BMJ Open

Qualitative study exploring reintegration of clinical trial participants with HIV to public health services in Johannesburg, South Africa

Sibongiseni Thandazani Nxumalo ,[1,2] Bernice Harris ,[1] Lizeka Napoles,[1] Kelechi Elizabeth Oladimeji,[2] Samanta Tresha Lalla-Edward [2]

To cite: Nxumalo ST, Harris B, Napoles L, *et al*. Qualitative study exploring reintegration of clinical trial participants with HIV to public health services in Johannesburg, South Africa. *BMJ Open* 2024;**14**:e084947. doi:10.1136/bmjopen-2024-084947

► Prepublication history and additional supplemental material for this paper are available online. To view these files, please visit the journal online (https://doi.org/10.1136/bmjopen-2024-084947).

Received 01 February 2024
Accepted 01 October 2024

[1]School of Health Systems and Public Health, Faculty of Health Sciences, University of Pretoria, Pretoria, South Africa
[2]Ezintsha, A Division of Wits Health Consortium, University of the Witwatersrand Faculty of Health Sciences, Johannesburg, Gauteng, South Africa

Correspondence to
Sibongiseni Thandazani Nxumalo;
snxumalo@ezintsha.org

ABSTRACT

Objective People living with HIV (PLHIV) are often recruited from primary healthcare clinics (PHC) into clinical trials. On trial completion, they are transferred back to the facility for continued care and support in managing their condition, potentially leading to better health outcomes. Because transferring PLHIV back to PHCs post-clinical trials may result in decreased access to specialised care or resources that were available during the trial, this study explored insights into challenges faced during reintegration from clinical trial settings into PHCs and antiretroviral therapy (ART) adherence post-clinical trials.

Design This cross-sectional study was conducted using a qualitative research approach. Participants were recruited using purposive sampling.

Setting The study was conducted at the Ezintsha Research Centre in Johannesburg, South Africa, between November 2022 and February 2023.

Participants The study population consisted of PLHIV who had participated in two clinical trials (DORA and ADVANCE) at the Ezintsha Research Centre in Johannesburg, South Africa.

Methods Using a semistructured guide, 12 in-depth interviews were conducted with PLHIV until data saturation was reached. Data were then transcribed verbatim and analysed thematically with MAXQDA software.

Results The majority (n=8, 67%) of participants were female, and the average age of all participants was 40 (SD 7.2) years. Two main themes emerged: reintegration from clinical trials to public healthcare and barriers to ART adherence. These themes were further separated into seven subthemes, namely, negative attitude of healthcare workers, poor healthcare service delivery, poor communication to patients, waiting time at healthcare facilities, lack of privacy and confidentiality, mistakes in ART dispensing and bad reception at facilities post-clinical trials.

Conclusion Clinical trial sites should cultivate better stakeholder engagement with PHCs to facilitate a smoother transition of research participants, especially PLHIV, back into public healthcare for continued care.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This study adds to the body of literature about the process of how people living with HIV are reintegrated into public healthcare facilities post-clinical trials by delving into their first-hand experience.
⇒ The study involved a sample of respondents who completed two clinical trials, and the findings provide an understanding of their healthcare experiences and challenges faced at the public health facilities post-clinical trial participation.
⇒ The qualitative research methods applied allow for a nuanced exploration of participants' perspectives that allowed for insights into their experiences within the context of public health services in Johannesburg, South Africa, post-clinical trial participation.
⇒ Findings may not represent the experiences of individuals from other regions in South Africa, those with different socioeconomic backgrounds, and healthcare providers, necessitating additional qualitative explorations from other regions and stakeholders.

INTRODUCTION

The primary objective of clinical trial research is to enhance the effectiveness of practice.[1] A fundamental tenet of good public health practice is to base all health service choices on the most reliable, transparent and unbiased scientific evidence possible.[2] While clinical trials provide this cutting-edge clinical evidence that can guide medical judgement, provision of healthcare services and public health policy,[3] a major challenge has been poor integration of patients who were previously part of clinical research trials back into standard patient care in public primary healthcare clinics (PHCs).[4] This suggests that although clinical research and standard medical care are separate activities with distinct boundaries, their interrelatedness necessitates integration measures to ensure patients receive optimal care.[5] The reintegration of clinical trial participants into public health services is a complex process that requires the careful consideration of

various factors, including the nature of health service delivery received during preclinical and postclinical trial participation.[5] In the context of HIV-related clinical trials involving people living with HIV (PLHIV), the nature of health service delivery is critical, particularly in South Africa, where UNAIDS statistics indicate that in 2023, 7.7 million adults and children were living with HIV, just under 6 million of whom were receiving antiretroviral therapy (ART).[6]

Despite South Africa having the world's largest ART programme, challenges persist with retaining patients and ensuring that they adhere to treatment.[7] In fact, even in patients enrolled in same-day initiation on ART, about 40% of them abandon their treatment within a year of diagnosis.[8] Non-adherence can lead to escalation in morbidity, mortality, antiretroviral resistance and viral transmission.[7] It is important to understand what drives non-adherence, and various studies have been carried out to this end in sub-Saharan Africa. While various structural and individual barriers have been identified, a universal approach is unlikely to be effective; instead, it is important to tailor interventions to specific settings to ensure their effectiveness.[9] In the case of our study, it is delving into understanding what influences ART adherence in PLHIV once they exit the clinical trial and must reintegrate into the public health system.

