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Please do not leave us' Qualitative excerpts of HIV-infected participants' perspectives towards a clinical trial endpoint in Tanzania.

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ABSTRACT

Introduction: The field of bioethics lacks empirical evidence to support the debates surrounding human involvement in clinical investigations. We focused on HIV clinical trials to explore participants' perceptions and experiences towards clinical trial endpoints.

Methods: This qualitative multiple case study used in-depth interviews (IDIs), and case narratives to collect data. IDIs were conducted with HIV study participants at the Care and Treatment Centers (CTC) and the Child Centred Family Care Clinic (CCFCC) until data saturation was achieved. The interviews covered motivations for participation, perceived risks and benefits, and trial endpoint expectations. Additionally, participants were also encouraged to provide relevant recommendations.

Results: A total of 18 in-depth interviews were conducted with individuals visiting CTC and CCFCC for various reasons including routine medication, voluntary counselling and testing, for visits as mandated by clinical trials, or as caretakers/guardians accompanying their children to HIV clinic for prevention of mother to child (PMTCT) programs. Participants reported different reasons for their motivation to participate in clinical trials. They perceived no risks involved in participating in clinical trials and highlighted financial benefits and high-quality healthcare received from health workers during the clinical trial at the period of participation. However, at the exit of the study, all participants expressed uncertainties about their fate and their children after the trials. Participants wished to continue accessing post-trial medical services similar to the one provided during the clinical trials even after being linked to other health facilities for standard care. They appreciated friendly service, regular professional advice, and follow-up of their health during the clinical trials.

Conclusion: Our findings show that although at the end of the trial, patients are linked to standard care, continuation of supportive measures after the trial is also essential. Our findings highlight the importance of providing post-trial benefits for participants in HIV studies as a basic ethical practice such as intervention treatment, professional advice, and devices found beneficial to participants. Further research should focus on participants' transition to standard care and their post-trial coping strategies.

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Background

Since the historical atrocities were documented in the Nuremberg trials (Nuremberg, 1947) and the subsequent revisions of the Helsinki Declaration (WMA, 2013), significant advancements have occurred, leading to heightened debates and conflicts regarding human involvement in clinical trial investigations (Lawton, et al., 2017). One of the conflicts is posttrial care. The Universal Declaration on Bioethics and Human Rights (CIOMS & WHO, 2016) highlights the ethical responsibility, to compensate clinical trials participants who are exposed to risks and/or invasive procedures and emphasizes the importance of providing post-research access to interventions identified as beneficial to participants before the trials begin. However, these guidelines are merely suggestive, and adherence to them is not obligatory, leading to conflicting perspectives and varying approaches to post-trial care (CIOMS, 2002); (UNAIDS, 2000); (WMA, 2013.); (Wellcome, 2004) (NIH, 2005).

Despite the diligent efforts to ensure safety and efficacy before market approval of new drugs, it is important to acknowledge that imperfectness and biases may exist regarding benefits and risks experienced by participants. Consequently, numerous practical and ethical challenges arise once the study concludes. Ensuring the continuity of treatments and maintaining the quality of care for patients as they transition back to their normal routine can be particularly demanding.

In low- and middle-income countries (LMICs), the issue of posttrial benefits for participants becomes even more delicate as it touches on poverty-related factors involved in the use of economically disadvantaged human participants with little or no education. Additionally, in LMICs there are no specific laws and regulations stipulating who should be responsible for addressing participants' rights and access to posttrial treatments and interventions (Dainesi, 2011); (Sofaer & Daniel, 2011). This situation is further complicated by the prevalence of vulnerable individuals as participants in these settings where uninformed participants who initially entered the trials are exposed to novel drug regimens and/or interventions (Mujugira, Nakyanzi, Muonge, & Haberer Jesica et al, 2022).

Protection of participants beyond clinical trial endpoints is imperative to safeguard individuals who may encounter challenges in accessing healthcare once the trial concludes especially in cases where trials are discontinued due to lack of efficacy or other reasons. However, it is noteworthy that in LMICs, there is no specific legislation that mandates the provision of post-trial treatment in clinical trial agreements. Research studies have indicated that local researchers, driven by concerns about the potential reallocation of funds, may acquiesce to the terms imposed by sponsors. This underscores the need for robust scientific discourse and regulatory frameworks to ensure the post-trial well-being of participants in clinical trials (Glaser & Bero, 2005) (Glenna, 2011).

