International Journal for Equity in Health

RESEARCH

Open Access

Balancing solidarity, normality and trust: reasons for (non-)participation in an injectable HIV antiretroviral therapy study in the United Kingdom

Sara Paparini[1*], Rosalie Hayes[1], Bakita Kasadha[2], Vanessa Apea[1,3], Fiona Burns[4] and Chloe Orkin[3,5,] on behalf of the ILANA study group

Abstract

Many new drug trials fail to recruit participants that are representative of the populations they are intended to serve, resulting in research gaps which contribute to health inequalities. In the United Kingdom, reasons for non-participation in HIV drug trials remain poorly understood. Accordingly, we present a thematic analysis of interview and survey data gathering the perspectives of individuals who chose to participate and those who chose not to participate in the ILANA study – an implementation study of the first ever long-acting injectable HIV treatment, cabotegravir and rilpivirine. Drawing on the theoretical concepts of 'biosociality' and 'therapeutic citizenship', we identified three main thematic areas in participants' narratives: solidarity with other people living with HIV; the pursuit of normality; and patient-clinician trust. We argue that our analysis offers insights into how decision-making across a diverse group of research participants can be motivated by similar factors but lead to different outcomes. This has implications both for how (non-)participation is understood by researchers, and how attentions may best be focused among those seeking to address inequity in research participation.

Keywords Research participation, HIV, Research inclusion, Research equity

Background

It is well established that many research trials tend to happen 'away from' or 'without' the population groups where the burden of disease is higher. A global review of studies reporting on RCT representativeness found that 71.2% of studies ($n=37$) explicitly concluded that RCT samples were not broadly representative of real-world patients [1]. In England, it has been estimated that 12% of nationally-funded clinical research would need to be redistributed to align with disease prevalence [2]. Studies therefore need to develop deliberate strategies to improve recruitment of under-represented populations in clinical research so that their study populations better reflect the

*Correspondence:
Sara Paparini
s.paparini@qmul.ac.uk
[1]SHARE Collaborative, Wolfson Institute of Population Health, Queen Mary University of London, London, UK
[2]Nuffield Department of Primary Care Health Sciences, University of Oxford, Oxford, UK
[3]Barts Health NHS Trust, London, UK
[4]Institute for Global Health, University College London, London, UK
[5]SHARE Collaborative, Blizard Institute, Queen Mary University of London, London, UK

communities they serve [3, 4]. The current lack of inclusion of underserved populations in new drug trials is particularly problematic; research gaps perpetuate inaction on addressing issues for those suffering a disproportionate burden of health inequalities [5, 6].

HIV prevention and treatment research is no exception to this. Women and racially minoritised people are chronically underrepresented in HIV prevention and treatment research [7, 8], with one review finding that women represented a median of 19.2% participants in HIV treatment studies despite making up half of all people living with HIV globally [9]. Reasons for non-participation in HIV drug trials remain poorly understood in the United Kingdom, with the majority of studies exploring the barriers and facilitators to participation in HIV treatment studies conducted in the United States [7, 10].

The broader international literature on non-participation is also fragmented and includes a variety of medical interventions and trial designs (e.g., vaccine, therapeutic or surgical trials) whose different characteristics, and current and historical meanings, further add to the number of potential variables leading to participants' decisions not to take part in research [11]. Few studies describe the characteristics and explore the perspectives of 'non-participants' in any depth, beyond recording refusals or rates of attrition [6, 12]. Even fewer studies disaggregate their information or analysis by personal characteristics such as sex, gender, ethnicity, ability, socio-economic or carer status of the people who declined to participate [11]. This makes it difficult to disentangle what may often be complex reasons for non-participation and improve practice in trial design and recruitment. Finally, reflexive research regarding how study design and methods could *implicitly* exclude a diversity of groups from research is rare [13].

Existing research on the perspectives of those asked to participate does point to a heterogeneity of *kinds of reasons* for non-participation. Common barriers may be practical issues, such as additional demands on patients' time and lack of funds (e.g. travel or childcare costs) [6, 11, 12, 14, 15]. Study-related barriers can also include poor communication of study aims and methods [11, 12], restrictive eligibility criteria [14, 16] such as a requirement to use long-acting contraception [17], language barriers [16], and patients' concerns about use of data and data privacy [6, 11]. Intervention-related reasons may originate from preferences for a particular treatment (or no treatment) [6, 12], lack of trust in research and/or the medical profession for current or historic reasons related to discrimination on the basis of social identity [11, 14, 15], or concerns about side-effects and drug interactions [11, 12, 15]. Self-perception of candidacy [18] for research, i.e. whether or not individuals think the research is relevant or necessary for their health needs, also plays a part [12, 16]. Other reasons may relate to individual and social differences in health and healthcare experience, including negative or discriminatory experiences when using the health service or taking part in previous research [11, 14, 16].

Conscious of such heterogeneity, in this paper we present, specifically, the perspectives of individuals who chose to participate and those who chose not to participate in the ILANA study [19] – an implementation study of the first ever long-acting injectable HIV treatment, cabotegravir and rilpivirine (CAB+RPV LAI). We draw from established theories of 'biosociality' [20] and 'therapeutic citizenship' [21] to illuminate what we term *(non-) participation* (a spectrum of decisions about participation) and advance our conceptual understanding so that research methodology can improve.

Long-acting novel antiretroviral therapies and the ILANA study

CAB+RPV LAI was approved for use in England in 2022 by the National Institute for Health and Care Excellence [22]. Phase III clinical trials of CAB+RPV LAI substantially underrepresented women, racially minoritised people, and older people, with only 25%, 28% and 18% of participants from these groups, respectively [23].

The ILANA (Implementing Long-Acting Novel Antiretrovirals) study was a sponsor-led commercially funded implementation study exploring acceptability and feasibility of delivery of CAB+RPV LAI in clinical and community health settings. It was led by a co-author (CMO). In order to recruit a sample that would be more representative of the global population of people living with HIV, ILANA employed an anti-racist, anti-sexist, anti-ageist, purposively inclusive study design with recruitment targets of 50% women, 50% racially minoritised people, and 30% people ≥50 yrs across six large HIV clinics across the UK [19].

This design was developed in collaboration with a co-author living with HIV and a Community Advisory Board with lived experience of HIV. Sites were assessed and selected based on recruitment target feasibility, and targets were written into the study protocol and managed throughout the study. ILANA exceeded its recruitment targets: of 114 participants, there were 53% women, 70% racially minoritised people, and 40% aged ≥50. The study found significant improvements in the lives of people living with HIV thanks to the relief from the pressures of daily oral drug adherence. A full set of results has been published elsewhere [24].

At the time of designing the ILANA study, it became clear that it offered a timely opportunity to undertake additional linked qualitative research to understand the views of those who were eligible and offered a place in the study but chose not to join it. Accordingly, No-LANA is an associated sub-study which aimed to describe the

characteristics of non-participants in ILANA and explore their reasons and perspectives through a mixed-methods approach. Moreover, people who did participate in the ILANA study were also asked questions regarding their participation in the third phase of longitudinal interviews as part of ILANA.