Globally, there is a growing interest in incorporating the perspectives of clinical trial participants when conducting research studies on improving treatment adherence, as their viewpoints contribute significantly to treatment optimisation.[10] When patients are enrolled in a clinical trial and either removed from PHCs or have never received care at a public PHC, adequate planning, training of healthcare providers, continued patient support and provision of required infrastructure need to be addressed ahead of reintegration to ensure continuity of care and adherence.[11] Inadequate reintegration and provision of health services will result in patients failing to comply with treatment regimens, missing scheduled dates and experiencing treatment interruption.[12]

Healthcare providers in PHCs must ensure that all patients, including those referred from HIV clinical trials, are integrated into the PHC's standard of care. For more favourable health outcomes, this also entails ensuring, where possible, that the treatment plan or options, as received from the clinical trial setting, are continued. The transition from clinical trial clinics to PHCs may cause some patients to visit a clinic they were not initially referred to for a variety of reasons, including subpar service delivery in many PHCs, staff attitudes and lack of transportation.[13] Other, more socially related barriers, such as a lack of family support and stigma, may also be detrimental to patient reintegration and treatment adherence.[14] Therefore, evidence on patient experiences following clinical trial participation is critical to the development of context-specific strategies for closing the gap between clinical research and standard medical care for improved health outcomes. Unfortunately, evidence on clinical trial participants' transition experiences to PHCs is limited, particularly in Africa.[5 15 16] For this reason, and to better understand the nature of health services received as well as the barriers that may influence adherence to ART following participation in clinical research trials, this study explored the experiences of postclinical trial participants reintegrated into PHCs in Johannesburg, South Africa.

METHODS

Study design

Researchers applied an exploratory qualitative research method in this descriptive cross-sectional study to gain insight into the experiences and challenges PLHIV face as they transition from clinical trial clinics to public health facilities for ongoing care.

Setting

This study was conducted between November 2022 and February 2023 at the Ezintsha Research Centre (ERC), situated in Johannesburg, South Africa. Clinical research in communicable diseases like HIV and non-communicable diseases (eg, cardiometabolic conditions) is conducted at the ERC. All research is conducted in compliance with the local human research ethics committees and the South African Health Products Regulatory Authority (https://www.sahpra.org.za/) rules, including adhering to good clinical practice, the South African Good Clinical Practice: Clinical Trial Guidelines (https://www.sahpra.org.za/document/sa-gcp-guidelines/) and the South African Ethics in Health Research Guidelines (https://www.health.gov.za/nhrec-guidelines/).

There are approximately 15 PHCs in Region F. Healthcare services are predominantly nurse-led, covering acute and chronic care, HIV and tuberculosis treatment, sexual and reproductive health, maternal and child health, and mobile services at select facilities.[17]

Study population, eligibility and sampling

The study population comprised participants purposively sampled from a pool of clinical trial participants who had previously completed the ADVANCE (NCT03122262) and DORA (NCT04433780) HIV treatment clinical trials conducted at the ERC and were transferred to the PHCs for continued care. The ADVANCE clinical trial recruited newly diagnosed HIV-positive individuals who were ART-naive from different public PHCs in Johannesburg after they tested HIV-positive and initiated them on a dolutegravir-based regimen. A total of 1053 patients were enrolled from February 2017 to May 2018 and followed up for a 96-week period, after which some were referred to public PHCs of their choice (while others continued to be followed up for 192 weeks).[18 19] The DORA clinical trial enrolled 100 participants who were already taking ART at public PHCs and switched

them to doravirine for a duration of 1 year.[20] Again, on study completion, these clinical trial participants were referred to their respective PHCs to continue with the ART regimen that they were taking while in the trial.

In the reported study, purposive sampling was applied, and eligible participants (ie, 18 years and older, of any sex, participant in the ADVANCE or DORA trial and reintegrated into primary healthcare at a PHC, previously consented to be contacted for further research, and willing and able to consent) were contacted telephonically and invited to participate in the study. Participants who dropped out of the clinical trials, no longer receiving medication from PHCs and were virally unsuppressed were excluded. The sample size target was 10–15 participants, depending on data saturation.[21] The intention was to obtain a balanced sample (ie, a similar number of participants from each trial), and recruitment was done in parallel such that eventually 12 participants, six from each trial, were included.