In low-income settings, patients may lack awareness of their participation in an experimental context during clinical trials, leading to therapeutic misconceptions (Franklin, Miller, & Howard, 2003); (Mwangi, Paul, & Ann, 2017). Thus, their motivations and justifications for involvement in clinical trials can vary significantly. For example, a study by Mwangi et al. (2017) reported that altruism was not identified as a motive for participation among mothers who participated in malaria vaccine clinical trials. The alignment between participants and their personal needs and treatment outcomes may not be directly linked and can encompass a wide spectrum ranging from lifesaving medical procedures, such as anti-retroviral treatment to financial compensation during the period of the clinical trial (Tarimo, Bakari, Sandstrom, & Kulane, 2016).
The conclusion of a study brings forth numerous practical and ethical issues, particularly concerning the continuity of treatments and the quality of care as patients transition (Pace, et al.,

2006) (Cohen, O Neil, Joffres, Upshur, & Mills, 2009) (Dainesi, 2011); (Das NK, 2017). (Mujugira, Nakyanzi, Muonge, & Haberer Jesica et al., 2022) (Sofaer & Daniel, 2011). To obtain context-specific evidence, we conducted this study to investigate the perspectives of participants regarding the desired outcomes and processes of the after clinical trials.

Ethical principles and goals for biomedical research: A conceptual framework for global health improvement.

Biomedical research for improving global health seeks to advance medical knowledge, develop innovative therapies, and promote uniform care worldwide. By addressing health disparities, enhancing healthcare systems and collaborating across the borders, it aims to improve health outcomes for all individuals regardless of their geographic location or social and economic status. Ethical principles guide the framework of biomedical research for improving global health by ensuring respect for autonomy, promoting beneficence, avoiding harm and ensuring justice and fairness. These principles help to promote ethical conduct and equitable healthcare practices in pursuit of global health improvement.

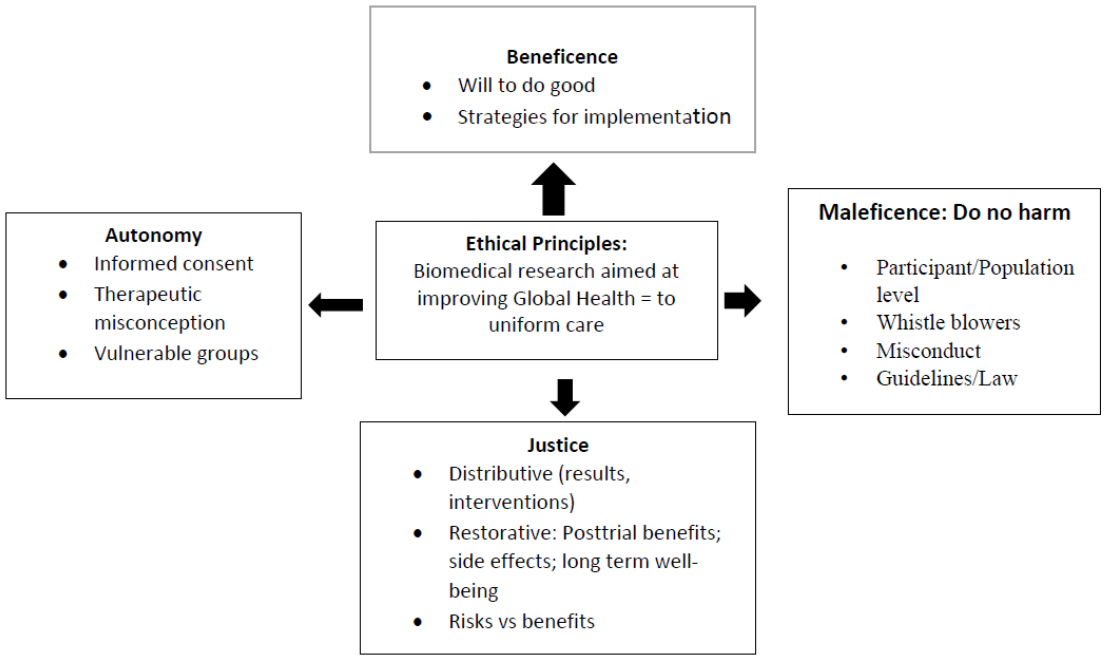

Figure 1: Conceptual framework for biomedical research advancing global health

Methodology

Study design

This study employed a qualitative phenomenographic approach utilizing a multiple case study design (Miles & Huberman, 1994). Data were collected through in-depth interviews and case narratives to explore the various aspects related to the experiences of individuals involved in clinical trials.

