

**Participating in HIV Prevention Clinical Trial: Reasons and Experiences among  
Female Participants in Antibody Mediated Prevention Study at UNC Project,  
Lilongwe, Malawi**

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## **Abstract**

**Aim:** The overall aim of the study was to assess the reasons and experiences of participants involved in Antibody Mediated Prevention (AMP) HIV prevention clinical trial at University of North Carolina (UNC) Project, Lilongwe, Malawi. We determined the participants' reasons for participating in HIV Prevention clinical trials; and the experiences of participants in HIV Prevention clinical trials.

**Methods:** We adopted the qualitative cross-sectional study method. Data were collected using in-depth interviews (IDIs). Purposive sampling was used to select 12 study participants who consented to take part in the study. All participants were the ones taking part in the AMP HIV prevention study at the UNC Project. Data analysis was done concurrently with data collection using content analysis.

**Results:** Individuals were motivated to participate in HIV research due to a range of perceived benefits. These included personal, health, and financial benefits. Participants' research experiences and their continued participation in HIV research were influenced by the research clinic context and the nature of their interactions with research staff.

**Conclusion;** When the clinical trial study participants' expectations are met through what they experience in the study, the chances of them adhering to the study visits and procedures are high. Even for those who did not have any expectations prior to the study, feeling welcomed and being able to open up to the study staff encouraged their continued participation. In the end, this outweighed the negative comments made by the people in their communities or their friends

## **Keywords:**

HIV/AIDS, Community Health Worker, Clinical Trial, Informed Consent, HIV Positive, STI

## Introduction

Since the beginning of the HIV epidemic, over 75 million people have been infected with HIV and about 32 million people have died due to the virus [1]. At the end of 2018, more than 37.9 million people were living with HIV[1]. Increasing rates of HIV infection have characterized the Acquired Immune-Deficiency Syndrome (AIDS) epidemic in Sub-Saharan Africa with an estimated 25.5% of 78 million HIV infected people living in sub-Saharan Africa [2]. Malawi is one of the African countries that have been affected by the epidemic of HIV and AIDS, with 900,000 people aged 15-64 currently living with HIV in the country [3].

Several HIV prevention strategies have proved highly effective in reducing the risk of, and protecting against HIV infection. These methods include the use of male and female condoms, antiretroviral medicines use as pre-exposure prophylaxis (PrEP), voluntary male medical circumcision (VMMC), behaviour change interventions aimed at reducing the number of sexual partners, the use of clean needles and syringes, and the treatment of people living with HIV to reduce viral load and prevent onward transmission [4]. There remains a gap in women initiated HIV prevention technologies especially for women who are unable to negotiate the current HIV prevention options of abstinence, behaviour change, condoms and medical male circumcision or early treatment initiation in their relationships [5]. This calls for the need for more HIV preventive interventions and understanding the experiences of the women currently in their (HIV preventive interventions) trials for better implementation of the interventions under study if it becomes a success.

Clinical trials are a crucial step in providing scientific evidence of diagnostics and therapeutic safety and efficacy in humans [6]. Participants' involvement and retention are crucial in HIV clinical trials, hence improved understanding of research participants'

experiences with respect to autonomy, safety, and satisfaction can help researchers: enhance human subjects protection, including informed consent; enhance recruitment and retention; improve the quality of clinical research processes; and increase public trust in the research enterprise [7]. HIV Prevention Trials Network (HPTN) studies evaluate new HIV prevention interventions and strategies in populations and geographical regions that are bearing a disproportionate burden of infection. This is intended to facilitate rapid scale-up of proven interventions and to have the greatest possible impact on the pandemic [8].

One of the clinical trials is the Antibody Mediated Prevention (AMP) study [9]. The AMP study, also known as HIV Vaccine Trials Network (HVTN) 703/HIV Prevention Trials Network (HPTN) 081 is the idea of giving people antibodies called VRC01, that fight HIV to see if they will protect people from becoming HIV infected [10]. The study enrolled healthy, HIV un-infected, non-pregnant nor breastfeeding women in sub-Saharan Africa including Malawi, who are at risk of HIV-1 infection [10,11]. Understanding the socio-economic and cultural context in which these products are being evaluated, and are likely to be introduced is crucial to identifying the factors that may facilitate or hinder their use in future.