Interview guide and data collection

An in-depth interview guide consisting of open-ended questions was designed after a preliminary review of the literature (online supplemental material file 1). The question areas were on ART adherence and perceptions and attitudes towards health services rendered by the PHCs. Some demographic data, such as age, gender, employment status and place of residence, were also collected from all participants. The in-depth interviews were conducted by a multilingual interviewer (STN) in a private setting and in English. Participants had the option to speak in vernacular; however, all elected to conduct their interviews in English. Where there were instances of needing to explain terms or questions in the vernacular, the interviewer was able to do so. The interviews lasted between 30 and 45 min and were audio-recorded. The interview process included both planned and unplanned probing questions, as well as note-taking based on observations made during the interview.

Data management and analysis

Recorded interviews were stored on a password-protected computer and only available to selected research staff. Data were later transcribed verbatim for analysis. After familiarisation with the quality-checked transcripts, STN, EKO and STL-E developed an iterative coding framework that was used until all the data had been thematically coded. Both inductive and deductive thematic analysis techniques were employed, and MAXQDA 2022 software was used to analyse the data.

Patient and public involvement

Participants were not involved in the design of the study. Their first involvement was at the point of providing consent and participating in the subsequent interview. The results of the study will be disseminated to study participants after publication.

Table 1 Sociodemographic profile of the study participants

Variable	Frequency (n) n=12	Per cent (%)
Sex		
Female	8	67
Male	4	33
Age		
30–44	8	66
45–60	4	33
Employment status		
Employed	4	32
Not employed	7	58
Self-employed	1	8
Place of residence		
Joburg CBD	8	67
Outside CBD	4	33

CBD, central business district.

FINDINGS

Profile of study participants

The mean age of the participants was 40 (SD 7.2) years. The majority (n=8, 67%) were females, more than half (n=7, 58%) were unemployed, and most (n=8, 67%) resided in the Johannesburg central business district (table 1).

Emerging themes

Two major themes and seven subthemes emerged from the data as presented in table 2. In figure 1, we further depict how the themes and subthemes interact in a clockwise direction to influence patient satisfaction with care, adherence to ART treatment

Table 2 Emerging themes and subthemes

Themes	Subthemes
Challenges with reintegration to public healthcare postclinical trial	Negative attitudes of healthcare providers Poor healthcare service delivery Poor communication to patients Waiting time at the healthcare facility
Barriers to ART adherence	Lack of privacy and confidentiality Incorrect/errors/mistake in ART dispensing Bad reception postclinical trial at the facilities

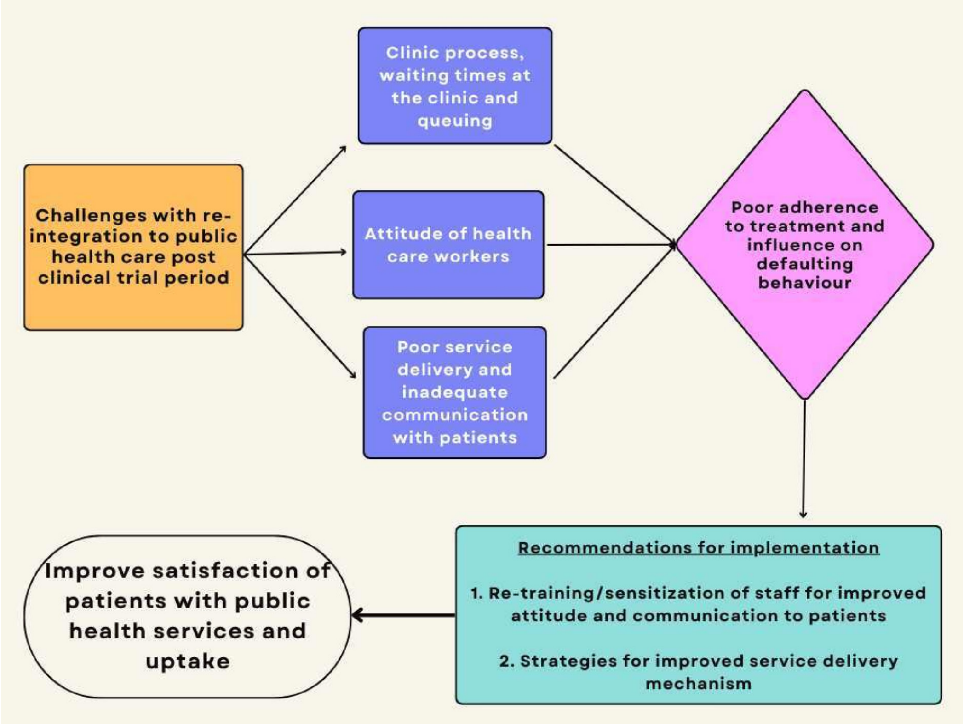

Figure 1 Relationship between themes and its influence on satisfaction with and uptake of public health.

and health-seeking behaviour after the transition from clinical trials to public health services.

Theme 1: challenges with reintegration to public healthcare postclinical trial

Reintegration challenges post-clinical trial participation was one of the emerging themes. The attitude of healthcare providers, poor service delivery, poor communication with patients and waiting time at primary healthcare clinics were subthemes and are discussed below.

