



Willingness of young persons in Western Nigeria to participate in HIV vaccine trials

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ABSTRACT

Background

An estimated 36.7 million people live with HIV/AIDS in 2015, with more than 3 million people living with the virus in Nigeria, ranking the country among the top three most affected. Because adults are mostly affected by this epidemic, their inclusion in HIV vaccine trials is of utmost importance in obtaining an effective and acceptable vaccine. This study was thus aimed at evaluating the factors determining adults (young persons) willingness-to-participate (WTP) as well as their entire knowledge and perception about HIV vaccine trials.

Methods

Data was obtained from 3500 young persons (18-49 years) recruited by a multi-stage sample technique. The cross-sectional study was carried out using a face-to-face interview. An informed consent was obtained through a pre-tested structured questionnaire, with questions addressing socio-demographics, HIV vaccine studies knowledge and perception, sexual behaviour and possible stigma from HIV vaccine trial participation. Data was analysed using SPSS software, with significance fixed at $P < 0.05$.

Results

The mean age \pm SD was 27.53 ± 3.46 years. 1094 (31.3%) expressed their willingness to definitely participate in the vaccine studies while 999 (28.5%) reported that they may participate especially if a very tangible incentive will be given. Unwillingness to participate was associated with safety concerns (12.0%), side effects (5.0%), fear of HIV infection from vaccine (4.1%), time required for study (1.9%) and partner's sexual intercourse refusal (1.2%). 983 (28.3%) reported people in good health, HIV negative individuals and at low risk of HIV infection, are eligible for HIV vaccine trial. There was a significant association between willingness to participate in HIV vaccine trials and age as well as gender.

Conclusion

Participation in an HIV vaccine trial in a Nigerian context is likely to be influenced by comprehensive education about the vaccine trial concept, addressing issues relating to concerns and possible risks pertaining to

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participation as well as incentives, as the WTP in the vaccine trial is quite low probably due to the participants' perception and inadequate knowledge as evidenced in this research.

Keywords: Vaccine, Trial, Willingness, Young Person

INTRODUCTION

Since the beginning of the Human Immunodeficiency Virus (HIV) epidemic, more than 70 million people have been infected with HIV virus and about 35 million people have died of HIV, thus, this epidemic continues to be a major global public health issue. In 2015, an estimated 36.7 million people were living with HIV (including 1.8 million children), a global HIV prevalence of 0.8% of adults aged 15-49 years worldwide living with HIV. The vast majority of this people live in Low and Middle Income Countries (LMICs) with sub Saharan Africa being the most severely affected, nearly 1 in every 25 adults (14.4%) living with HIV and accounting for nearly 70 % of people living with HIV worldwide, with Nigeria ranking among the top three countries with the highest number of infections.^{1,2} Because adults are mostly affected by this epidemic, their inclusion in HIV vaccine trials is of utmost importance in obtaining an effective and acceptable vaccine.

A research carried out in Dar es salaam, Tanzania showed that 50.6% participants expressed willingness was positively correlated.³ In Soweto, 35% of the participants indicated that they were probably willing to participate in the HIV vaccines while 52.5% were definitely willing to participate. It was reported that there were misconception regarding vaccine research particularly regarding placebo and potential eligibility criteria for prophylactic vaccine trials. These were also no significant differences in willingness by gender, age, school grade or institution.⁴ A research work carried out in south western Uganda, showed that 95% of participants were willing to participate in preventive HIV vaccine trial.⁵ A study on the willingness to participate in HIV-1 vaccine trials among Thai young man revealed that only 32% of respondents reported that they would definitely join an HIV-1 vaccine trial, with tangible incentives and intentions to reduce condom use in a vaccine trial were associated with increased willingness to participate.⁶ In Uganda, 60.2% of the participants thought that HIV- positive

persons were eligible for the vaccine could help control HIV.⁷ A study carried out in Abuja, Nigeria showed that 55% participants expressed willingness to participate in a hypothetical vaccine trial, with age, population group and ethnicity significantly associated with willingness-to-participate (WTP).⁸ 35% respondents reported that they will be willing to join HIV vaccine trials, greater willingness associated with higher levels of awareness about HIV/AIDS and tangible incentives while decreased WTP was associated with concerns about physical harm, social stigmatization, among others.⁹ The aim of the study was to determine the proportion of young adults in Western Nigeria willing to participate in HIV vaccine trial and evaluate the factors determining the willingness to participate.

