = 0.0042$). There was also as significant association between religion and knowledge level ($\chi^2 = 10.35$, $p = 0.0158$). Again, significant association was observed between knowledge levels and education ($\chi^2 = 100.3$, $p < 0.0001$). The association between knowledge and gender was however not significant ($\chi^2 = 3.429$, $p = 0.3301$).

3.4. Attitudes towards participating in clinical trials

Most of the respondents 482(75.43%) would be willing to participate in a clinical trial if they were given more time to think about it before approving. Understanding the study was the most important element 496(77.62%) out of the four elements enhancing participation in clinical trials that were tested. Respondents were more motivated to participate in clinical trials if they considered the disease as life threatening 418 (65.41%), Table 3.

3.5. Perceptions towards participating in clinical trials

When participants perceive that their participation in clinical trials was going to help society 361(56.49%) or help in advancing medical knowledge 383(59.95%), that was a good reason for them to participate in clinical trials. On the other hand, fear from risks of participation 313 (48.98%) and fear from the unknown 326(51.02%) were reasons not to participate in clinical trials. Majority of the respondents 470(73.55%) expressed an overall neutral opinion, that is they didn't express either

Table 2a
Table showing respondents' knowledge about clinical trials.

Question	Response	Number (%)
Have you heard about clinical trials	Yes	291 (45.54)
	No	74(11.58)
	Not sure	274 (42.88)
What is the definition of a clinical trial?	Right	0(0)
	Partly right	392 (61.35)
	Wrong	157 (24.57)
	Not sure	90(14.08)
Potential benefits of clinical trials	Right	141 (22.07)
	Partly right	444 (69.48)
	Wrong/no benefits	104 (16.15)
Have you heard of IRB	Yes	123 (19.25)
	No	516 (80.75)
Have you heard of the FDA	Yes	623 (97.50)
	No	16(2.50)
Does the FDA play a role in regulating clinical trials	Yes	455 (71.21)
	No	184 (28.79)
Are there ethical guidelines to regulate the conduct of clinical trials	Yes	536 (83.88)
	No	103 (16.12)
Are there direct benefits for participants in clinical trials	Definitely	263 (41.16)
	Definitely not	29(4.54)
	No benefit or harm	64(10.02)
	Possible benefit or harm	283 (44.29)
Do clinical trials have direct benefits for the community	Yes	417 (65.26)
	No	222 (34.74)
When can an investigator start clinical trials?	Right	244 (38.18)
	Wrong	302 (47.26)
	Not sure	93(14.55)
Should recruitments be based on patients consent	Yes	609 (95.31)
	No	30(4.69)
Can participants freely withdraw from clinical trials anytime	Yes	539 (84.35)
	No	100 (15.65)

IRB = institutional review board, FDA=Food and drugs authority.

Table 2b
Table showing overall knowledge level of respondents.

Percentage score	Classification	No. (%)
80 and above	High	61(9.55)
60 and 79	Average	350(54.77)
40 and 59	Low	185(28.95)
Below 40	Very Low	43(6.73)
Overall mean score ± SD 7.56 ± 1.76		
Overall mean knowledge score 63%		

SD−standard deviation.

Table 3
Attitudes towards participating in clinical trials.

Attitudes	Number (%)
Factors associated with willingness to participate in clinical trials	
Take more time to think before approving	482 (75.43)
Consultation of family physician	200 (31.30)
Researchers are willing to participate in the same study	250 (39.12)
Presence of family members	98(15.34)
Elements enhancing participation in clinical trials	
Understand the study	496 (77.62)
Researcher had explained the study	329 (51.49)
Family physician read the protocol	138 (21.60)
Signing informed consent form	247 (38.65)
Clinical conditions motivating participation in clinical trials	
Healthy status	409 (64.01)
Life threatening disease	418 (65.41)
None life threatening disease	155 (24.26)
Feeling offended if asked to participate in clinical trials during a regular doctor visit	47(7.36)

* Respondents could select more than one answer.

good or bad opinion about participating in clinical trials. A summary of the perceptions toward participating in clinical trials is shown in Table 4 below.

3.6. Discussion

This study aimed at improving community participation in clinical trials in Ghana by evaluating the knowledge, attitudes and perceptions towards participation in clinical trials among respondents in the New Juaben South Municipal Assembly. There were more males than females in this study which compares with other similar surveys which all reported more male respondents than females [19,20]. This observation could probably be due to higher uptake of research among males than females. Similarly, in this study there were more respondents of Christian religious affiliation than others. This is consistent with the overall religious affiliation in the municipality, where majority are of the Christiana affiliation [16]. Most of the respondents were educated to at least the secondary education level. This is reflective of the urban nature of the study area. On the other hand, majority of the respondents had not participated in any clinical trials in the past.