Biosociality and therapeutic citizenship

The ILANA study is situated in a long history of HIV clinical research and (non-)participation and can be better understood in this context. The history of research has been one in which those responsible for recruiting research participants "find themselves engaged in a vexing and time-consuming body hunt" ([25], p208). During the 1980s and 1990s, people living with HIV were therefore somewhat atypical in their demands to be included in clinical research, insisting on their right to take part in the search for an effective HIV treatment [25]. This history of collective action, solidarity and support on the basis of a shared diagnosis of HIV has long been identified as a form of 'biosociality' [26–28] – a concept first coined by the anthropologist Paul [20] in the wake of the Human Genome Project. Rabinow suggested that identities bestowed through biomedicine, such as diagnoses or genetic testing, would form increasingly important bases for new social networks [20]. These new *biosocial* networks create opportunities for making collective claims regarding the right to appropriate healthcare and treatment, and to research [29].

The concept of 'biological citizenship' [27] evolved from that of biosociality to encompass citizenship projects linking: i) the responsibility of active citizens to take care of their health and, ii) the role of states in apportioning limited resources with the role of biomedical technology in shaping human worth [27, 30, 31]. Further, a focus on global access to early HIV treatment in the 1990s led to the development of the linked concept of 'therapeutic citizenship' [21, 32]. Therapeutic citizenship describes 'responsibilised' patients' [33] who engage in exemplary treatment adherence (e.g. within patient advocacy groups) to present themselves as worthy candidates for treatment, particularly where treatment resources are rationed [31].

The history of HIV treatment research has changed, as access to treatment has improved in most settings. However, we suggest that fundamental citizenship narratives about responsibility for contributing to scientific advancement and biosocial solidarity continue to influence decision-making about trial participation [34, 35]. In this paper, we ask whether 'biosociality' and 'therapeutic citizenship' concepts might inform a more nuanced understanding of participation/non-participation as a spectrum of (non-)participation in an HIV trial like ILANA. These insights may contribute to a deeper understanding of what drives different people to take part in research and therefore how to make research offers more inclusive and research outputs more equitable.

Methods

Study design

ILANA was a 12-month, UK-based multicentre, longitudinal study evaluating implementation and effectiveness outcomes for 2-monthly on-label CAB + RPV injection delivery (ClinicalTrials.gov identifier: NCT05294159, registered 24 March 2022). ILANA included longitudinal surveys (at baseline month 4 and month 12) and interviews (at baseline and month 12) with participants. The full methods have been published elsewhere [19, 24].

No-LANA was a mixed-methods sub-study of ILANA, involving a survey and in-depth interviews with people living with HIV who had declined to take part in ILANA. The design was descriptive and exploratory. Study materials were reviewed by clinical academics, a lived experience researcher and the Community Advisory Board.

Setting and participants

ILANA and No-LANA were conducted in six HIV clinic sites in England. The eligibility criteria for ILANA participants are detailed in the study protocol [19]. As outlined above, study sites were required to meet recruitment targets of 50% women, 50% racially minoritised people and 30% people aged 50+ years. Those who chose not to take part in ILANA were eligible to participate in No-LANA.

Data collection

Local study teams at each clinic invited individuals eligible for No-LANA to complete an anonymous online survey via text message, after waiting at least one month after individuals declined participation in ILANA (to avoid excessive pressure to participate). The survey was conducted between November 2022 and November 2023 and contained 5 new (non-validated) questions assessing recall of invitation to participate in ILANA, reasons for declining participation, and previous experience of research participation, along with questions regarding demographic characteristics (see Supplementary Appendix 1). The survey used closed questions to limit survey fatigue and encourage completion. At the end of the survey, respondents were invited to provide contact details if they were willing to undertake an individual qualitative interview to explore their answers in greater depth.

Individual interviews took place between December 2022 and November 2023. Participants were interviewed once. Participants were asked demographic and open-ended questions (see Supplementary Appendix 2) on topics including: starting injectable antiretroviral therapy in routine care (i.e. outside of the trial or other research); reasons for declining participation in ILANA; and

suggestions for improving future recruitment. Interviews were short (around 20 mins) and were conducted by SP and RH online, based on participant preference (in-person and phone interviews were also offered). Interviews were audio-recorded and transcribed verbatim.

Data analysis

Survey data were extracted, cleaned and summarised using descriptive statistics by RH. Denominators (n) are shown in the text when missing responses occurred.

Our approach to qualitative analysis was informed by mixed-methods research design principles and reflexive thematic analysis. Since the two sets of interviews were largely conducted by the same researcher (RH) and related to the same research question, our analysis effectively treated the two sets of interviews (No-LANA and ILANA) as a *joint qualitative dataset* (albeit with a specific focus on the answers to the ILANA questions that related to participation rather than the rest of the ILANA interview). Reflexive thematic analysis offers a level of flexibility that allows for examination of data beyond an idiographic sample (i.e. only those who refused to participate in ILANA) [36].

Following each interview, RH wrote fieldnotes summarising key topics discussed in the interview and emerging analytical ideas. Fieldnotes informed team discussions and guided the direction of subsequent interviews and the conceptualisation of data. For example, ILANA participants' accounts of why they were asked to be part of ILANA led RH to explore this further in subsequent interviews and to review theoretical thinking on therapeutic citizenship.

Once interviews were completed, RH and SP iteratively developed a coding framework based on the research questions, interview transcripts and the process of coding. RH wrote descriptive summaries of codes, and these informed the generation of initial themes. Interpretations of themes were then reviewed and discussed by the broader study team and iteratively refined. Our approach to analysis was inductive (through close attendance to participants' accounts) and informed by theoretical concepts of biosociality and therapeutic citizenship.

The findings from both the quantitative and qualitative datasets were then 'merged' by mapping survey data against qualitative themes [37], allowing us to triangulate findings with attention to completeness, convergence, and dissonance of key themes [38]. The interpretation of both quantitative and qualitative findings was subsequently integrated through narrative 'weaving' theme-by-theme within the presentation of the results of this paper [37]. Specific highlights from the survey are presented together with the interview findings in the Results section below.

Ethical considerations

The study was conducted in accordance with the Declaration of Helsinki and approved by City & East London Research Ethics Committee on 14 April 2022 (REC 22/PR/0318). Participants received a £15 'thank you' voucher for participating in the survey and a £50 voucher for participating in the interview, with the amounts reflecting the inherent challenges of including people in a study about non-participation.

Amendment to the study design

Uptake of the No-LANA survey was limited due to the small numbers of people not joining ILANA, and to the nature of the study. Therefore, to supplement this small sample, the study was revised (with the agreement of the ethics committee) to also include additional questions in pre-planned longitudinal interviews with ILANA interview participants ($n = 14$). These interviews took place between July and December 2023 and included questions about experience of being invited to participate in ILANA; reasons for participating in ILANA; experience of participating in ILANA; and suggestions for improving future research (see Supplementary Appendix 3). Interviews (13 in total) were conducted online and by phone by RH and lasted an average of 40 minutes. Interviews were audio-recorded and transcribed.