Study area

Data was collected from the Care and Treatment Centres (CTC) - and the Child Centred Family Care Clinic (CCFCC) located at the Kilimanjaro Christian Medical Centre, a renowned referral hospital known for hosting numerous clinical trials including studies related to HIV. Alongside

these clinical trials and Prevention of mother-to-child transmission (PMTCT), initiatives, the hospital provides standard care for HIV- infected patients. The patient's population ranges from 1000 to 2000 individuals per month, with clinic days scheduled twice a week during which 30-45 patients are attended to.

Study population

The study encompassed individuals engaged in ongoing clinical trials regardless of the specific phase in which they were involved, as well as those who had participated in previous clinical trials. Additionally, eligible participants included patients awaiting treatment at CTC-CCFCC. Since the majority at the CTC- CCFCC mostly were women, the participant pool consisted of a combination of individuals participating in PMTCT, CTC, and CCFCC programs. All individuals meeting the criteria were eligible to participate.

Participants Selection

Everyone waiting at the CTC was eligible to participate irrespective of age, gender, HIV status, race, etc. The selection of participants was carried out by approaching individuals who were waiting at the CTC/CCFCC. This approach was essential to provide potential participants with adequate time and opportunity to freely consider whether they wished to participate or decline. Eligibility criteria encompassed individuals from various demographics, with no restrictions on age, gender, HIV status, linguistic abilities, or any other relevant factors. Selecting participants from the CTC also ensured an unbiased representation of the study population and facilitated the recruitment of individuals involved in HIV clinical trials while safeguarding them from unnecessary discomfort associated with disclosing their HIV status. Upon approaching potential participants, they were provided with information about the study objectives, followed by a consent process. If they agreed to participate, they were invited for an in-depth interview at a location of their preference. The interviews were conducted in Kiswahili, audio recorded, and held in a normal social setting without any interruptions, often in a private room. The duration of the interviews ranged from forty-five minutes to one hour.

Study tools

The in-depth interviews (IDIs) were directed by topic guides with questions to explore the views, motivation, and experiences of participating in clinical trials. The tools were tested on several respondents prior to data collection.

Data collection methods

A graduate social scientist with appropriate training was appointed to provide assistance in the administration of in-depth interviews and collaborated closely with the principal investigator who is also the first author of this manuscript. Eighteen (18) IDIs were held with patients who had come to collect medication, for voluntary counselling and testing, caretakers/guardians who had brought their children for clinic visits, and/or had been enrolled in an ongoing research project. Data collection took place over a period of three months

Ethical issues were addressed at each phase of the study with the most important principles related to ethical considerations in the study (Marton & Pong, 2005). The fact that participants in this study were patients waiting for service at CTC made it even more sensitive and therefore measures to avoid unnecessary judgement of HIV status were highly considered. The research assistant sat in the queue and quietly talked to the next person and requested if they could step aside and talk in private. Only then would the information about the study be provided, followed

by consent procedures and a plan for the in-depth interview. Written informed consent was obtained from all study participants prior to the interviews. The study protocol was approved by the College Research Ethics Review Committee (CRERC) at the Kilimanjaro Christian Medical University College with Reference Number 2506. Data collection took place over a period of three months, from December 2021 to February 2022.

Data analysis and management

All interviews were conducted in Kiswahili and audio recorded using recording devices. The audio was then transcribed and anonymized during each transcription after which the scripts were translated to English. A phenomenographic approach was used to analyse data as described by (Marton & Pong, 2005). A coded manual was then developed and each completed interview was coded using NVivo version 12. The coding was then grouped within the broad themes: (1) motivation to participate; (2) Information about the clinical trial; (3) Perceptions of risks involved; (4) Benefits of participating; (5) Perceptions related to exiting the trial, and (6) Perceptions on what should happen after the trial. Field notes were subjected to manual analysis wherein any information that had not been included in the transcripts was incorporated.