Attitude of healthcare providers

The participants expressed dissatisfaction with the attitude of healthcare providers towards their work. The participants narrated that the nurses spend most of their time talking to each other rather than providing service to patients.

> 'The clinic is quite busy, but the truth is that the people that work at the clinics are too relaxed, they take their time. They aren't as busy as they sometimes make themselves to be. The workers are the main problem if we're being honest, I know they might say I'm being harsh, but they aren't motivated to work at all, you would find that after an hour a nurse has seen only two patients. Some people like working, others don't.' (PID 2, Male, 45–60 years)

> 'You just sit there, after they take time to even get you inside. Even when you eventually get inside, they just chat and not pay attention to you.' (PID 9, Female, 45–60 years)

Poor healthcare service delivery

Participants expressed reservations about the quality of service delivery. They reported that healthcare providers do not devote enough time to either checking on treatment progress or explaining to patients how they were responding to treatment, unlike their clinical trial study visits.

> 'That side (public health facility), it's—take the pills, bye! There is no time to talk and find out what's happening in your life. How are the pills treating you, what are the challenges that you are encountering?' (PID 7, Female, 30–44 years).

> 'There (public health facility), the workers don't care about the patients. They don't have the care you have here (ERC). You get there, they check your file, you take your pills and go' (PID 12, Female, 45–60 years).

> 'I said that if I arrived at the new clinic and they didn't take my health seriously and started their own things, I would have to come back here, but when I arrived, I found that the service was good. But they have only drawn our blood once to do tests and we have not yet been given the results of the blood tests they did…Thats what makes me want to come back to Ezintsha, because here at Ezintsha every single visit you will know exactly what the status of your health is, you would take bloods every visit, and they would make sure to give you a full update, those guys don't do it the same way' (PID 2, Male, 45–60 years).

Poor provider-patient communication

Participants shared that a lack of communication between healthcare providers and themselves makes them unsure when to enquire about their health or whether their questions will be answered if they continue to ask. This also includes communication of blood results. Once the blood was drawn or laboratory tests ordered, patients did not often receive their results. Therefore, there was no indication to either the patient or healthcare providers whether patients were responding to treatment and what the patient's immune response to the prescribed HIV treatment was.

> 'We have not yet been given the results of the blood tests they did' (PID 2, Male, 45–60 years).

> 'I don't know how to explain it. Sometimes you get there wanting to explain something to them. The person won't have time for you and will tell you that they still have a lot of things they need to do. Some of us are even scared to talk anyway. You see from when you start talking to them that this is not going to get you anywhere, let me just leave it. Sometimes you just keep what you wanted to say, to yourself' (PID 6, Female, 45–60 years).

Waiting time at primary healthcare clinics

Most participants complained about the clinic's procedures and time commitment. They expressed dissatisfaction with having to wake up early to be in the front of the queue, but their consultations are only completed in the late afternoon. They also noted that although the PHCs were closer to them than the research centre, the total time they spent per visit/per day was much longer at the PHC.

> 'Ever since I was born, that was the first time I went to the clinic. Getting to the clinic at 8:00am and leaving at 15:00 (pm), waiting for pills. You leave there at 16:00 (pm), waiting for pills' (PID 3, Male, 30–44 years).

> 'The clinic opens at 7:30. They start taking cards from 7:30. So, if I want to be on time, I will request an Uber because it's still very early in the morning. I'll leave at 5:30 just to go stand in the queue. The queue is so long; it would go as far as—it's quite long' (PID 7, Female, 30–44 years).

> 'The clinic needs to improve on their line system, here if I arrive late, I could leave at about 2pm or so, there I could arrive at 6am and still leave at 2pm. When I look at the distance it's much closer to (clinic name) but the waiting time is so much longer' (PID 2, Male, 45–60 years).

Theme 2: barriers to ART adherence

Subthemes like lack of privacy and confidentiality, healthcare provider mistakes on ART dispensing and bad reception post-clinical trial at the facilities emerged in the interviews.

Lack of privacy and confidentiality

As a result of the clinic process, participants identified privacy as a source of concern. This is attributed to patients needing to line up outside the clinic to wait for their medications, where passersby can easily identify those who are on ART, potentially resulting in stigma and discrimination.

> 'The ones collecting ARVs (antiretrovirals) are on one side, the ones collecting BP (blood pressure) medication are also on one side, etc. That's where it becomes a problem. That's why people end up defaulting and dying because your status ends up being exposed' (PID 3, Male, 30–44 years).

> 'It is painful because I work with a lot of people. When people go to or come back from work, they see me there. I sometimes feel like getting a hat to hide myself. You don't want everyone to know that you are taking treatment because people can be gossipers at work' (PID 5, Male, 30–44 years).