Results

Seven out of a total of 30 individuals (23%) who had declined participation in ILANA across all clinics completed the No-LANA survey, and two of these individuals also participated in interviews. All seven No-LANA survey participants were aged above 30, with the largest group aged 50–59 years (n/$N = 3/7$). All survey participants were cisgender, and there were four women and three men. The majority were heterosexual (n/$N = 4/7$). Participants were predominantly from racially minoritised groups, including Asian (Indian, Pakistani, Bangladeshi, Chinese, Japanese) (n/$N = 2/7$), Black African (2/7) and Black British (1/7). Supplementary Table 1 outlines the full characteristics of the survey sample.

Of the seven No-LANA survey participants, two agreed to be interviewed. Thirteen ILANA participants were also interviewed. The characteristics of interview participants in No-LANA and ILANA are outlined in Table 1.

The analysis of interview data identified three main thematic areas in participants' narratives, which included solidarity with other people living with HIV; the pursuit of normality; and patient-clinician trust. The survey responses to reasons for non-participation are available in Table 2.

Table 1 Interview participant characteristics ($N = 13$)

Pseudonym	Study	Gender	Age	Ethnicity
Julia	No-LANA	Cisgender woman	50	White European
Luke	No-LANA	Cisgender man	45	White British
Jacob	ILANA	Cisgender man	62	Black African
Abimbola	ILANA	Cisgender woman	55	Black African
Michael	ILANA	Cisgender man	62	White British
Grace	ILANA	Cisgender woman	54	Black African
Jackie	ILANA	Cisgender woman	37	White British
Dev	ILANA	Cisgender man	47	Asian Indian
Yasmin	ILANA	Cisgender woman	42	Asian Other
Max	ILANA	Cisgender man	39	White European
Joshua	ILANA	Cisgender man	37	Black British
Jamelia	ILANA	Cisgender woman	54	Black African
Robert	ILANA	Cisgender man	51	White British
Sue	ILANA	Cisgender woman	50	White British
Emily	ILANA	Cisgender woman	37	White British

Theme 1: Participation as an expression of biosocial solidarity with other people living with HIV

A key theme generated from both ILANA and No-LANA accounts was a recognition that participating in research is a way of expressing biosocial solidarity with other people living with HIV.

ILANA participants frequently referred to the importance of HIV research endeavours, and their optimism that research would lead to improvements in treatment and care for others living with HIV. Participants drew on personal experiences of witnessing how HIV treatment research has benefitted themselves and their community, with some explicitly drawing on the legacy of HIV activism in driving research participation:

> *I remember what was HIV in the 1980s, and I'm happy to contribute to fight HIV – so that's why I want to help. I wanna help people ahead of me.* **Max** *(White European, Male, aged 39, ILANA participant)*

While most participants spoke in general terms about HIV research, some located the importance of research participation in the context of ultimately finding a cure for HIV. While they recognised that CAB+RPV LAI is not a cure for HIV, they considered long-acting treatment as a step towards a cure, and felt that by participating in research they were helping to advance scientific knowledge which could ultimately lead to a cure, as expressed here by Jackie:

> *Well, for me, I feel like any sort of, like, research is good and, you know like, I eventually want there to be a cure … So, these sorts of things are really helpful … any kind of research because then hopefully it will get to the end of being a cure or getting help for people to have the six month one [injection] or a year [yearly].* **Jackie** *(White British, Female, aged 37, ILANA participant)*

The perception of research as important was also evident among No-LANA participants. Two out of seven survey participants (who did not take part in ILANA) had been asked to participate in previous research studies, and both had agreed. Reasons for participating in these other studies included a desire to support the advancement of medical science of HIV treatment, and that it was convenient for them at the time.

No-LANA interview participants were also asked about previous research participation. No-LANA interview participant Luke (White British, Male, aged 45) had participated in research previously, describing how he is happy to do to support the "development of medical science" but in the case of ILANA, it simply wasn't practical to participate. In contrast, Julia discussed how she had not previously participated in HIV treatment research due to her fears around developing drug resistance – a decision she nonetheless perceived as "selfish":

> *No. No. I think it depends on what, to be honest, probably not. I mean, with HIV and the resistance, it makes me quite uncomfortable that I, you know, I think I know it's very selfish and I'm very grateful for people [who have] done that.* **Julia** *(White European, Female, aged 50, No-LANA participant)*

Here, Julia acknowledges the importance of research by expressing that she is grateful for others living with HIV who have taken part in treatment research, and feels that she is not enacting the same level of solidarity with others by declining to take part. It clearly is a factor in her decision-making, but her concerns about resistance take greater priority.

Grace, an ILANA participant, highlighted how the specific experiences of Black women living with HIV – shaped by the intersection of their race and gender – influenced her decision to take part in the study. She discussed how other women living with HIV in her peer group had expressed fears about injectable treatment being potentially unsafe for women due to the majority of HIV research being conducted with white, gay men and that doctors would "*use us as guinea pigs*". She expressed empathy for this viewpoint, drawing a direct link between these fears and the history of unethical medical experimentation on Black people, but felt it was her responsibility to be a role-model to other Black women and demonstrate that they could benefit from the treatment:

> *I wanted to be like show my peers that no, it is a pill, it is a medication. They're already giving us medication guys. [laugh] So if they're going to kill us, they're going to kill us anyway … So yes, that is one of the reasons why I also wanted to do it. It's also to be*

Table 2 Reasons for non-participation in ILANA provided within No-LANA survey, by survey participant and in total (*N* = 7)

Reasons given for non-participation	P1	P2	P3	P4	P5	P6	P7	Total
Time commitments								
Too busy to do all the study activities					✓			**1**
Too busy caring for children or other family members								**0**
Too busy working		✓			✓			**2**
Too busy to come to clinic for the study					✓	✓	✓	**3**
Travel and costs								
I live far from the clinic		✓			✓			**2**
I do not want to spend money/cannot afford to travel to clinic			✓		✓			**2**
I cannot afford childcare to cover time for the study								**0**
I do not want to use data on my mobile device for the study								**0**
Communication								
I did not understand the language of the materials								**0**
I did not understand the aim of the study								**0**
The study was not explained to me properly								**0**
My questions about the study were not answered properly								**0**
Study Design								
I do not want to be seen in community settings		✓	✓					**2**
I do not want to be seen by a nurse I do not know								**0**
I do not want to change my clinic routine				✓			✓	**2**
I had concerns about changes to my medication				✓		✓	✓	**3**
I did not agree with the aim of the study								**0**
I did not want to fill in the surveys								**0**
Concerns about research								
I do not like taking part in research		✓						**1**
I find it difficult to trust research						✓		**1**
I do not like filling in forms								**0**
I have had negative experiences in previous research								**0**
Concerns about information								
I worry about the confidentiality of my information		✓						**1**
I worry about the confidentiality of records about me		✓						**1**
I don't want to provide personal information to research teams								**0**
I don't like to talk about my health to other people that are not my doctor or nurse						✓		**1**
Concerns about privacy								
I have no privacy where I live		✓						**1**
I do not like to have correspondence about my health		✓				✓		**2**
Other*	✓							**1**

*Other response was 'I travel in and out of the UK for work, sometimes for extended periods, so cannot be sure of being in London every 2 months.'