RESEARCH HYPOTHESIS

- 1) Knowledge about HIV vaccine studies does not influence willingness to participate in HIV vaccine trials
- 2) There is no association between age and willingness to participate in HIV vaccine trials
- 3) There is no association between gender and willingness to participate in HIV vaccine trials

MATERIAL AND METHODS

This cross sectional study was carried out in towns across Ekiti State, Western Nigeria. The target population was young 18 to 49 year old adults. A pre-tested questionnaire was administered consecutively on 3500 respondents. Data was collected in accordance with ethical standards by trained volunteers and supervised by appointed supervisors and investigators, by a face-to-face interview using a pre-tested structured questionnaire on the knowledge about HIV/AIDS, HIV vaccine studies knowledge & perception, possible stigma from HIV vaccine trial, sexual behaviour, factors influencing willingness to participate in early HIV vaccine trial (EHVT), among others.

A multi-stage sampling technique was used to select the respondent from selected local government areas

(LGAs) in each of the three senatorial districts in each of Ekiti State in Western Nigeria. In stage 1 from a sampling frame of the entire number of local government areas in each senatorial districts of the state, one-third number of LGAs was selected using simple random sampling method. In stage 2, a list of towns in each of the selected LGA's was randomly made. In stage 3, houses in the towns were randomly selected. The final stage involved in the selection of consenting adults (18 – 49 year old).

Sample Size

Sample size calculation was done using 95% confidence interval, 0.05 precision and prevalence rate. The report of the 2014 study revealed 50.6% of the participants expressed willingness to participate in HIV vaccine trials.³ Using Leslie Fischer's formula for population >10,000, the formula for sample size calculation is: $n = Z^2PQ/d^2$.¹⁰

$$n = Z^2PQ/d^2$$

Where:

n = minimum sample size, d = degree of precision (taken as 0.05),

Z = standard normal deviation at 95% confidence interval which is 1.96,

P = proportion of the target population (estimated at 50.6% which is 50.6/100 = 0.506),

Q = alternate proportion (1-P) which is 1-0.506= 0.494

$$n = \frac{(1.96)^2 (0.506)(0.494)}{(0.05)^2} = 384$$

Also, adding a 5% non-response rate, the minimum sample size (n) will be 5/100 X 384 = 19

Thus, it will be 19 + 384 = 403 = n

Statistical Analysis

Data was statistically analysed using Statistical Package for the Social Sciences (SPSS) for windows version 23.0 software (SPSS Inc., Chicago, IL, USA). All data were expressed as Mean ± Standard Deviation (SD). Frequency counts were generated for all variables and statistical test of significance was performed with Chi-Square test. Significance was fixed P < 0.05 and highly significance when P < 0.01.

RESULTS

Socio-Demographic Data

A total of 3500 consenting respondents participated in the study. Most of the respondents are in the age range of 18 – 24 years, 2586 (73.9%), with a mean age ± SD of 22.04 ± 5.25 years. Most of the respondents' highest education level is diploma certificate, 1504 (43.0%) followed by secondary/high school leaving certificate, 1247 (35.6%).

Table 1 Demographic Characteristics of the Study Population

Variables	Frequency (%)
Age Group (Years)	
< 20	1506 (43.0)
20 – 24	1080 (30.9)
25 – 29	434 (12.4)
30 – 34	370 (10.6)
35 – 39	81 (2.3)
≥ 40	29 (0.8)
Gender	
Male	1142 (32.6)
Female	2358 (67.4)
Highest Level of Education	
No formal education	52 (1.5)
Primary	42 (1.2)
Secondary	1247 (35.6)
Diploma	1504 (43.0)
Degree	587 (16.8)
Masters	68 (1.9)

HIV Vaccine and Sexual Behavior Data

One thousand and ninety-four (31.3%) reported they will definitely participate in HIV vaccine trial, nine hundred and ninety-nine (28.5%) said they may participate while one thousand and thirty (29.4%)

said they are not willing to participate in the vaccine trial. Majority of the respondents listed weight loss, fever, sores, rashes, nausea, malaise and vomiting as symptoms of HIV/AIDS.

Table 2 HIV Vaccine Data

Variables	Frequency (%)
Do vaccines generally protect against disease	
Yes	2105 (60.2)
No	497 (14.2)
Don't know	696 (19.9)
No Response	201 (5.7)
Do vaccines generally protect against infection	
Yes	2220 (63.4)
No	483 (13.8)
Don't know	570 (16.3)
No Response	227 (6.5)
Are most vaccines prophylactic (prevent person from getting disease)	
Yes	2382 (68.1)
No	287 (8.2)
Don't know	584 (16.7)
No Response	247 (7.0)
Are most vaccines therapeutic (increase body's immune response to disease already present)	
Yes	1899 (54.3)
No	664 (19.0)
Don't know	520 (14.9)
No Response	417 (11.9)
Can killed or weakened HIV viruses be used in a vaccine	
Yes	1061 (30.3)
No	752 (21.5)
Don't know	1340 (38.3)
No Response	347 (9.9)
Will HIV vaccine protect individuals who do not have HIV from contracting it	
Yes	945 (27.0)
No	1246 (35.6)
Don't know	825 (23.6)
No Response	484 (13.8)
HIV vaccine may have a therapeutic effect for persons who have or later contract HIV	
Yes	965 (27.6)
No	508 (14.5)
Don't know	1401 (40.1)
No Response	623 (17.8)
Eligibility for HIV vaccine trial	
Person in general good health (male & female)	545 (15.6)
HIV Negative individual	590 (16.9)