> 'That makes me very bad, because sometimes you meet a family member or a neighbour. When they see you sitting there, they know you are collecting ARVs. And others ridicule you because of your status. So, it's not nice' (PID 8, Female, 30–44 years).

> 'Not good at all because everyone who passes there sees you, and even people you didn't want to know your business' (PID 9, Female, 45–60 years).

Healthcare provider's mistake in ART dispensing

Some participants shared experiences of inadequate communication by healthcare providers that resulted in the facility failing to change their regimen and participants being given the wrong ART. As an example, doravirine is not available at public PHCs and is currently being tested in clinical settings. The referral public health facility and ERC coordinate around the patient for ART collection 1 day in advance, which means the PHCs must inform the ERC to deliver doravirine for patients who are coming the next day. This is done to ensure post-clinical trial access. However, it was noted that the PHCs do not follow this procedure, causing participants to discontinue taking doravirine post-clinical trial participation.

> 'They (ERC staff) called me from here (ERC) as they usually call and check on us. They (ERC staff) asked me when I was collecting my pills because they still have them. I told them that I collected my pills. They then asked me which pills I collected. I told them and even sent them a photo of the pills. They (ERC staff) said those were the wrong pills. I went back to the clinic, and they said it was a mistake' (PID 8, Female, 30–44 years).

> '(ERC staff) gave me a letter to give them at the clinic when I left here, so when I got there (PHC) they said I should go home and come back just before my medication finished. When I did that, they kept shouting and reprimanding me about not coming to book a

date, they even gave me the wrong medication' (PID 10, Female, 4 years).

Bad reception postclinical trial at the facilities

Participants were observed receiving bad reception at the facilities. These were noted as the PHC healthcare providers were being disrespectful and rude towards participants, stating that post-clinical trial participants thought they would receive special treatment when they came back to PHCs.

> 'They (public health services) are different; they are not the same (like ERC). It depends on who (healthcare provider) you are dealing with for that day. Others will treat you well and others will tell you that you are doing this because you are from Ezintsha, you think that you are special?' (PID 4, Female, 30–44 years)

Furthermore, public healthcare providers accused post-clinical trial participants of leaving the public facility because of clinical trial reimbursements.

> 'The real problem came when I had to go back (to the public health facility), they were saying you left here for the study thinking you would get money and all those kinds of things. It even discourages you from joining future studies' (PID 10, Female, 30–44 years).

Although participants did link the negative treatment to them being clinical trial participants, they did not express any blame towards the research centre or regret participating in the trials.

DISCUSSION

The study sought to explore the experiences of clinical trial participants with reintegration into public health services, as well as understand any experiences with ART adherence after participation in clinical trials. To do this, we recruited participants who had previously participated in the ADVANCE and DORA HIV treatment clinical trials that were conducted at the ERC and who thereafter transferred to the PHCs for continued care. In this study, participants, irrespective of their sex, age and/or the specific clinical trial that they participated in, shared similar encounters with public PHCs. These experiences were health system-related factors like staff attitudes, poor clinic routine processes or workflow and communication having a negative impact on participants' experiences with service delivery and subsequent adherence to HIV treatment. While some systems issues were applicable to public healthcare facilities in South Africa in general, others were specific to clinical trial participants' reintegration into public PHCs. Participants from both the ADVANCE and DORA clinical trials did not receive adequate health services when they returned to PHC facilities after clinical trial participation. Based on the study findings, we accede that follow-up of transferred participants after the end of a clinical trial is vital as it could enhance effective linkage to care.[22]

Staff attitudes towards patients and the quality of their communication both with patients and among their different groupings (clinical trial healthcare providers and PHC) came up short in the opinions of many of the participants. Some participants reported disturbing remarks from healthcare providers, including healthcare providers who assumed that clinical trial participants expected preferential treatment because they were in the clinical trial. Such negative interactions are concerning and could jeopardise patients' willingness to access health services at such centres in the future, since other studies have shown that cordial relationships with healthcare staff drive HIV care retention. For example, Offie *et al* draw on their own and other research to demonstrate that men who have sex with men were more likely to remain in HIV care when they had a positive relationship with healthcare personnel.[23]

Furthermore, participants in our study were dissatisfied that healthcare providers rushed their visits, leaving their medical-related queries and concerns unaddressed. The focus seemed to be mostly on dispensing pills. Having said that, Wilson *et al* in their investigation, point out that one of the hurdles to affording longer consultation and counselling times to individual patients is logistical—there is simply insufficient time in the day to be able to cater to patients' individual needs and be able to attend to all of the patients for that day.[24] While this may be true, what cannot be avoided is the reality that the quality of care that patients receive in these instances is compromised. Apart from suboptimal communication between healthcare providers and patients, healthcare provider to healthcare provider communication also impacts the patient experience. Our participants were vocal about the fact that they often did not receive results of blood tests after having had blood drawn and, at times, were even given the incorrect medication. Participants put the incorrect pill dispensing down to different medicine dispensing procedures being followed at clinical trial facilities versus public health facilities, poor communication between personnel at these two types of facilities and different medications being available at each type of facility. For PLHIV, this is especially worrying because their treatment plans are more complicated, and they have an increased susceptibility to medication errors. Such errors can cause further health complications. Although there are very few studies about the extent of medication errors, particularly in PLHIV in South Africa, those that have been conducted show that in hospitalisations, such errors were not uncommon.[25] Our study reinforces the need for further research, as we have shown that even in clinics, such errors occur, especially when patients move from one facility to another. It becomes imperative to identify and remedy the root cause to be able to provide responsible healthcare services to PLHIV. Perhaps looking more closely at how the Central Chronic Medicine Dispensing and Distribution (CCMDD) programme in SA mitigates