> *almost one of the first few Black women on injectables so that I can say to other, you know, you can do it. It's nothing.* **Grace** *(Black African, Female, aged 54, ILANA participant)*

This sense of solidarity based on social ties was evident in other accounts. Participants with a history of migration discussed how the more limited access to HIV treatment in their countries of origin meant they were keen to contribute to research that they felt could support broader access to treatment globally. Two female participants described how their awareness that the study was seeking women participants, in particular, motivated their agreement to participate.

These accounts indicate that biosocial solidarity does factor into decision-making in research participation, even where someone decides not to take part. In many cases it appeared that this sense of solidarity with others was also built on and shaped by pre-existing social ties based on other forms of community belonging, such as their gender and/or countries of origin, in addition to HIV status.

Theme 2: pursuing normality through (non-)participation

The second key theme generated from both ILANA and No-LANA accounts was participants' desire for a sense of 'normality' in their lives, in the context of living with a chronic, stigmatised health condition.

The disruption that research participation itself can present to a sense of normality is evident in No-LANA participants' survey responses and interviews. Reasons given for declining to take part included the time commitments involved ('too busy to come to clinic' ($n = 3$), 'too busy working' ($n = 2$) and 'too busy to do all the study activities' ($n = 1$)), travel and costs ('I live too far' ($n = 2$) and 'I don't want to spend money/can't afford to travel to clinic' ($n = 2$)), and concerns about changes to medication ($n = 3$) and clinic routine ($n = 2$) (Table 2). Although inconvenience and lack of capacity to take part are not the same as a sense of normality, these responses can additionally be interpreted as concerns about disruption to normal life caused by the demands of the study. When asked for 'any other comments', two survey participants similarly responded in the free-text box that they would have participated in ILANA but the requirement to attend the clinic every two months to receive the injection was not practically compatible with their normal lives.

For some No-LANA participants these were matters of convenience – as appeared to be the case for Luke, who described how he declined to participate because the treatment schedule wasn't compatible with the regular travel he was required to undertake for work. However, Julia's interview highlighted instead that the disruption to her life already created by her HIV diagnosis meant that she was wary of undertaking anything that might further destabilise the equilibrium that she had attained since:

> *But if I had less options probably I would but considering that I have something that works well and why compromise that, that was my worry and, and it's been such a shock for me for eight years [since my diagnosis]. I thought I really need to stay calm now and look after myself instead of putting myself through anxiety [by taking part].* **Julia** *(White European, Female, aged 50, No-LANA participant)*

ILANA participants were also conscious that participating could be disruptive to their lives, citing increased frequency of appointments, increased travel to clinic, but also treatment-related issues. The latter included concerns about possible side-effects and injection pain, but also effects on their HIV viral load and health from changing treatment. Yet most considered these disruptions to be balanced by the potential gain of the benefits of a new treatment.

Jackie shared Julia's concerns about treatment failure, but she felt reassured that CAB+RPV LAI was already approved on the NHS and considered that any potential harm was reversible:

> *Yeah, so then I don't want to see any changes in the viral load, in anything, you know. Like the most important thing, I want to keep everything as it should be (…) I don't want to have any health complications through it. You know, like, that was a sort of a bit of a gamble I was taking by having the injections. Like, for me, it was a little bit worrying because obviously it was a research thing. So, I was like – has it been approved by the NHS? Because I'm not going to be a guineapig at all. So obviously it had, but it's still quite new. So that was the thing I was worried about, was that obviously I needed to be keeping everything as it should be. There was no leeway on that. That would be the only reason I'd stop, is if it weren't working properly.* **Jackie** *(White British, Female, aged 37, ILANA participant)*

The difference for ILANA participants was that many felt accessing CAB+RPV LAI through ILANA was, in turn, instrumental in helping them to feel more 'normal' and this balanced the risks of disruption from participation. In their accounts, ILANA participants described the many challenges they experienced with oral medication – including pill fatigue, side effects, difficulties swallowing pills – all of which simultaneously served as a constant daily reminder of their HIV status. In contrast, the long-acting nature of CAB+RPV LAI offered the prospect of reducing the mental load, allowing them to feel "more like normality. I'm like everybody else now. It's one less thing to worry about", as Robert (White British, Male, aged 51), an ILANA participant, described. Consequently, many ILANA participants knew about CAB+RPV LAI well in advance of being invited to participate in ILANA, through their own personal research and/or conversations with their clinician, and were keen to find a way to access it, as exemplified by Sue's experience:

> *I was having my six-monthly check-up with the consultant, and they'd mentioned that injectables were becoming a thing. I think I'd always said I'd like to try it because of the horrible time I had taking pills. But then I think they were just waiting for a trial that I would meet the criteria for, so I think when there was one then they suggested it to me and I said yes, please.* **Sue** *(White British, Female, aged 50, ILANA participant)*

While the pursuit of 'normality' may be shared by many whose lives have been disrupted by the diagnosis of a chronic illness, this desire is often heightened for those confronted by the stigma that surrounds living with HIV. Here, we consider stigma as "[a] social process inherently linked to the production and reproduction of structural inequalities" [39]. Underpinning many of the accounts

in our study were worries about inadvertent disclosure of HIV status, and fears of shame, discrimination and marginalisation that could occur as a result of being identified as part of a group that is 'devalued' by society [39]. Although many ILANA participants considered CAB+RPV LAI to offer greater discretion than taking pills, No-LANA participants highlighted how participating in research could instead *increase* the risk of inadvertent disclosure, with survey respondents reporting concerns about being seen in community settings ($n = 2$), confidentiality of information ($n = 2$) and records ($n = 2$), receiving correspondence about their health ($n = 2$), talking to clinicians who are not their usual clinician ($n = 1$) and a lack of privacy where they live ($n = 1$) (Table 2).

Julia's account highlights how she weighed up the potential benefit of greater discretion offered by CAB+RPV LAI in the context of travel to countries where being identified as someone living with HIV can result in deportation against the disruption to her treatment routine and risk of treatment failure:

> *In my previous job I had to travel to the Middle East (…) that gave me a lot of anxiety throughout all these years. (…) I do very well with my treatment, and I've never had an issue, so I never had any issue with my treatment in itself. The issue was having to travel to those countries. (…) Initially I said yes [to participate in ILANA], but then I started making a few researches. So, there were a few reasons why I said no. I think the main reason was that there were a few cases with the injectables every two months of viral rebound. (…) And then the other reason was, umm, logistically for me with the job that I had, every two months was really a pain.* **Julia** *(White European, Female, aged 50, No-LANA participant)*

Consequently, our participants accounts demonstrated that the pursuit of 'normality' can motivate either participation or non-participation in research, wherein the disruptive nature of research can be deemed too great a threat to stability or offer the hope of a new treatment that can lead to a novel state of 'normality', freed from the more disruptive elements of living with a highly stigmatised, chronic condition.

Theme 3: the role of trust in clinicians in (non-) participation decision-making

The third key theme generated from both ILANA and No-LANA accounts was the trust that participants had in their clinical team and how this supported patient autonomy in decision-making around (non-)participation.