Notwithstanding the fact that only 14.40% of the respondents had ever participated in a clinical trial, there was an overall average level of knowledge about clinical trials among the participants; Chatio and colleagues have also reported a positive knowledge of clinical trials in Northern Ghana [21]. A similar study conducted in Saudi Arabia also reported satisfactory knowledge level of respondents about clinical trials [18]. The level of knowledge displayed among the respondents could be due to the fact that, majority of the respondents had at least a secondary level of education. With this level of education among the respondents, they were more likely to have come across, read or heard about clinical trials. Our study was a strong significant association between education level and the level of knowledge about clinical trials.

On respondents' attitude towards participation in clinical trials, we found that most of the respondents would be willing to take part in a clinical trial if they were given enough time to think about their decision. We deem it important that participants are helped to understand the pros and cons of participating in clinical trials as understanding the study was the most important element to the respondents in their decision to participate in the trials. Kummervold and colleagues pointed out that lack of education about the nature, risks and benefits of the clinical trial was a factor in the suspension of the Ebola vaccine trial in Ghana [15]. The implication of these findings on the conduct of future clinical trials in urban communities in Ghana is that researchers would have to provide adequate time and explanation to participants in order to enhance participation. In a study assessing the attitude of cancer patients in participating in randomized control trials, it was reported that providing additional information to the understanding of participants enhanced participation among those who initially refused to participate [22]. Other similar findings about participants understanding the clinical trial have been reported [18,23]. If the clinical condition under trail was considered life threatening, a good number of respondents would consider participating in a clinical trial. On the other hand, manipulating or getting people to feel bad by always asking them to participate in a clinical trial during a visit to the health facility was not motivating enough to get them to participate in clinical trials as only a few respondents chose this as their motivation to participate.

Our study reports key reasons for respondents' participation in a clinical trial to be "Helping the society" and "Help in advancing the medical knowledge". This finding is in contrast to the report by Jones and colleagues who reported "the wish to have a good relationship with your treating physician" and "the wish to have your health monitored closely by study physicians and nurses'' as their key reasons to participate in clinical trials [24]. The difference in response could probably be due to the different populations used in the two reports. While our participants were apparently healthy participants from the general population, the latter participants were patients receiving various treatments from an urban hospital.

There was the perception of mistrust of the medical system and this was a major reason some respondents will not be willing to participate in a clinical trial. The mistrust in the medical system for clinical trials could be due to the lack of knowledge about the safeguards in the conduct of clinical trials. From our study, although institutional review boards (IRBs) are available to ensure trials are safe and conducted within acceptable ethical standards, majority had no idea of their existence and their role in clinical trials. Similar mistrust in pharmaceutical companies and the government in the conduct of clinical trials have been reported in Mauritius [25]. Notwithstanding the mistrust expressed by some

Table 4
Summary of respondents' perception towards participating in clinical trials.

Reasons to participate in clinical trials	Number(%)
Helping the society	361(56.49)
Help in advancing the medical knowledge	383(59.95)
Others may benefit from participation	226(35.37)
Helping in developing new medications	327(51.17)
Receiving best medical care	172(26.92)
Getting financial compensation	175(27.39)
Reasons not to participate in clinical trials	
Fear from risks of participation	313(48.98)
Fear from the unknown	326(51.02)
Medical reasons	263(41.16)
Mistrust the medical system	352(55.09)
No financial compensation	153(23.94)
Moral reasons	146(22.85)
Patients who participate in clinical trial get the best care	45(7.04)
Participation in clinical trials could cause patient exhaustion	55(8.61)
Opinion about clinical trials conductions	
Clinical trials are conducted in a responsible and ethical manner	180(28.17)
I don't have an opinion regarding clinical trials	470(73.55)
Clinical trials are conducted by unqualified personnel	35(5.48)
Clinical trials are conducted in unethical manner	22(3.44)

Respondents could select more than one answer.

respondents, there was a general neutral perception towards participation in clinical trials as expressed by the participants who selected "I don't have an opinion regarding clinical trials as their opinion about clinical trials. A good percentage of the respondents had a positive perception towards participation in clinical trials as shown in the number that selected "clinical trials are conducted in a responsible and ethical manner. The implication of this finding is that, a lot more transparency in clinical trial process such as providing adequate information about the benefits and risks associated with the clinical trial would greatly enhance participation.

3.7. Factors to consider to improve participation in clinical trials

Following the findings from this study, future groups interested in conducting clinical trials should take all the necessary steps to ensure that enough information is provided to participants in order to enhance their understanding of the benefits and risk in participating. Since most of the respondents are already aware of the FDA and its role in clinical trials, it is recommended that the FDA leads risk communication and education about participation in clinical trials incorporating all the safeguards and ethical guidelines that IRBs provide and ensure in clinical trials. Lastly, future educational and sensitization programmes toward the initiation of clinical trials should highlight the importance of clinical trials in the development of new drugs and vaccines which are all critical for human health as well as disabusing the minds of the population about mistrust and myths surrounding participating in clinical trials.

4. Conclusion

This study has shown an average knowledge level of participants within the New Juaben South Municipal Assembly about clinical trials. There is a general positive attitude and an overall neutral perception towards participation in clinical trial.

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Declaration of competing interest

Authors declare no conflict of interest.

Data availability

Data will be made available on request.

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