Results

A total of 18 respondents were invited to take part in the in-depth interviews, and all but one were women. These participants represented a wide spectrum of sociodemographic characteristics, including age, marital status, family sizes, occupations, and educational backgrounds. The study focused on females involved in HIV-related research, categorizing them into two groups: those who were either receiving HIV medication or serving as caregivers for children enrolled in a clinical trial, with the mother, child, or both included in the study. However, determining whether these participants belonged to the control arm or were randomized into specific groups posed a challenge. Additionally, all participants were either transitioning from a previous study to the current one or exiting from a study that was already in progress.

Table (1) below demonstrates the diversity in sociodemographic characteristics among participants, which contributes to a comprehensive understanding of our research context.

Table 1: Characteristics of Participants

ID	Age	Sex	Marital Status	Children	Occupation	Education (Tanzania)
R01	24	F	Married	3	Small Business	Form 2
R02	21	F	Married	2 (1) deceased)	Housewife	Form 4
R03	23	F	Divorced	1	Small business	Form 4
R04	22	F	Student	0	Student	Degree
R05	32	F	Married	3	Farmer	Std 7
R06	32	F	Divorced	5	Day Worker	Std 2
R07	23	F	Married	2	Housewife	Std 7
R08	32	F	Married	3	Farmer	Std 7

ID	Age	Sex	Marital Status	Children	Occupation	Education (Tanzania)
R09	42	F	Divorced	4	Business Woman	Form 2
R10	18	F	Single	0	Student	Form 4
R11	31	F	Married	5	Small Business	7
R12	18	F	Single	0	Student	Form 3
R13	28	F	Single	3	Small business	Std 7
R14	26	F	Divorced	3	Unemployed	Form 2
R15	38		Married	4	Farmer	7
R16	45	F	Married	4	Housewife	Form 2
R17	28	F	Married	4	Small Business	7
R18		M	-	-	-	-

Themes

Six themes emerged from the in-depth interviews: *1) motivation to participate; 2) information about the clinical trial; 3) perceptions on risks involved; 4) benefits of participating; 5) perceptions related to the exiting trial, and 6) perceptions on what should happen after the trial.*

Motivation to participate

Participants reported different reasons for motivation to participate in the clinical trials. However, although the reasons for participation were at different levels, none of the participants mentioned that they participated to contribute to science.

The majority of caretakers [mostly mothers] of participating children reported that they participated in the trials to:

"Just to know the health of the baby" (R02, girl, 21 years)

"To know the baby's progress" (R05, woman, 32 years)

Information on clinical trial and consent process

Participants acknowledge receiving information about the clinical trial and the consent process. However, when specifically questioned about their understanding of their participation in the study, a mother provided the following response;

"Yes, I was told that they wanted to check the health of the child and if this child was infected in the stomach. They also told me how to use the medicine" (R06, woman, 32 years).

Others, in response to information given about the study, provided their perspectives of the medication administered to the child expressing the belief that it contributed to monitoring the child's health. One participant stated:

"It helps to know the health of the child" (R15, woman, 38 years).

In the context of emerging pharmaceuticals and treatment protocols for PMTCT mothers encountered challenges in distinguishing between participation in a clinical trial and engagement in a

Routine PMTCT implementation program. When specifically asked about their involvement in a clinical trial, the majority of participants expressed their confusion and lack of clarity:

"It is difficult to say what is a clinical trial" (R02, girl, 21 years).

" What is a clinical trial anyway? (Kwani majaribio ya dawa ni nini?") (R4, girl, 22 years).

One participant expressed awareness that participation in the study constituted research. However, this participant also conveyed a sense of limited options or alternatives available in the given situation.

"I knew it was research but there is no alternative" (R03, woman, 23 years).

Perceptions of risks involved in participation

As stated above, it was difficult to establish from the mothers whether they were on a treatment regimen or a routine PMTCT program. However, according to all participants, there were no risks involved in participating in clinical trials. From the participants' perspective, reported benefits were either looked at from a financial, health service provided, or professional advice they got from health workers working in the clinical trial. In terms of the trial drugs, the majority of participants commonly repeatedly stated that "These drugs will provide protection to the child".

Benefits of the trial

Several benefits from participating in the trial were reported, in which free medication emerged among main reasons for participation

An excerpt from the participant echoed what was indicated by other participants:

Interviewer: Where do you take your medication?

Respondent: Kilema hospital

Interviewer: What happens in Kilema?

Respondent: I was given that money

Interviewer: What made you agree to participate?

Respondent: The medication is free and the fare is up to them and there is nothing I have to pay (R05, woman, 32 years).