The perceptions and experiences of women taking part in HIV prevention trials were explored in Soweto, South Africa whereby the central finding was that the participants felt the sense of empowerment in spite of their being embedded in a culture that has come to fear, deny, or ignore AIDS [12]. Currently, there is no information on reasons and experiences of research participants in the AMP study at UNC project, Malawi. Therefore, this study aimed at filling this gap in the Malawian context.

The aim of the study was to source information on the reasons, experiences, and challenges of female participants in AMP study, Lilongwe research site. This information will hence be useful for the design and implementation of future HIV prevention clinical trials, as well as the provision HIV prevention and care for women and the Malawian population at large.

## **Methods**

### **Type of research study**

This was a qualitative cross-sectional study which used in-depth interviews (IDIs) to collect data. A cross-sectional study design is a type of observational study design in which the investigator measures the outcome and the exposures in the study participants at the same time. The participants in a cross-sectional study are selected based on the inclusion and exclusion criteria set for the study. Once the participants have been selected for the study, the investigator follows the study to assess the exposure and the outcomes. In this study, the exposure was their participation in the study, while the outcomes were their experiences in the main AMP study [13]. Qualitative research is critical in unpacking social contexts and understanding phenomena in their natural setting [14]. The research design enabled the investigator to gain an in-depth understanding of participants' reasons and experiences in participating in HIV prevention clinical trials, mainly the AMP study.

### **Study place and population**

The study was conducted at UNC Project within the Kamuzu Central Hospital (KCH) campus, Lilongwe - Malawi. The study was conducted among female participants involved in the AMP study; one of the HIV prevention clinical trials being conducted on site. [10].

The study recruited women among the 100 participants who were enrolled and actively participating in the Antibody Mediated Prevention (AMP) study, an HIV prevention trial currently being conducted at the UNC Project, Lilongwe. The enrolled participants in the main AMP study are given cash stipend as transport reimbursement. Purposive sampling method was used to select approximately 20 participants aged 18 to 35 years from the 100 participants enrolled in the main AMP study. Purposive sampling is a non-random sampling which employs a deliberate choice of an informant based on the qualities the informant poses [15]. This is the technique whereby informants with desired characteristics and knowledge regarding the problem and research question are selected. Therefore, the selection of participants is based on the likelihood of the informant to provide adequate information required to respond to the research question. Only 12 participants were interviewed out of the planned 20 participants because saturation was reached on the way as the responses became similar.

### **Inclusion and Exclusion criteria**

Participants were eligible to participate upon meeting the set inclusion criteria. Eligible participants were female participants enrolled in AMP study; 18 to 35 years of age; and willing to participate in the study. The study excluded participants who were not willing to participate in the study, and all participants not available during the study period.

### **Study period**

The research study was conducted for a period of 5 months (from September, 2018 to February, 2019). The activities started from the beginning of research assistant training and data collection using In-depth Interviews (IDIs), transcription of data, data analysis, and report writing.

### **Sampling strategy**

A total of 12 female participants enrolled in AMP HIV Prevention clinical trial were purposively selected from a list of all participants in the study. The participants were selected based on the fact that they share the same characteristics. This was done so to ensure that each participant involved in the AMP HIV prevention clinical trial was given an equal chance of participation. The accepted technique used in qualitative research to determine sample size is that of saturation [16]. Data saturation refers to the point in the research process when no new information is discovered in data analysis, and this redundancy signals to researchers that data collection may cease. It is a point at which observing more data will not lead to discovery of more information related to the research questions [17,18]. During the study, data saturation was reached after interviewing 12 participants. Data saturation is reached when there is enough information to replicate the study when the ability to obtain additional new information has been attained, and when further coding is no longer feasible [16]. Qualitative inquiry assumes that information is collected until redundancy and saturation are reached [16,19].