Both ILANA and No-LANA participants described how the quality of their HIV care and the trust they have in their clinical teams meant they were more amenable to participating in research. Luke, a No-LANA participant, was first approached to participate in research when he was very recently diagnosed due to some unusual features of his diagnosis. He highlights that the quality of care and kindness he received from the clinical research team meant he is *always* open to participating in research if it is practicable for him:

> *It was just, just very much like the care provided by that that team at [clinic name] and so I've always been very open to hearing whatever is sort of, you know, that they're trying to do next, and if I can be of help with it, I'm open to it.* **Luke** *(White British, Male, aged 45, No-LANA participant)*

The stigmatising nature of HIV and its disproportionate burden on marginalised communities appears to add another layer to participants' trust in their clinical team, particularly in the context of long-term patient-provider relationships. Many participants described how their clinical team were aware of their needs, histories and the challenges they faced around living with and managing their HIV and understood them as whole beings.

Grace had not participated in research prior to being part of the ILANA study. As described above, she had heard from other women who had expressed fears about injectable treatment. When asked why she felt differently about injectables than her peers, she replied that:

> *I was confident in the team because when I was so unwell, unfortunately, the doctor who treated me personally, they treated me with so much humanity that it actually makes me a bit emotional talking about it … They didn't see my skin colour. They didn't see my sexuality. They saw a human being who was unwell, and they didn't see my status – because I was, I didn't have [immigration] papers. They saw a human being who needed to be treated when I didn't believe there was treatment … So, I was in the hands of the best team, the best human beings you can ever think. And so it wasn't that I had confidence in the injection. I had the confidence in the team that was for me.* **Grace** *(Black African, Female, aged 54, ILANA participant)*

As well as feeling 'seen' by their clinicians, participants described how they felt 'heard' by them too. The invitation to participate in research was an opening for collaborative dialogue and decision-making between clinician and patient, as illuminated by Jamelia's account:

> *What I liked most was communication. I was able to ask and get answers. That's most of it. I was just*

> *myself. Not once did I ever have to argue with anyone about it or anything. It just went all smoothly.* **Jamelia** *(Black African, Female, aged 54, ILANA participant)*

Jamelia's ability to feel 'just myself' in this encounter highlights the mutual respect and care between clinician and patient. She was able to ask questions and have them answered. This is particularly notable given the experiences of many patients in health services, particularly minoritised people, of medical silencing and epistemic injustice – wherein patients are ignored and their credibility doubted due to stereotypes about their identity [40].

ILANA participants highlighted that it was often the clear and transparent conversations they had with their clinicians, rather than the written information they were provided by the research team, that helped them with the decision to participate. None of the No-LANA survey respondents selected communication issues (not understanding the language or aim of the study, study not being explained properly, or questions about the study not being answered properly) as reasons for declining to participate in ILANA (Table 2). However, No-LANA survey participants expressed concerns about not being able to afford travel costs, whereas these were in fact covered by the study, reflecting poor communication from study staff in these instances.

Some interview participants' accounts illuminate how the invitation to take part in research can reinforce a sense of being a 'responsible' patient, which can further build trust between patient and clinician. When asked why they thought they had been invited to participate in ILANA, ILANA participants often referred to their viral load test results and being 'entitled' or a 'good candidate' for injectable treatment, as described by Joshua:

> *She goes oh, I could put you forward, 'cause I think I had quite, always had quite good results. She said I'll be probably a good candidate for it, and she said she'll try and put me forward and see from there. I said yeah, I'd be happy to trial it and see how it goes.* **Joshua** *(Black British, Male, aged 37, ILANA participant)*

An invitation to participate in a study of a desirable treatment can therefore be perceived as a reward for being a 'responsible' patient, further reinforced in this case by the eligibility criteria for CAB+RPV LAI requiring an undetectable viral load [22]. As well as gaining access to CAB+RPV LAI, participants also noted that participating in research meant they accessed more attentive and consistent care than they might otherwise in routine care provision. For some, this offered reassurance in the context of trying a new treatment, as they felt they would be more closely monitored for side-effects and treatment failure. Michael, an ILANA participant, had some initial concerns about switching treatments due to previous bad experiences with side-effects, and felt the study offered the prospect of more personalised and accessible care:

> *I thought because it's all quite new, the injections, I did wonder whether I'd be, um what would be the word? (-) Erm, (-) … whether you would be with a dedicated team type of thing. I knew it would be with the research nurses, so it wouldn't be a different nurse each time, etc. I felt maybe you would feel a little bit more secure … You have a dedicated number that you can contact them at any time if you have a problem, etc. So, it felt a little bit more comforted if you know what I mean? Yeah, that also came in, it sounded quite attractive to be part of the trial … The thing I liked about it was the regularity with the nurse, and predominantly with [nurse's name]. You build up a rapport with your healthcare professional, you get used to them. It was nice to have consistency, because over on the NHS side you might have a different nurse each time you go.* **Michael** *(White British, Male, aged 62, ILANA participant)*

In the context of a long-term trusting relationships with clinicians, and particularly where an invitation to participate in research enables access to a desired treatment, offers of participation may confer a sense of privilege or gratitude among patients. Participation in research can therefore make the relationship between patient and clinician feel more reciprocal, whereby the patient is an active contributor rather than a passive recipient, as highlighted by Dev:

> *I think being part of something like that and being able to give back, I guess … I've been a user of the service so if there's something I can give back to the service then I would like to help out.* **Dev** *(Asian Indian, Male, aged 47, ILANA participant)*

Nevertheless, while trust in the clinical research team may encourage reciprocity, this does not necessarily translate into a sense of obligation. Julia illustrates how trust in the clinical research team may be a necessary component to considering research participation, but also to making an autonomous decision not to take part. In her account, she describes how her doctor knows her well and the challenges she has with carrying her medication when travelling for work. But her reluctance to expose herself to the risk of potential treatment failure meant she ultimately found a solution which she felt more comfortable with and that also met her needs:

> *When I took the decision [to say no], I was very, I searched a lot, took me a few weeks to take my decisions, spoke to a lot of people because I knew I was being given an opportunity. Many people wanted it, and they couldn't get it, and I say no. So, I felt a bit bad, but I'm very glad I did because I'm so relaxed now.* **Julia** *(White European, Female, aged 50, No-LANA participant)*

These accounts demonstrate, therefore, that trust in clinicians is also a key influence in decisions around (non-) participation in research. The high-quality, non-judgmental care that participants had received from their clinical teams meant they trusted that they would not risk their health through research, but also that they could participate in shared decision-making about whether taking part was right for them. This collaborative dialogue was underpinned, in many accounts, by a sense of having gained trust from clinicians through being a 'responsible' patient. Yet this also allowed participants to choose to say no to taking part, highlighting how trust and open dialogue supports patient autonomy.