People at low risk	412 (11.8)
People between 18 to 50 years old	492 (14.1)
Is there an effective HIV vaccine currently	
Yes	341 (9.7)
No	1721 (49.3)
Don't know	614 (17.5)
No Response	824 (23.5)
Will you use an effective HIV vaccine if available now	
Yes	1257 (35.9)
No	1008 (49.3)
Don't know	720 (20.6)
No Response	515 (14.7)

Table 3 Chi Square Results Showing Influence of HIV Vaccine Knowledge, Age and Gender on the Willingness to participate in HIV Vaccine Trial

Variables	χ^2	df	Critical Value	Decision
Influence of HIV vaccine trial knowledge on willingness to participate	782.02	12	21.03	Rejected
Influence of age on the willingness to participate	824.72	20	31.41	Rejected
Influence of gender on the willingness to participate	78.21	8	15.51	Rejected

The null hypothesis is rejected when the test statistic is greater than the tabled value or critical value.

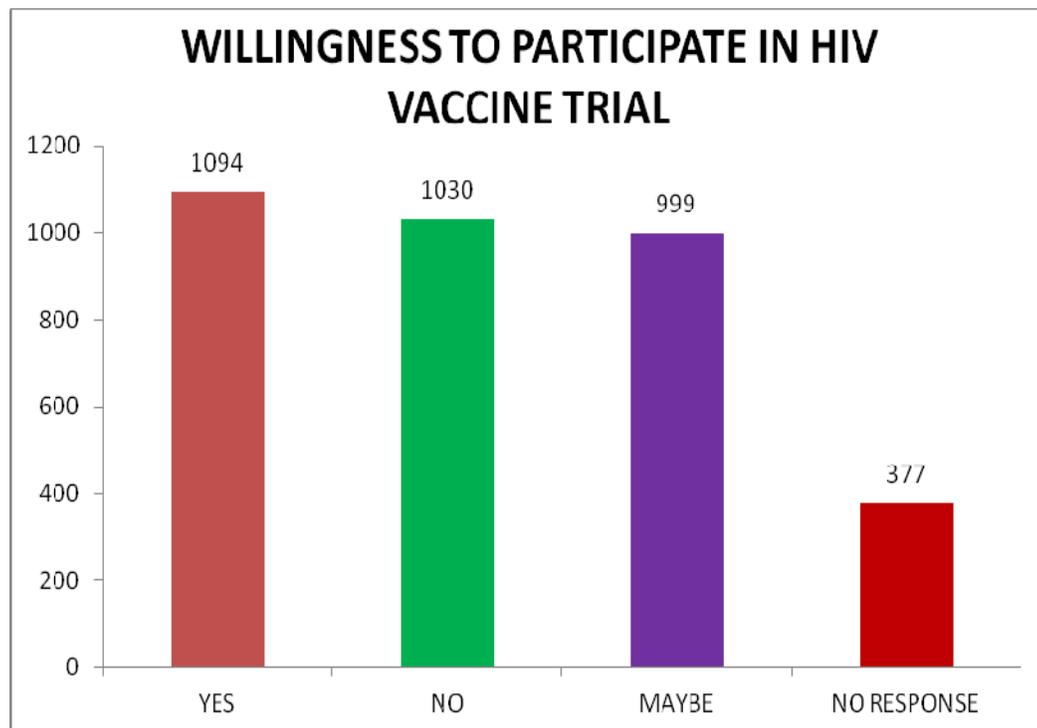


Fig 1 Willingness to Participate in HIV Vaccine Trial

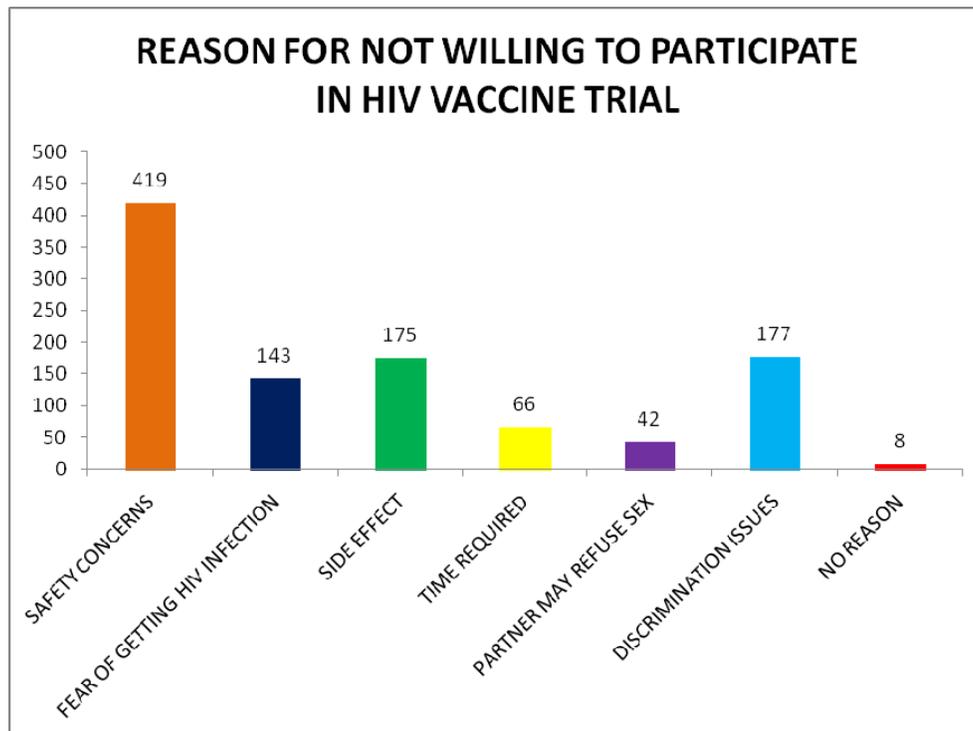


Fig 2 Reasons for Not Willing to Participate in HIV Vaccine Trial

DISCUSSION

This research outcome has shown a 31.3% definitely willing to participate while a further 28.5% may also participate especially if tangible incentive is given. This is similar to other previous studies, 50.6% willingness reported in Tanzania,³ 52.5% willingness in South Africa,⁴ 35% & 55% willingness of participants reported Nigeria,^{8,9} and 32% willingness reported in Thailand⁶ while the outcome is not in agreement with other research work, such as 95% participants willing to participate in the HIV vaccine trial in Uganda.⁵

This study revealed that greater willingness is associated with higher levels of information/awareness of participants especially about HIV/AIDS and HIV vaccine trials, as well as, tangible incentives while decreased willingness is associated with concerns about discrimination & stigmatization, physical harm by the vaccine or side effects, safety concerns etc, as evident in the rejection of first hypothesis on the knowledge about HIV vaccine studies, which revealed that information

about HIV/AIDS and HIV vaccine studies are crucial in determining the willingness to participate in such vaccine trial studies. The findings of this study also reflect some degree of misconception about vaccine trials partly due to the fact that clinical trials are not commonly done in this country, thus, making it more important to further stress the need to orientate the society at