### **Data collection**

Data addressing the study objectives was collected using in-depth interviews which were conducted in Chichewa language. IDIs are a form of discussion or directed conversation between a researcher and a respondent designed to reveal the underlying motives of the interviewee's attitudes, behaviour, and perceptions [20]. The IDIs were used to deeply explore the point of view, feeling, and perspectives of participants. The IDI allowed the participants to express their story in their own voice. This helped in exploring the participants' experiences of participating in the HIV prevention clinical trials. The study used 12 in-depth interviews with its respondents to collect data. The PI and research assistant who was not directly involved in the AMP study, and was

selected based on research experience and orientation on the questionnaires, conducted data collection and transcription from 29<sup>th</sup> October - 18<sup>th</sup> December. The interviews were conducted during AMP study clinic visits at the UNC Project, Lilongwe. All interviews were audio recorded to ensure that vital information is not lost during transcription.

### **Data management and analysis**

The study PI conducted spot checks during data collection to ensure compliance to the study protocol. At the end of each day a meeting was set up with the research assistant to address any challenges faced during data collection. During this process, the PI and the research assistant debriefed on how the interviews were being conducted. Any issues were addressed before the next data collection process. The interview recordings were translated from Chichewa to English by the PI and to ensure consistency of data, the translations were checked by an independent person. Transcription of the data was carried out by the PI and the research assistant concurrently with data collection. Audio recordings were translated verbatim. Each transcription was labelled with the interview identification code which was assigned to the participant during the interview. Transcribed data was checked by the PI against the recorded data to ensure that there was no misinterpretation of data.

Data was analysed using inductive content analysis, which is also known as the bottom up approach of content analysis. In inductive reasoning, specific observations and measures are evaluated, then patterns and regularities are detected, which is followed by formulation of some tentative hypotheses that can be explored, and finally general conclusions or theories developed [21]. A thematic analysis approach was followed during the data analysis process to extract key themes and the supporting themes. Thematic analysis is the process of identifying patterns or themes within qualitative



data. This involves a rigorous process of data familiarization, data coding, theme development, and theme revision [22]. Subsequently, codes were generated as they emerged from the data, and grouped thematically within and across study areas. Analysis entailed development of a codebook, coding of the data, developing a list of emerging themes, categorizing the themes within a hierarchical framework of main and sub-themes, looking for patterns and associations between the themes, and comparing and contrasting within and between the different groups of participants. Findings from the analysis were summarized, compiled and used to develop recommendations and final report.

### **Study limitations**

The conduct of the study was dependent on participants' AMP study visit schedules, therefore we had to wait for the participants to report, but the interviews were successfully done.

### **Ethical considerations**

The involvement of contact with human subjects in research studies requires that the internationally accepted ethical standards in conducting all study activities are followed. Ethical clearance for conducting the study was sort from the College of Medicine Research and Ethics Committee (COMREC). Further permission was obtained from the Country Director of UNC Project for the study to be conducted in the respective HIV prevention clinical trial. To ensure study participants' privacy, all study staff were carefully trained in human subjects' protection, especially the importance of protecting privacy and confidentiality and obtaining informed consent from each study participant using the approved consent forms. Research participants were informed of all risks and protections in the written consent form. Participants were also informed of their right

to withdraw from the study and not to answer any questions they did not feel comfortable answering. Confidentiality of the individual responses was observed to the greatest extent possible. This was done by the use of random numbers instead of the participants names. All data and other information was maintained confidentially and kept anonymous.

## **Results**

### **Characteristics of participants**

Twelve AMP study participants consented and participated in this study, all of which were HIV non-infected females. The participants' demographic characteristics collected were age which ranged from 18 to 35 years, education, and employment status. Table 1 summarizes the participants' demographic characteristics.

#### **<TABLE1>**

### **Level knowledge on the AMP study objectives**

Majority of the participants from the sampled number managed to explain what research means to them which showed that they were knowledgeable of the research study and its activities. *"There are different types of research. Some say that research aims at finding medicine for different diseases."* (Respondent number 3); *"...to know how something would be or how it would work if they were to start using it."* (Respondent number 6). Most of the study participants knew about the AMP study. They could explain the main objective of the AMP study, and what happens during their study visits. However, some participants lacked knowledge on the research study. Unlike most of the participants who expressed knowledge on the study, one respondent had to say this as her understanding of the research study, which displayed lack of knowledge. *"The AMP study, I know that [silence] like, how to prevent...how we can*

*prevent the diseases, they give us umm, they give us the drips so that if someone has HIV, they should not transmit it to us. Like, we have also read some books before on ways of preventing yourself from contracting diseases using this medicine, and things like that.” (Respondent number 4)*

### **Source of study information**

The study participants were informed of the AMP study either through their friends in their communities who had the information on the study or were already participating in one of the studies at the UNC Project; or through the community educators from the project.