In terms of perceived benefits, one participant summarized the notion by highlighting the provision of comprehensive resources and the absence of personal financial burden associated with participating in a clinical trial.

Additionally, other reported benefits included the ongoing monitoring of the child's health and compensation in the form of cash:

"Because they [clinical trial site] give you everything and you do not have to spend anything"

(R15, woman, 38 years).

"You get some money for use" (R07, woman, 23 years).

"They help me with bus fare (40,000Tsh) and pampers for the baby" (R02, woman, 21 years).

"The child will have gotten well" (R03, girl 23 years).

"From the test of the child, I was told the child was not infected but I was given medicine to continue giving him" (R06, woman, 32 years).

"They said that the child would be given medication and it will get better" (R02, girl, 21 years).

Perceptions related to the exit of the trial

While there were perceived benefits related to the end of the trial; participants frequently raised concerns about the exit from the trial with some suggesting that the project (*mradi*) should be allowed to continue providing similar health services.

All participants particularly expressed a clear wish to be allowed to continue with the process that was arranged during the clinical trials. However, at the exit of the trial, participants did not know what would follow next or the fate of their babies after the trial had ended;

An excerpt from a participant on a trial exit:

Interviewer: Were you told that after a while you will stop taking the medicine?

Participant: Yes, I will finish in 12 weeks

Interviewer: What happens after that?

Participant: I don't know but it will be fine

Interviewer: What happens to the baby?

Participant: The baby will just continue breastfeeding and I will continue to take medication. They gave me 4 [tablets] initially and then they reduced them with time (R08, woman, 32 years).

There was a notable presence of uncertainties regarding the course of action following the conclusion of the trial, as evidenced by this excerpt featuring participant R17, a woman, 28 years:

Interviewer: What were your expectations when you agreed to participate in the trial?

Respondent: I expected to get medicine, I expected to get help/assistance (msaada)

Interviewer: Now that the trial ends what next?

Respondent: I did not know that I was going to stop taking these medicine

In another excerpt, it was observed that an alternative medication was prescribed upon cessation of the investigational treatment.

Interviewer: Were you given any medicine to use after the trial?

Respondent: She (the nurse) gave me cetirizine; She advised that there is cod liver oil (dawa ya mafuta ya Samaki)

Interviewer: So now after this, the child won't have any medication?

Respondent: I will call Dada W. (Nurse) but I don't know…. (R14, woman 26 years).

As participants exited from a clinical trial, additional benefits served as motivating factors for continued engagement in the study. However, communication between the participants and the healthcare providers from the trial site or facilities was likely to be discontinued as indicated by this excerpt. Moreover, even the provision of advice which was available during the participation period, ceased upon reaching the trial's endpoint:

Interviewer: Who told you that the trial has ended?

Participant: Those nurses told me

Interviewer: How did you feel?

Participant: I was okay because I have been getting the right medication, but it is a big challenge to stop because when I come here, I get only the advice (ushauri) through the telephone message

Interviewer: Aha; so, it helped you in taking medicine compared to back then before you were given the device.

Participant: It helps

Interviewer: How was it back then before you had the reminding tool?

Participant: Back then I said I didn't feel like taking [medicine] but I don't feel that way again. But since I was given [the device], if a message comes and I just get the alarm, half an hour later I would go to take the medicine

Interviewer: Ahaa okay, when you used it, you saw it is needed and you would like to use it for a long time or what do you think?

Participant: I hoped I would be allowed to own it maybe (R15, woman, 38 years).

Perceptions on what should happen at the end of the trial

This participant's response emphasizes the desire for continuity in services, including ongoing communication and the provision of advice. The participant also conveyed a sense of resignation stating there is not much else to be said or done as they perceive the trial to have concluded.

'The service should go on like it has always been…but what is there to say? I just find that it has ended' (R16, woman, 45 years).

When asked about their suggestions for the post-trial period, they expressed the following perspective:

Interviewer: What do you suggest should happen after the trial ends?

Participant: In my opinion, they [researchers] should just continue to communicate with us and provide advice on one -two- three [meaning on several things]

Interviewer: Anything specific?

"They should keep giving advice (ushauri)

"They should continue caring" (Aendelee kujali) (R07, woman, 23 years).