such errors can be a good starting point, since according to Otwombe *et al* (2022), the CCMDD has enjoyed success in doing so.[26]

Service delivery issues as they relate to communication can be largely addressed through retraining and upskilling healthcare staff, not only in facilities that are catchment venues for clinical trial participants but for all patients generally. Empirical studies have shown that healthcare professionals who received additional training in counselling, testing and treatment are better equipped than other health workers who have not received such training to relate to and treat clients in a professional manner.[27 28] Although the perspectives of healthcare providers were not the focus of our study, other research has shown that healthcare providers who have insufficient knowledge themselves about certain medications or who felt uncomfortable talking about matters relating to sexual behaviours found it difficult to engage with patients and provide the correct medication to patients. Again, continuous professional development of facility-based healthcare providers may go a long way in boosting the professional confidence of healthcare providers to improve service delivery and communication with patients.

Waiting in queues that were visible to the public outside the PHCs was another barrier to linkage to care and treatment adherence. Patients expressed concern about being recognised by residents in their neighbourhood or community when they stood in disease-specific lines as they feared public stigmatisation and discrimination. This corresponds with available evidence, which reported the lack of confidentiality and privacy at the public PHCs as a barrier to adherence.[29 30] Another issue worth addressing is the error in ART administered to patients following clinical trials by public health personnel. Medical research ethics require that, following a clinical trial, participants have access to the study drug if it is still not available in the public domain or to a Food and Drug Administration (FDA)-approved alternative that is superior pending FDA approval of the study drug.[22] It appears that at times this policy was not completely followed, resulting in participants receiving incorrect medication, which resulted from a lack of communication and possible negligence on the part of the public primary healthcare clinics. We reason that because of incorrect assessments of participants' clinical records by healthcare professionals at the PHCs and participants' fear of asking questions, participants had no choice but to take the wrong medication because they were unable to ask questions to better understand the medication taken. These findings are consistent with previous research from Uganda, which discovered that poor communication between patients and providers can result in medication errors.[31]

Participants expressed several other concerns about waiting times and how this impacted their clinic visits, contributing to suboptimal adherence to ART. The study's findings indicate that more formal training on how to treat patients, combined with enhanced patient flows, is needed to prevent patient loss to follow-up and treatment interruption. Long clinic wait times and staff attitudes towards patients can both be reduced by implementing quality improvement strategies such as streamlining clinic booking processes, identifying specific areas for improvement and retraining to provide healthcare professionals with strong interpersonal skills.[32]

While the patients' concerns are sound, they cannot be looked at in isolation. Ngcobo *et al* in their investigation into community health workers who provide community-based HIV care in sub-Saharan Africa, explain that the consequence of absent structured action plans causes inaccuracies in communication, mistrust and inefficiency among combinations of patients, healthcare workers and a variety of stakeholders and organisations.[33] This suggests that collaborations between clinical trials and public healthcare facilities should be to improve patient referral, continued clinical care and treatment outcomes. The outcome of our research indicates that patients, when reintegrating into public health facilities after clinical trial participation, are returned to healthcare systems and facilities that are not necessarily able to live up to their expectations of receiving acceptable HIV treatment.

Limitations

The study only involved PLHIV who maintained their ART regimens and who were virologically suppressed. It did not include patients with virological failure and who consequently may experience other challenges. Thus, the results from our study can only be generalised to patients who share similar characteristics to the participants in our study. Adolescents were not represented in our study. Given that their social context and experiences are likely to be different from the entirely adult participants in our study, our study's result may not be reflective of adolescents living with HIV. To thoroughly identify areas of healthcare services for improvement, it would have been more informative to gather opinions from stakeholders and healthcare providers. Therefore, future studies should consider involving healthcare providers and other stakeholders, like health facility partners, who are working closely with patients undergoing ART. Additionally, because there has been a scarcity of studies reporting on the experience of PLHIV reintegration to PHC post-clinical trials, it was difficult to compare the current study findings with similar studies.