### **Motivators to study enrolment**

Participants in the study had various reasons that motivated them to enrol into the study, majority of which said they anticipated to benefit more towards their health as they made their decision to join the study. Other motivators included financial benefits and just willingness to help the society.

#### **Health benefits**

*“When they take the blood samples, they test for different diseases and they find diseases which you did not even think you would have; Gonorrhea, syphilis, even AIDS. So that is what I liked.” (Respondent number 2)*

#### **Financial benefits**

*“I was told that you are given money and gifts which can make you enjoy.” (Respondent number 10)*

#### **Willingness to help the society**

*“I just prepared myself to take part since I was told that the drug that I will be getting might benefit a lot of people if they work better in my body.”*

*(Respondent number 8)*

### **Experiences during the study**

All participants expressed that the study intervention; Vaccine Research Center 01(VRC01) that is given through drips is user friendly since they have not encountered any problems from the time when they started getting the drips. Friendliness of the research staff was mentioned as one the factors that motivated the participants to remain in the study. Apart from that, they explained that they would recommend HIV prevention trials participation to their families and friends if given a chance. Some of the respondents had the following to say during the interviews;

*“My thoughts are that it is good, I should not lie, and I don’t experience any problems.” (Respondent number 4)*

*“Mmm, it has no problem. I should just say it is good, it does not have problems. We people have different bodies, but to me as an individual, it has no problem, I don’t have any problems with it.”(Respondent number 6)*

*“From what I have benefited from the study, I would encourage my friends and even my family members to join these kinds of studies. I would tell them the importance of the research studies, the rest would be up to them to decide.”*  
*(Respondent number 12)*

### **Benefits from participating in the study**

Participants in the study expressed having benefitted from the AMP study both, personally and health-wise. Personal benefits were cited by few respondents which

included desire to gain financial assistance, and a passion for personal behavior change as shown in the excerpts below.

*“The good that I experienced in this study, I am not married, I just have casual partners, which is also why I enrolled in this study. My marriage ended a long time ago, in 2007, I have little children. One has gone to school, one started working and the other one is in college. So, on the benefit of this study, the money you give me here, I am able to buy relish with that for 3 or 4 days and the children eat”. (Respondent number 5)*

*“The benefit I have experienced, from the money I get here, I am able to buy clothes. Sometimes I am also able to share my mother.” (Respondent number 7)*

*“....all my thoughts and all my heart and all my mind, I want to be that one girl in my community who is an example. That is what I think of. I should prove everyone wrong [defeat everyone] and be...even though people say that I have a bad reputation, I want that within that bad reputation, I should prove people wrong.”(Respondent number 3)*

The desire to know their HIV status, empowerment to protect themselves from HIV infection, and the health care that they get when needed were the health benefits that were uncovered as illustrated by the following excerpts.

*“...when we are sick, they give us enough medications.” (Respondent number 2)*

*“We are warmly welcomed, get the right assistance, we get the right treatment when we are sick.” (Respondent number 9)*

*“The benefits I have seen are that...it is good because it encourages me to protect myself against HIV. Thinking of it, it is really good to protect myself. So I think that to me, it is good.” (Respondent number 4)*

### **Challenges from the study**

While majority of the participants reported that they never experience any challenge during their participation in the AMP study, some participants said that they were getting negative comments from their communities due to their participation in the study.