A 31-year-old mother who was breastfeeding a 3-month-old baby voiced apprehension regarding the transition back to the original health facility to continue with treatment after participating in a clinical trial for two years. In her expressed sentiments, she emphasized the importance of the trial's continuity:

"They just told me to communicate with them. Some medicines were changed. Here [at trial site] I was told that I would be in the project only for a while and that there would be a time when I will be asked to stop. But since I don't know how I will be received in Majengo health center [a health center apart from the trial site], I will just wait. They [Majengo health facility] told me to wait. For here [trial site] I get my results immediately (chap!) …I wish I could go on here [at the site] …. I have benefitted from the service, the advice and instructions I get. It is different from others…. like we sit and talk with the nurse" (R11, woman, 31 years).

Another participant upon exiting the clinical trial expressed their concern and plea for continued support:

Interviewer: what do you think will happen after the trial ends?

Participant: I expect to continue getting advice (ushauri); Please do not leave us; help us. (Msituache tu mtuisaidie) (R16, woman 45 years).

This respondent conveyed additional distress signals making heartfelt pleas for assistance

"I want to continue being together with you [researcher]. Don't leave me" (Naomba kwendelea kuwa na nyinyi; msiniache) (R6 woman, 32 years).

Researchers' Responsibility

In a clinical trial investigating an intervention aimed at promoting medication adherence, participants were provided with devices designed to mitigate stigma by discreetly storing antiretroviral drugs. These devices also supported adherence by alerting participants to the designated medication intake time.

However, upon completion of the trial, the lack of intervention continuity was expected to pose challenges. One participant expressed the belief that continuing the intervention beyond the trial would yield benefits for both the researcher and the participant.

"I was thinking maybe in this study you would be giving people this gadget permanently and not just for a month and then you take them and go away with them. That is, if you give people to own them, it is the right place to store the medicine…. thus, if you put efforts to give people these gadgets to own them permanently even for you it will be easy to follow adherence of medication" (A care taker exiting from a clinical trial) (R15 woman, 38 years).

A 28-year-old mother who was HIV positive and breast-feeding raised a particular concern about the removal of her pill box which she utilized to store her medication, following an intervention. In her comparison to the standard medication package provided at the hospitals, she emphasized her preference for the pill box:

"No…. I am saying that one [from hospital] when you put medicine, when you walk, it also makes notice! But thank you I love your [trial] service and I beg that you bring those gadgets [pill box] back so we can carry [the medication] in them please" (R17, woman 28 years).

An additional participant conveyed the following statement:

"The nurse advised me to continue taking the medicine on time and she told me that she will take this device, and even if she takes this device in case, I may not be able to because I am already used to this device, I can park it every time it reaches half past three and set the alarm, because every three and a half hours the alarm rings, I know it is time give the child medicine" (R11, woman, 31 years).

Discussion

In this study we have explored the reasons for participating in clinical trials, what the participant perceived as the benefit of being in the trial, how they understand exit in the trial, and their recommendation of what should happen at the trial endpoint. The findings highlight perceived benefits experienced by participants such as financial support, having a close relationship with healthcare workers, advice, and good care for their children. However, it also reveals areas where participants demonstrated less understanding including trial exit plans, and an increased desire to continue in the trial or maintain a close relationship with the study team. This finding underscores the significance of effectively communicating trial exits to participants and providing them with the necessary support and resources. It also highlights the importance of considering the well-being of study participants beyond the trial period, as emphasized by (WHO, 2016); (Joffe, Cook, Clearry, Clark, & Weeks, 2001); and (Shalowitz & Miller, 2008).

The current study findings align with qualitative studies which showed that study participants were desperate for continued support after the trial endpoint as compared with interventions during the period of the trial (Odero, Ondenge, & Mudhune, 2018); (Tso, Beanland, & et al., (2016)); (Lawton, et al., 2017); (Pratt, Paul, Hyder, & et al, 2017); (Ushirani & Naqvi, 2013). Reasons could be attributed to participants' need for ongoing support, the challenges of transitioning out of the trial environment, uncertainties about post-trial care and the potential discrepancy between participants' expectations and actual trial outcomes. Addressing these factors through comprehensive transition planning and continued support can help alleviate participants and enhance their overall trial experience. Several studies have also identified the urgent requirement for robust ethical regulations governing research conducted in low-resource settings, aimed at preventing the exploitation of research participants (Weigmann, 2015); (Sofaer & Strech, 2011).

Should interventions be continuous for the participating patients?