Study implications

The periodic evaluation of health services based on the patient's experiences is a crucial tool for the management and formulation of public health policies whose aim is to strengthen health systems and improve health outcomes.[30] Sustainable Development Goal 3, in tandem with health sector reform policies, emphasises the need for equity, efficiency, quality and sustainability in the provision of healthcare and also refines the policies based on periodic evaluations.[31] Based on the experiences shared by the participants, poor service delivery could negatively

impact the uptake of public health services and treatment adherence. Therefore, there is a need for health stakeholders in South Africa to strengthen reintegration strategies and improve health literacy and knowledge of healthcare providers providing care to patients who are reintegrated or referred to PHCs post-clinical trial period.

Recommendations

There is a need for a proper patient transfer plan after the end of the trial. This should include an appropriate communication plan between the clinical trial site and PHCs' staff about the patients who are transferred back to their facilities for continued care. In addition, clinical trial teams should integrate adherence counselling sessions into study participant visits and emphasise the importance of treatment adherence to patients after the clinical trials. Patients should be comfortable communicating with the healthcare providers if they are facing any challenges with the treatment they are taking. Implementing efficient booking systems will assist with alleviating the burden of workload and the ratio of patient volume to clinical staff faced by the PHCs.

CONCLUSION

Factors such as clinic processes, patient flows and staff attitudes remain barriers to the reintegration of PLHIV on ART from clinical trial facilities back to the standard of care within PHCs. This study highlighted areas of concern in public health services that necessitate effective remedial strategies to improve access to PHCs for patients referred to care from clinical trial facilities. More research is needed to understand the perspectives of healthcare workers on the barriers to care and ART adherence for patients. If pressing issues such as PHC processes, communication gaps and discriminatory elements are actively addressed, reintegration from clinical trials to PHCs could be improved.

X Samanta Tresha Lalla-Edward @Lalla-Edward

Acknowledgements The authors would like to thank all participants who made their time to come and share their experiences. They would also like to thank Leanne Singh for providing editing services.

Contributors STN, BH and LN conceived the design and theoretical basis for this study. STN conducted the research, supervised by BH and LN. EKO, STL-E, STN and LN did the data analysis. All authors contributed to the article writing and approved the final version. STN is responsible for the overall content and is the guarantor.

Funding The funding for the project was made possible through the academic support from Ezintsha.

Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants. Ethical approval was granted by the Research Ethics Committee, Faculty of Health Sciences, University of Pretoria, reference number 459/202. Participants gave informed consent to participate in the study before taking part.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available upon reasonable request.

ORCID iDs
Sibongiseni Thandazani Nxumalo http://orcid.org/0009-0005-0677-6402
Bernice Harris http://orcid.org/0000-0002-0924-3178
Samanta Tresha Lalla-Edward http://orcid.org/0000-0003-3597-1643

REFERENCES

1 Portney L. *Foundations of clinical research – applications to evidence-based practice, 4th edn*. Philadelphia: FA Davis Company, 2020.
2 Frieden TR. Evidence for Health Decision Making - Beyond Randomized, Controlled Trials. *N Engl J Med* 2017;377:465–75.
3 Chow N, Gallo L, Busse JW. Evidence-based medicine and precision medicine: Complementary approaches to clinical decision-making. *Precis Clin Med* 2018;1:60–4.
4 Weng C, Li Y, Berhe S, *et al*. An Integrated Model for Patient Care and Clinical Trials (IMPACT) to support clinical research visit scheduling workflow for future learning health systems. *J Biomed Inform* 2013;46:642–52.
5 Sacristán JA. Clinical research and medical care: towards effective and complete integration. *BMC Med Res Methodol* 2015;15:4.
6 UNAIDS. *Fact sheet - South Africa*. Geneva: UNAIDS, 2022.
7 Ndoro T, Ndlovu N, Nyasulu P. Factors associated with ART adherence among HIV-positive adherence club members in Ekurhuleni Metropolitan Municipality, South Africa: A cross-sectional study. *PLoS One* 2022;17:e0277039.
8 Onoya D, Hendrickson C, Sineke T, *et al*. Attrition in HIV care following HIV diagnosis: a comparison of the pre-UTT and UTT eras in South Africa. *J Int AIDS Soc* 2021;24:e25652.
9 Jopling R, Nyamayaro P, Andersen LS, *et al*. A Cascade of Interventions to Promote Adherence to Antiretroviral Therapy in African Countries. *Curr HIV/AIDS Rep* 2020;17:529–46.
10 Centers for Disease Control and Prevention. Center for Disease Control and Prevention. HIV Prevention Research Synthesis Project. Compendium of Evidence-Based Interventions and Best Practices for HIV Prevention, Available: https://www.cdc.gov/hiv/research/interventionresearch/compendium/index.html
11 Madlala ST, Miya RM, Zuma M. Experiences of mental healthcare providers regarding integration of mental healthcare into primary healthcare at the iLembe health district in KwaZulu-Natal province. *Health SA* 2020;25:1143.
12 Hattingh R, Joubert PM. Patients' opinions about referral from a tertiary specialist psychiatric hospital to primary healthcare. *S Afr J Psychiatr* 2019;25:1212.
13 Filimão DBC, Moon TD, Senise JF, *et al*. Individual factors associated with time to non-adherence to ART pick-up within HIV care and treatment services in three health facilities of Zambézia Province, Mozambique. *PLoS One* 2019;14:e0213804.
14 Mukumbang FC, Mwale JC, van Wyk B. Conceptualising the Factors Affecting Retention in Care of Patients on Antiretroviral Treatment in Kabwe District, Zambia, Using the Ecological Framework. *AIDS Res Treat* 2017;2017:7356362.
15 Bekker LG, Alleyne G, Baral S, *et al*. Advancing global health and strengthening the HIV response in the era of the Sustainable Development Goals. *Int AIDS Soc Lancet Comm Lancet* 2018;392:312–58.
16 Ahmed I, Demissie M, Worku A, *et al*. Virologic outcomes of people living with human immunodeficiency virus who started antiretroviral treatment on the same-day of diagnosis in Ethiopia: A multicenter observational study. *PLoS One* 2021;16:e0257059.