Discussion

In this study about (non-)participation in a long-acting injectable HIV treatment study, we found that some of the decision-making was shaped by practical decisions around convenience and cost. However, it was also informed by solidarity, the pursuit of normality and trust in clinicians within the context of living with and managing a chronic, stigmatised health condition. Our findings demonstrate that reasons for non-participation are not simply the reverse of reasons to participate, and the decision not to participate can involve similar motivations yet lead to different outcomes. We argue that this has implications for how researchers perceive and characterise those who decline participation in research. It also highlights that barriers to research participation should be considered in the context of what can be addressed through changing research structures, culture and practices, (for example, the use of mandatory recruitment targets to overcome potential investigator bias and practical support for facilitating participation) and what requires change within the broader healthcare and social environment and concerns (for example, the trust between a patient and clinician, and the competing demands on an individual's time).

In the ILANA study, participants were mainly women (62/114) and mainly from racially minoritised groups (80/114), with over a third of participants (41/114) identifying as Black women [24]. This was achieved through meaningful public involvement, the implementation of mandatory recruitment targets, and practical support such as covering travel and childcare costs and offering evening appointments outside of working hours [41]. We propose that the diversity of our research participants resulting from the intentional and inclusive study protocol allowed us to trouble assumptions about the kinds of people who are willing to participate in research. In this sub-study also, 7/15 interviewees were from racially minoritised groups. This enabled us to delve deeper into the multiplicity of influences on people's (non-)participation decisions. This accords with prior research from the UK indicating that ethnic minorities are often as willing to participate in research as white British people but are much less likely to be deemed eligible and interested and invited to participate. Factors influencing this include language restrictions, locating study sites in ethnically homogenous areas, and clinician stereotyping around who is likely to comply with research processes [16, 42–44]. Consequently, researchers focusing more on an equitable *offer* of research participation may be more impactful than focusing solely on changing the attitudes underserved groups towards research [45, 46]. The nature of this offer will depend on the health condition or issue being researched, the underserved groups on this topic, and the type of research. While suggestions on how this can be done abound in the literature, more research is needed to evaluate how these approaches may contribute to more equitable research in different contexts for various underserved groups [14, 15, 47, 48].

Our findings have also allowed us to 'test' the theoretical concepts of biosociality and therapeutic citizenship in the context of a contemporary HIV therapy study in underserved groups. Biosocial intentions in relation to other people living with HIV or people from similarly marginalised or minoritised communities were evident among the narratives of both sets of participants, yet these seemed to be secondary to their individual needs and convenience. Those who chose to participate in ILANA perceived CAB+RPV LAI as a 'technology of hope' [49] offering a return to 'normality', and an immediate relief from daily oral treatment as well as a way (for some) to contribute to the ultimate goal of finding a cure for HIV (an ultimate 'normality'). The wish to 'return to a normal life' has previously been identified as limiting individuals' desire to participate in new (bio) social networks such as research [50]. In this context, it may be aligned with a motivation to demonstrate biosocial solidarity with others living with HIV through research participation. Nevertheless, research participation may disrupt normality through treatment-related issues (e.g. side effects, treatment failure, etc.), increased clinic attendance or lengthier appointments, unfamiliar research team members, or potential inadvertent disclosure through research correspondence. As a result, research participation appeared to conflict with forms of

social support that participants greatly valued, as has also been described elsewhere in the literature [50, 51].

In this study, aspirations for therapeutic citizenship can be seen as active in the context of a desirable treatment innovation (injectables), rather than in the context of scarcity and 'triage' during the global roll-out of HIV treatment in the 1990s. In the case of ILANA, an invitation to participate in research about long-acting therapy largely available only to those with an undetectable viral load was perceived as a reward for successful therapeutic citizens. Viral loads (the biological marker of treatment success) have been discussed elsewhere as markers of 'biolegitimacy' [51, 52], thus unlocking access to additional forms of support available only to people on successful treatment (desirable therapies, more personalised and attentive care, etc.). However, accounts of No-LANA interview participants also characterise decisions not to participate in research as 'responsible' therapeutic citizenship – optimising adherence and protecting the self from viral rebound and treatment failure [53].

The trust between participants and the clinical research team appeared to be the crucial foundation which enabled individuals to feel confident in their decision-making, regardless of the outcome. We have seen how participation in research was narrated as an opportunity to express responsibility through reciprocity towards the "consistent good will of potential helpers (…) required for survival" [54] – in this context, the clinicians with whom participants have had long-term therapeutic relationships. Kingori [55] discusses how invitations to participate in research may amount to 'soft coercion' in resource-limited settings, but this was not borne out in our findings from a high-resource setting where treatment is universally available and free at the point of use. Instead, open dialogues about decisions regarding participation between patient and clinicians appeared to encourage autonomous decisions, enabling research participants to decline participation without fear of jeopardising their care. Importantly, such open dialogue in turn keeps the prospect of future participation in research alive.

We are conscious that there are specificities to our case when transferring our findings to other contexts and conditions. We consider important specificities to be considered are that our participants were 'healthy' participants already on therapy, living with a chronic rather than acute illness, and most described long-term relationships between themselves and their clinician. HIV itself and HIV-associated stigma shaped the decision-making for many participants and therefore our findings are mainly applicable to the context of a stigmatising chronic illness. Our No-LANA sample was small (although the overall number of people declining to take part was also small) and survey respondents may have different views from the two interviewees that we have not been able to capture. We also recognise that the heterogeneity of our datasets (from both those in ILANA and those in No-LANA) presents challenges in interpretation, although merging our datasets afforded us opportunities for comparing and contrasting accounts in order to gain a more holistic view of research (non-)participation decision-making.

Conclusion

Non-participation of underserved groups in clinical research is often framed as a 'problem' to be solved, underpinned by the assumption that participation in research is both necessary and beneficial [45]. This assumption may inadvertently increase stigmatisation of individuals from underserved groups who choose not to participate, by implying that they are unwilling to contribute to improving medical care for their communities [46]. Our analysis therefore offers insights into how decision-making across a diverse group of research participants can be motivated by similar factors but lead to different outcomes. In the case of the ILANA study, an inclusive protocol design and mandatory recruitment targets meant a broad range of patients were invited to participate, and both participant and non-participants balanced solidarity, the pursuit of normality, and trust in their clinicians within their decision-making. Aspirations to therapeutic citizenship were evident in the narratives of both groups.

We suggest that focusing on improving equity of *offer* through inclusive research design is therefore a central first step to addressing inequity in research participation. Ensuring individuals' ability to make an informed choice to decline participation should be regarded as important as agreement to participate when seeking to promote equity in research participation of underserved groups. Considering a framework to understand how individuals balance their needs and aspirations in relation to *solidarity, normality* and *trust* as part of their interpretation of their role as health citizens can be helpful to inform clinical practices of recruitment, reduce bias about who may (or may not) be a 'good candidate' for research and, ultimately, ensure open dialogue about (non-)participation that supports inclusion in the long term.

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12939-025-02709-7.