*“Our friends were the one saying a lot of things... they were saying that they are drawing our blood here and that when we are sick, we will have no one to share us blood.” (Respondent number 2)*

*“In the communities they say that they collect drips of blood from us and sell it to sick people, and yet they don’t collect drips of blood from us... There is no challenge which I have experienced here, it is only when we are home and people are saying all those things. But there is no other challenge.” (Respondent number 7)*

### **Lessons learned and knowledge gained from the study**

Some participants expressed change in their life style due to their participation in the HIV prevention AMP study. In particular, the women discussed how they experienced an improved awareness of their individual sexual health. This is because of the emphasis in the study on examining and treating women for Sexually Transmitted Infections (STI), and HIV testing and condom counselling. The HIV prevention education, HIV tests and its influence on how the women felt about their current relationships and risk of HIV acquisition were most noticeable in the interviews. They

related how HIV and STI testing has had a significant impact on their sexual relationships and positive change of behaviour. Many talked about their commitment to using prevention strategies offered to avoid infection apart from being in the study where they were receiving a product (VRC01) under trial to test if it can effectively protect individuals from HIV infection. The following quote from an interview with one of the study participants was part of these of these responses:

*“This study has still helped me because like I said, I had 5 boyfriends and I would have unprotected sex with them and I was not even getting tested... If I still led the same life I had before the study, would I be saying that I want to be an example? That would not have been possible because I don’t know what the others were doing and it’s not like we were getting tested together, no.”*  
(Respondent number 3)

Respondent 3 commented on the effect of the study on her sexual behaviour:

*“Since I enrolled in the study, I follow the counsel they give us here. They said that just because we are in the study, it does not mean that we should just be having unprotected sex. They give us condoms and so we should use those to protect ourselves. So we listen to what they tell us. You cannot use condoms every day [laughs], there is still someone you can decide to just have sex without a condom with. That is very risky however because you don’t know their status and you can only know if you have come and gotten tested together with them.*

## Discussion

According to a report by The National Institute for Health Research (NIHR) a record number of patients are now taking part in clinical trials. This has seen a rise of the number of trials conducted as well as the number of participants in such trials compared to the previous years [23]. This change can be attributed to the safety measures looked

into before and while each trial is underway or general awareness by the general communities on what research is and why to take part. However, it was observed in this study that while those factors are important, there are other reasons why people decide to take part in any trial.

Despite hearing of the trial from different people – some heard it from friends, relatives and others heard it from the community team – that did not have an impact on their decision to whether to enrol or not, crossing out influence from others as a reason for enrolment. When interviewed, participants in the AMP study gave a range of reasons as to why they took part in the study as well as what they were expecting as presented in the findings.

### **Reasons for participating in the study**

#### ***Health benefits***

The participant's health was a key factor in their decision to enrol in the study or not. Either because they felt at risk of contracting HIV or prior to being enrolled, they had been diagnosed with another disease. Of the participants interviewed, most of them perceived to be at risk of contracting HIV and so they needed to protect themselves. Knowing themselves to have more than one sexual partner, they felt at risk of contracting HIV and so taking part in the AMP trial provides them the ability to protect themselves regardless of not knowing whether they are being given active drips or placebo.

Not knowing the kind of drip they are being given came up as a concern for some participants who felt that if they knew, they would protect themselves better. However, as part of the study, they are encouraged to use condoms which they were given. This gave them the surety that if not the medicine in the drip, at least their condom use will



help them prevent HIV although still, some reported inconsistent use of condoms because they believed they were being protected by the medication in the drip. Regardless, they felt it was better to be in the study and monitor their health unlike not enrolling. This is in line with Andisen and Newman's concept of need factors whereby the way people perceive their own general health and experience symptom of illness, pain, and worries about their health will influence their health seeking behaviour.

For some, the discomforts and uncertainty that came with participating in the study, like pain when the drip is being inserted were outweighed by the benefit of being able to protect themselves long term. They were sure that even if something were to happen, for instance side effects because of the medicine, they would be assisted by the clinic staff and did not see a need to stop taking part in the study.

Access to better health services that are offered to the study participants was among the reasons as to why most participants felt the need to participate in the AMP study. This is consistent with the findings of the study in Brazil on motives for participating in clinical trials [24]. During the AMP study, participants who are diagnosed with other health problems are given care directly at the study site by health workers. A good number mentioned being tested for other diseases including STIs which they mostly did not know they had. Before the study, most participants reported not knowing that they had a certain disease but only knew about it after they enrolled in the AMP study. The more they remained in the study, the more opportunities they had of knowing if there is anything in their bodies that needs medical attention and once diagnosed with any disease, they reported getting treated from them which when they compared to the way treatment is offered in normal healthcare settings, would not be the case.