large about the importance of conducting and participating in such trials and shedding light on the imminent anxiety, especially as only 49.3% know there is no effective HIV vaccine currently, 27.6% know that HIV vaccine may have a therapeutic effect for persons who have or later contract HIV, 27.0% know that HIV vaccine will protect individuals who do not have HIV from contracting it and only 19.0% know that most vaccines don't have therapeutic effect.

In the eligibility for HIV vaccine trial, only 15.6% respondents know that both male and female in general good health are eligible, 16.9% reported that HIV negative individuals and 14.1% specified people between ages 18 to 50 years, as eligible for the

vaccine trial. This is similar to the Soweto study outcome which reported misconception regarding vaccine research particularly regarding potential eligibility criteria for prophylactic vaccine trials,⁴ as well as the Uganda study report that showed 60.2% of the participants thought HIV-positive individuals were eligible for the vaccine trials,⁷ which further underlines the significance of educating particularly young people about the concept of vaccine trials. Furthermore, only 35.9% of the respondents reported that they will use an effective HIV vaccine if available now, mainly as a result of fear of HIV infection through the vaccine.

The rejection of the first hypothesis on the knowledge about HIV vaccine studies not influencing the willingness to participate in HIV vaccine trials shows that information about HIV/AIDS and HIV vaccine studies are crucial in determining the willingness to participate in such vaccine trial studies. The rejection of both hypotheses on the association between age/gender and willingness to participate indicate that both age and gender have association with the willingness of participants, as there are more females and more respondents less than the age of 24 years old in this study, more associated with willingness to participate in the HIV vaccine trial studies.

CONCLUSION

Participation in an HIV vaccine trial in a Nigerian context is likely to be influenced by comprehensive education about the vaccine trial concept, addressing issues relating to concerns and possible risks pertaining to participation as well as incentives, as the WTP in the vaccine trial is quite low probably due to the participants' perception and inadequate knowledge as evidenced in this research.

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