Supplementary Material 1

Acknowledgements

We thank the No-LANA and ILANA study participants who consented to contribute data to improve our understanding about research (non-) participation in HIV research studies. We thank Sadna Ullah (Programme

Manager, SHARE Collaborative, Queen Mary University of London) and Nishat Halim (Trial Manager, SHARE Collaborative, Queen Mary University of London) in administrating the No-LANA study. We would like to thank Gill-Hilton Smith, Jenny Scherzer, Amber Haley, and Maggie Czarnogorski (all ViiV Healthcare) for their support with study design and set-up. We thank the SHARE Collaborative Community Advisory Board – Bakita Kasadha, Angelina Namiba, Zoch Nwaosu and Matthew Hodson – for their strategic oversight of ILANA and No-LANA, ensuring the studies meet the needs of people with HIV.

Author contributions

The study was conceptualised by SP, CMO and VA. SP and CMO acquired the study funding. FB peer reviewed the proposal. The methodology and recruitment plan and were determined by SP, RH, CMO, VA and BK. The curation and formal analysis of the quantitative survey data was conducted by RH. The qualitative interview data was collected and curated by RH and SP, and the formal qualitative analysis was conducted by RH with supervision from SP. The study findings were interpreted by all co-authors. The original draft of the manuscript was written by SP and RH. Reviews and edits of subsequent drafts were conducted by all co-authors

Funding

The study was funded and co-designed by ViiV Healthcare and sponsored by Queen Mary University of London. The funder had no role in conduct, data analysis or interpretation.

Data availability

Deidentified survey data collected will be made available from the corresponding author on reasonable request. Interview data which will not be shared, as contextual information shared during interviews may pose risks for participant identification despite anonymisation

Declarations

Ethics approval and consent to participate

The study was conducted in accordance with the Declaration of Helsinki and approved by City & East London Research Ethics Committee on 14 April 2022 (REC 22/PR/0318). Participants received a £15 voucher for participating in the survey and a £50 voucher for participating in the interview, with the amounts reflecting the inherent challenges of including people in a study about non-participation.

Consent for publication

Not applicable.

Competing interests

SP has received research grants from ViiV Healthcare and Gilead Sciences. BK has received speaker honoraria and consultancy fees from Gilead Sciences, GSK, and ViiV Healthcare. VA has received speaker fees from ViiV Healthcare, Gilead Sciences and MSD. FB has received speakers fees from Gilead Sciences and research grants from Gilead Sciences, ViiV Healthcare and MSD. CMO has received honoraria for advisory boards, lectureships, and travel sponsorships from Janssen, Gilead Sciences, ViiV Healthcare, MSD and Bavarian Nordic and has received research grants from Janssen, Gilead Sciences, ViiV Healthcare, MSD and AstraZeneca. RH has no interests to declare.

Received: 27 May 2025 / Accepted: 19 November 2025
Published online: 23 December 2025

References

1. Kennedy-Martin T, Curtis S, Faries D, Robinson S, Johnston J. A literature review on the representativeness of randomized controlled trial samples and implications for the external validity of trial results. Trials. 2015;16(1):495. https://doi.org/10.1186/s13063-015-1023-4.
2. Bower P, Grigoroglou C, Anselmi L, Kontopantelis E, Sutton M, Ashworth M, Evans P, Lock S, Smye S, Abel K. Is health research undertaken where the burden of disease is greatest? Observational study of geographical inequalities in recruitment to research in England 2013-2018. BMC Med. 2020;18(1):133. https://doi.org/10.1186/s12916-020-01555-4.
3. Rai T, Dixon S, Ziebland S. Shifting research culture to address the mismatch between where trials recruit and where populations with the most disease live: a qualitative study. BMC Med Res Methodol. 2021;21(1):80. https://doi.org/10.1186/s12874-021-01268-z.
4. Treweek S, Banister K, Bower P, Cotton S, Devane D, Gardner HR, Isaacs T, Nestor G, Oshisanya A, Parker A, Rochester L, Soulsby I, Williams H, Witham MD. Developing the include ethnicity framework-A tool to help trialists design trials that better reflect the communities they serve. Trials. 2021;22(1):337. https://doi.org/10.1186/s13063-021-05276-8.
5. Beard E, Dixon S, Rai T, Hayward G. Ethnicity and socioeconomic status: missing in research means missing in clinical guidance. BJGP Open. 2021;5(3). https://doi.org/10.3399/BJGPO.2021.0034.
6. Ross S, Grant A, Counsell C, Gillespie W, Russell I, Prescott R. Barriers to participation in Randomised controlled trials: a systematic review. J Clin Epidemiol. 1999;52(12):1143–56. https://doi.org/10.1016/S0895-4356(99)00141-9.
7. Castillo-Mancilla JR, Cohn SE, Krishnan S, Cespedes M, Floris-Moore M, Schulte G, Pavlov G, Mildvan D, Smith KY. Minorities remain underrepresented in HIV/AIDS research despite access to clinical trials. HIV Clin Trials. 2014;15(1):14–26. https://doi.org/10.1310/hct1501-14.
8. Johnston RE, Heitzeg MM. Sex, age, race and intervention type in clinical studies of HIV cure: a systematic review. AIDS Res And Hum Retroviruses. 2015;31(1):85–97. https://doi.org/10.1089/aid.2014.0205.
9. Curno MJ, Rossi S, Hodges-Mameletzis I, Johnston R, Price MA, Heidari S. A systematic review of the inclusion (or exclusion) of women in HIV research: from clinical studies of antiretrovirals and vaccines to cure strategies. JAIDS J Acquired Immune Deficiency Syndromes. 2016;71(2):181. https://doi.org/10.1097/QAI.0000000000000842.
10. Mills E, Wilson K, Rachlis B, Griffith L, Wu P, Guyatt G, Cooper C. Barriers to participation in HIV drug trials: a systematic review. The Lancet Infect Dis. 2006;6(1):32–38. https://doi.org/10.1016/S1473-3099(05)70324-8.
11. Rodríguez-Torres E, González-Pérez MM, Díaz-Pérez C. Barriers and facilitators to the participation of subjects in clinical trials: an overview of reviews. Contemp Clin Trials Commun. 2021;23:100829. https://doi.org/10.1016/j.conctc.2021.100829.
12. Houghton C, Dowling M, Meskell P, Hunter A, Gardner H, Conway A, Treweek S, Sutcliffe K, Noyes J, Devane D, Nicholas JR, Biesty LM. Factors that impact on recruitment to randomised trials in health care: a qualitative evidence synthesis. Cochrane Lib. 2020. https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.MR000045.pub2/abstract?cookiesEnabled.
13. Rai T, Hinton L, McManus RJ, Pope C. What would it take to meaningfully attend to ethnicity and race in health research? Learning from a trial intervention development study. Sociol Of Health Illn. 2022;44(S1):57–72. https://doi.org/10.1111/1467-9566.13431.
14. Gwadz MV, Colon P, Ritchie AS, Leonard NR, Cleland CM, Riedel M, Bowens D, Banfield AD, Chang P, Quiles R, Mildvan D. Increasing and supporting the participation of Persons of color living with HIV/AIDS in aids clinical trials. Curr HIV/AIDS Rep. 2010;7(4):194–200. https://doi.org/10.1007/s11904-010-0055-3.
15. Hawke LJ, Nelson E, O'Brien P, Crossley KM, Choong PF, Bunzli S, Dowsey MM. Influences on clinical trial participation: enhancing recruitment through a gender lens - a scoping review. Contemp Clin Trials Commun. 2024;38:101283. https://doi.org/10.1016/j.conctc.2024.101283.
16. Smart A, Harrison E. The under-representation of minority ethnic groups in UK medical research. Ethnicity & health. 2017. https://www.tandfonline.com/doi/abs/10.1080/13557858.2016.1182126.
17. Sullivan KA, Little MO, Rosenberg NE, Zimba C, Jaffe E, Gilbert S, Coleman JS, Hoffman I, Mtande T, Anderson J, Gross MS, Rahangdale L, Faden R, Lyerly AD. Women's views about contraception requirements for biomedical research participation. PLoS One. 2019;14(5):e0216332. https://doi.org/10.1371/journal.pone.0216332.
18. Dixon-Woods M, Cavers D, Agarwal S, Annandale E, Arthur A, Harvey J, Hsu R, Katbamna S, Olsen R, Smith L, Riley R, Sutton AJ. Conducting a critical interpretive synthesis of the literature on access to healthcare by vulnerable groups. BMC Med Res Methodol. 2006;6(1):35. https://doi.org/10.1186/1471-2288-6-35.
19. Farooq HZ, Apea V, Kasadha B, Ullah S, Hilton-Smith G, Haley A, Scherzer J, Hand J, Paparini S, Phillips R, Orkin CM. Study protocol: the ILANA study-exploring optimal implementation strategies for long-acting antiretroviral therapy to ensure equity in clinical care and policy for women, racially minoritised people and older people living with HIV in the UK - a qualitative multiphase longitudinal study design. BMJ Open. 2023;13(7):e070666–070666. https://doi.org/10.1136/bmjopen-2022-070666.