The participants reported that at a normal clinic or hospital, they have to wait in line for a while before they are treated. After waiting, they are told that the hospital does not have the medicine needed to treat their illness. This was the case when they (the participants) fall sick even if it is not a study related sickness when their children fall sick as they were being treated at the study clinic. This is viewed as a benefit because they save time and yet still get a better service while in the study. The study findings are not just relevant to understanding the motivations and experiences in participating in AMP study. The findings shed light on what may be a setback in the intersection of health care and health research. If potential participants rightly or wrongly believe that access to normal care, information or treatment can be easily accessed through research participation, then something is wrong with health services delivery and provision.

Andisen and Newman's concept of enabling factors was also observed in this study where he states personnel friendliness as one of the factors facilitating participation. It was noted that being welcomed and feeling welcomed played a role for some of the participants to enrol and remain in the study. When they feel welcomed, they no longer view coming to the clinic as a burden but rather, they look forward to it. This helps the participants develop trust in the personnel as they feel free to talk to them about anything.

### ***Financial benefits***

In addition, participants are motivated by the transport money they are given knowing that they will make savings and sustain their lives which in turn improves their socioeconomic status. Besides not having to pay for the drugs that are being tried out in the study or receiving free treatment when they fall sick as was a finding by SABCS 2019 article on clinical trials, some participants reported the stipend they are given in

the study as a study benefit. The stipend provides a platform of financial independence for some participants. With that, they plan on how to use their money according to their present needs thereby keeping them motivated to continue participating in the study and to enrol. Some openly said the main reason they enrolled in the study was that they heard there was money given as stipend which they felt they would benefit from it by participating.

### ***Willingness to help their society***

The perceptions and experiences of women taking part in HIV prevention trials were explored in Soweto, South Africa whereby the central finding was that the participants felt the sense of empowerment in spite of their being embedded in a culture that has come to fear, deny, or ignore AIDS [12]. This was also reported during this study where participants joined the AMP study just to willingly help the society in coming up with scientifically proven interventions to end the epidemic. The participants indicated that by volunteering to take part in the study, this will assist Malawi to have evidence based interventions to fight the virus and they will feel proud to have been part of the drive.

When enrolling in the study, the participants are clearly told that there will be no direct benefit to them since being a trial, they are only trying to see if the drip can be effective in preventing the transmission of HIV to those on it. Being aware of that, some enrolled with hope that they will be given the active drip while others enrolled because of a long-term goal of wanting to be a part of something that will help other people in future if proven effective. In the end, the satisfaction came in knowing that they played a role in other people's health.

### **Experiences of participants in the HIV Prevention clinical trial.**

From the responses of the participants, the experiences are grouped into the positive experiences, which can be looked at benefits of being in the study as well as the challenges they experienced while in the study. A link was observed between the benefits experienced, and their ability to adhere to study procedures and visits.

### ***Positive experiences***

As stated under health benefits as a motivator to study participation, knowing one's status was one of the positive experiences by the participants. They therefore looked to the next visit when they would be tested and depending on the results, they would either go home knowing that everything that they were tested for is fine or knowing that whatever they were diagnosed with has been treated and they will get better. Even for those who were informed of the study by friends who had enrolled before them, highlighted that they were encouraged by the good health their friends had and upon enrolling, were encouraged to know that their health will be monitored. Knowing their status, participants were encouraged to continue practicing safe behaviours such as maintaining one sexual partner in order to maintain their HIV negative status.

Beyond knowing their status, they felt empowered because through the study their knowledge of HIV was improved. This meant that they now have a better idea of how to prevent HIV as well as how it is transmitted. Most participants interviewed reported that before the study, they did not know that having multiple sexual partners put them at a higher risk of contracting HIV or that having unprotected sex also puts them at risk even for those who had one sexual partner. From what they learnt in the study, they were later on able to decide to have one sexual partner but still use condoms to increase their chances of preventing HIV. Participating in the clinical trial therefore made the participants feel that they have more control over their health which led to a more positive outlook and better quality of life.