Despite the provision of standard care upon completion of the trial, the findings suggest that participants may exhibit a preference for continuing with the care provided in the trial. Although this study did not investigate specific reasons behind this preference, it can be understood that the discontinuation of treatment interventions can potentially lead to negative consequences. Within the context of HIV/AIDS, the rationale behind transitioning from a situation lacking treatment options to one offering potential treatment becomes evident. Consequently, it further emphasizes the importance of providing patients with continuous therapy after the trial, given the potential benefits derived from the new interventions. Moreover, it is possible that the trial drug may be incompatible with the standard treatment provided after transitioning back to standard care. Similar observations have been made by Nalubega and colleagues (2021) and by Reynolds, Mangesho, Lemnge, Vestergaard, and Chandler (2013).

The findings highlight the importance of regular follow-up and monitoring of participants in clinical trials, as well as the need to psychologically prepare them for trial exit.

Informed consent, autonomy and follow-up

Participants were provided with information about the study. However, their responses indicate a potential lack of understanding regarding the nature of their participation. The findings further suggest that while participants may have been informed about certain aspects of the study, such as the purpose of assessing the child's health and instructions for medication use, they may not have fully grasped the concept that they were taking part in a clinical trial. A potential lack of understanding about their participation in a clinical trial can be linked to the fact that international guidelines have not sufficiently addressed post-trial benefits for participants (Cho & Grandy, 2018) (Lunes, et al., 2019). This disconnect between guidelines and addressing post-trial benefits may contribute to the exploitation of participants, particularly in low-income settings and may be considered a violation of ethical principles (Cohen, O Neil, Joffres, Upshur, & Mills, 2009).

Our findings highlight the importance of bridging this gap and ensuring ethical principles are upheld throughout the research process including post-trial care and benefits for participants as emphasized by UNAIDS (2017); and (Hudelson & Cluver, 2015). These sources highlight the importance of addressing ethical considerations and providing sustained support for participants even after the conclusion of clinical trials. In the context of HIV prevention trials, ensuring continuity aligns with the UNAIDS goal of achieving the 90-90-90 targets to end AIDS (UNAIDS, 2017).

Perceptions related to the exit of the trial

Despite being transitioned back to regular health facility routines once the trials concluded, participants in the current study expressed a strong desire to maintain the positive treatment experience they received, reflecting evidence of a therapeutic misconception. Comparable results have been documented in previous studies (Mwangi, Paul, & Ann, 2017), (Reynolds, Mangesho, Lemnge, Vestergaard, & Chandler, 2013) where research participants held the belief that they were receiving treatment despite being assigned to the experimental arm of the study. Other studies have highlighted the critical necessity for stringent ethical regulation in research in low-resource settings to safeguard against the exploitation of research participants (Weigmann, 2015); (Euzebiusz & J Selgelid, 2020) (Show, 2014) (Bambery, Selgelid, & Weijer, 2016).

Conclusions and Recommendations

Our findings emphasize the critical importance of ensuring posttrial benefits, especially for individuals participating in HIV clinical trials. While our study highlights the value participants place on counselling and post-trial support systems, there is room for improvement. Even though patients are transitioned to standard care at the conclusion of the trial, our results indicate the necessity of closely monitoring how participants adapt to standard care after leaving a clinical trial. Therefore, as a fundamental ethical practice, posttrial benefits should encompass providing participants with the intervention treatment and/or devices that have proven beneficial to them. This proactive approach will enable them to effectively manage with challenges associated with transitioning back to normal standard care routines. It is essential that local guidelines reinforce this as a mandatory compliance standard.

Who should pay for the post-trial healthcare treatment?

The allocation of responsibility for post-trial healthcare treatment expenses has become a contentious issue as the international guidelines have refrained from providing clear commitments in this regard (Cho & Grandy, 2018); (Lunes, et al., 2019) (Silva, Amato, Sousa, & Carvaiho, 2018). This lack of clarity can lead to potential exploitation, particularly in low-income settings (Cohen, O Neil, Joffres, Upshur, & Mills, 2009) which represents a clear violation of ethical principles.

Study limitations

Our study did not define specific clinical trials which participants were enrolled. These trials could have involved new drug regimens, mental care or standard care potentially resulting in varying

Post-trail care approaches. As a result, further studies are recommended to explore participants' awareness of their involvement in an implementation program for PMTCT and their understanding of being enrolled in new medication and treatment regimens for PMTCT.

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