17 Lalla-Edward ST, Mosam A, Hove J, *et al*. Essential health services delivery in South Africa during COVID-19: Community and healthcare worker perspectives. *Front Public Health* 2022;10:992481.
18 Venter WDF, Moorhouse M, Sokhela S, *et al*. Dolutegravir plus Two Different Prodrugs of Tenofovir to Treat HIV. *N Engl J Med* 2019;381:803–15.
19 Venter WDF, Sokhela S, Simmons B, *et al*. Dolutegravir with emtricitabine and tenofovir alafenamide or tenofovir disoproxil fumarate versus efavirenz, emtricitabine, and tenofovir disoproxil fumarate for initial treatment of HIV-1 infection (ADVANCE): week 96 results from a randomised, phase 3, non-inferiority trial. *Lancet HIV* 2020;7:e666–76.
20 SaC-PFVPIDS S. DORA: A Doravirine-based First-line Antiretroviral Therapy for Women of Reproductive Potential Living With HIV, 2023. Available: https://classic.clinicaltrials.gov/ct2/show/NCT04433780
21 Hennink MM, Kaiser BN, Marconi VC. Code Saturation Versus Meaning Saturation: How Many Interviews Are Enough? *Qual Health Res* 2017;27:591–608.
22 Erlwanger AS, Joseph J, Gotora T, *et al*. Patterns of HIV Care Clinic Attendance and Adherence to Antiretroviral Therapy Among Pregnant and Breastfeeding Women Living With HIV in the Context of Option B+ in Zimbabwe. *J Acquir Immune Defic Syndr* 2017;75 Suppl 2:S198–206.
23 Offie DC, Obeagu EI, Akueshi C, *et al*. Facilitators and Barriers to Retention in HIV Care among HIV Infected MSM Attending Community Health Center Yaba, Lagos Nigeria. *JPRI* 2021;33:10–9.
24 Wilson K, Bleasdale J, Przybyla SM. Provider-Patient Communication on Pre-Exposure Prophylaxis (Prep) for HIV Prevention: An Exploration of Healthcare Provider Challenges. *Health Commun* 2021;36:1677–86.
25 Bronkhorst E, Joseph-Busby M, Bezuidenhout S. Reducing medication errors in HIV-positive patients: Influence of a clinical pharmacist. *South Afr J HIV Med* 2024;25:1594.
26 Otwombe K, Munsamy M, Dheda M, *et al*. Tracking adverse drug reactions and medication errors in the Central Chronic Medicine Dispensing and Distribution (CCMDD) programme in South Africa. *South Afr J HIV Med* 2022;23:1366.
27 Dapaah JM. Attitudes and Behaviours of Health Workers and the Use of HIV/AIDS Health Care Services. *Nurs Res Pract* 2016;2016:5172497.
28 Nyblade L, Stockton MA, Giger K, *et al*. Stigma in health facilities: why it matters and how we can change it. *BMC Med* 2019;17:25.
29 Becker N, Cordeiro LS, Poudel KC, *et al*. Individual, household, and community level barriers to ART adherence among women in rural Eswatini. *PLoS One* 2020;15:e0231952.
30 Sundararajan R, Wyatt MA, Muwonge TR, *et al*. Understanding PrEP Acceptability Among Priority Populations: Results from a Qualitative Study of Potential Users in Central Uganda. *AIDS Behav* 2022;26:2676–85.
31 Berland A, Bentsen SB. Medication errors in home care: a qualitative focus group study. *J Clin Nurs* 2017;26:3734–41.
32 Manyisa ZM, van Aswegen EJ. Factors affecting working conditions in public hospitals: A literature review. *Int J Afr Nurs Sci* 2017;6:28–38.
33 Ngcobo S, Scheepers S, Mbatha N, *et al*. Roles, Barriers, and Recommendations for Community Health Workers Providing Community-Based HIV Care in Sub-Saharan Africa: A Review. *AIDS Patient Care STDS* 2022;36:130–44.