## Negative experiences

Fear that the drug under trial (VRC01) may have side effects, especially related to child birth since they were not allowed to enrol if they are pregnant, breastfeeding, or if they had plans of having children within a space of two years from the time of enrolment. Beyond that, they were required to be on a family planning method. The strictness brought about worries that they might have troubles conceiving after the study or that if they fell pregnant while in the study, there would be some complications.

Community stigma related to study participation came up from almost all those interviewed. They described that once people in the community learn of a person's study participation, they are told negative things to discourage their continued participation. In the communities, people have different views of research. Some think of research as being a satanic activity and they try to disassociate themselves with it while others think it is a scheme by the researchers to steal blood from the participants through the samples that are collected. However, regardless of what they were told, most participants still decided to continue taking part in the study because they had never experienced what they hear or heard of anyone in the study complain about the things the community described, and because they wanted to experience what was said for themselves and not just getting influenced by other people.

Decision making as to whether to take part in the AMP study or not was seen to have been made over other personal opportunities like getting married or being in good terms with relatives because they were mostly discouraging. The need to protect themselves and access to the different services in the study was seen as of greater importance compared to the community stigma, anticipated risk and discouragements from families and friends they experienced while taking part in the study.

When asked how they have overcome the challenges experienced, specifically for the community stigma, they responded that they chose not to listen and with time, the people stop discouraging them and they go on with their lives. Some however suggested holding meetings in the different communities where community recruiters from the project have never reached in order to raise awareness on the benefits of research. They explained that most people are against research because they don't really know what happens in a study and instead, they are misinformed by unfounded information. According to the study on Community Health Workers in Low-, Middle-, and High-Income Countries, community health workers (CHWs) are a powerful force for promoting healthy behaviours and extending the reach of health systems around the world [25]. During the past decade, there has been an explosion of evidence concerning CHWs and their potential for improving population health where (a) health workforce resources are limited and access to basic services is low (mostly in low-income countries) and where (b) large disparities in health outcomes exist between selected sub-populations and the population at large in spite of the presence of well-developed health systems (mostly in developed countries). Most participants in this study indicated that they knew about the AMP study from the Community Educators who were visiting the communities to sensitize people about the AMP study. The participants accorded that they could not have known about the AMP study had it been the CHWs didn't visit their areas. On the hand, other participants are encouraged to take part in the study by direct friends who are knowledgeable on health issues and research.

### **Study limitations**

All the participants were recruited within a period of two months. The participants who were interviewed for this study were those who came between those months. This

implied that those who came before or after the specified months were not given a chance to participate, limiting the range of responses we could have probably attained if it was done over a longer period of time.

The conduct of the study was dependent on participants' AMP study visit schedules, therefore we had to wait for the participants to report to the clinic on their scheduled dates. This meant that those who were unable to take part in the interview on the day they reported for their clinic visit did not have a chance to come in whenever they felt able.

## **Conclusion**

This study has shown that participants in the AMP study enrolled in the study first for personal benefits – health, financial – then, for the desire to have taken part in something that will help other people in future – for the greater good. When their expectations are met through what they experience in the study, the chances of them adhering to the study visits and procedures are high. Even for those who did not have any expectations prior to the study, feeling welcomed and being able to open up to the study staff encouraged their continued participation. In the end, this outweighed the negative comments made by the people in their communities or their friends, which is something almost all the participants who were interviewed mentioned to have experienced UNC project needs to continue providing other health services to the participants as this is promoting participation as well. Furthermore, the provision of transport money is encouraging participants to attend the clinic as per schedule.

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## **Declaration Confirming the Absence of Any Conflict Of Interest**

I Ruth Holla, confirm that I do not have any conflict of interest in connection to the article submitted. A conflict of interest may arise in particular as a result of economic interests, political or national affinities, family and emotional ties, or any other relevant connection or shared interest.

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**Table 1: Background characteristics of study participants**

Characteristic	Frequency
<b>Age</b>	
16-20	1
21-25	4
26-30	5
31-35	2
<b>Education</b>	
None	1
Primary	8
Secondary	3
<b>Employment</b>	
Employed	4
Un-employed	8