20. Rabinow P. Artificiality and enlightenment: from sociobiology to Biosociality. In: Essays on the anthropology of reason. Princeton University Press; 1996. p. 91–111.
21. Nguyen V-K, Ako CY, Niamba P, Sylla A, Tiendrébéogo I. Adherence as therapeutic citizenship: impact of the history of access to antiretroviral drugs on adherence to treatment. Aids. 2007;21:S31. https://doi.org/10.1097/01.aids.0000298100.48990.58.
22. NICE. Cabotegravir with rilpivirine for treating hiv-1 | guidance. 2022 January 5. https://www.nice.org.uk/guidance/ta757. NICE.
23. Elias A, Smuk M, Whelan I, Pepper NA, Halim N, Ring K, Apea V, Orkin C. P024 inclusion of women, racially minoritised people and older adults in real-world studies evaluating long-acting injectable cabotegravir and rilpivirine: a scoping review. Poster Session: Annual BHIVA Spring Conference 2024. Annual BHIVA Spring Conference. Birmingham, United Kingdom: 2024 May 29. https://onlinelibrary.wiley.com/doi/full/10.1111/hiv.13628.
24. Orkin C, Hayes R, Haviland J, Wong YL, Ring K, Apea V, Kasadha B, Clarke E, Byrne R, Fox J, Barber TJ, Clarke A, Paparini S, Group F. Perspectives of people with HIV on implementing long acting cabotegravir plus rilpivirine in clinics and community settings in the UK: results from the anti-sexist, anti-racist, anti-ageist ILANA study. Clin Infect Dis Ciae. 2024;523. https://doi.org/10.1093/cid/ciae523.
25. Epstein S. Inclusion: the politics of difference in medical research. University of Chicago Press; 2007. http://ebookcentral.proquest.com/lib/gmul-ebooks/detail.action?docID=408322.
26. Biehl J. The Activist state: global pharmaceuticals, aids, and citizenship in BRAZIL. Soc Text. 2004;22(3 (80):105–32. https://doi.org/10.1215/01642472-22-3_80-105.
27. Rose N, Novas C. Biological citizenship. In: Global assemblages: technology, politics, and ethics as anthropological problems. Wiley-Blackwell; 2005. p. 439–63.
28. Whyte SR. Health identities and subjectivities. Med Anthropol Q. 2009;23(1):6–15. https://doi.org/10.1111/j.1548-1387.2009.01034.x.
29. Heinemann T. Biological citizenship. In: ten Have H, editor. Encyclopedia of global bioethics. Springer International Publishing; 2016. p. 347–53. https://doi.org/10.1007/978-3-319-09483-0_453.
30. Petryna A. Biological citizenship: the science and politics of chernobyl-exposed populations. Osiris. 2004;19:250–65.
31. Rhodes T, Harris M, Martin A. Negotiating access to medical treatment and the making of patient citizenship: the case of hepatitis C treatment. Sociol Of Health Illn. 2013;35(7):1023–44. https://doi.org/10.1111/1467-9566.12018.
32. Biehl J. Pharmaceuticalization: aids treatment and global health politics. Anthropological Q. 2007;80(4):1083–126.
33. Robins S. From "rights" to "ritual": aids activism in South Africa. Am Anthropologist. 2006;108(2):312–23. https://doi.org/10.1525/aa.2006.108.2.312.
34. Mazanderani F, Paparini S. The stories we tell: qualitative research interviews, talking technologies and the 'normalisation' of life with HIV. Soc Sciamp Med. 2015;131:66–73. https://doi.org/10.1016/j.socscimed.2015.02.041.
35. Paparini S, Rhodes T. The biopolitics of engagement and the HIV cascade of care: a synthesis of the literature on patient citizenship and antiretroviral therapy. Crit Public Health. 2016;26(5):501–17. https://doi.org/10.1080/09581596.2016.1140127.
36. Braun V, Clarke V. Thematic analysis: a practical Guide. sage. SAGE Publications; 2021.
37. Fetters MD, Curry LA, Creswell JW. Achieving integration in mixed methods designs-principles and practices. Health Serv Res. 2013;48(6pt2):2134–56. https://doi.org/10.1111/1475-6773.12117.
38. Farmer T, Robinson K, Elliott SJ, Eyles J. Developing and implementing a triangulation protocol for qualitative health research. Qualitative Health Res. 2006;16(3):377–94. https://doi.org/10.1177/1049732305285708.
39. Parker R, Aggleton P. HIV and AIDS-related stigma and discrimination: a conceptual framework and implications for action. Soc Sciamp Med. 2003;57(1):13–24. https://doi.org/10.1016/S0277-9536(02)00304-0.
40. Dhairyawan R. Listening to the voices of the medically silenced. PLoS Global Public Health. 2024;4(10):e0003761. https://doi.org/10.1371/journal.pgph.0003761.
41. Hayes R, Smuk M, Kasadha B, Halim N, Apea V, Paparini S, Orkin CM & the ILANA study group. (Achieving equitable recruitment through inclusive protocol design: lessons learned from the ILANA study. Trials. 2025;26(1):229. https://doi.org/10.1186/s13063-025-08936-1.
42. Gill PS, Plumridge G, Khunti K, Greenfield S. Under-representation of minority ethnic groups in cardiovascular research: a semi-structured interview study. Fam Pract. 2013;30(2):233–41. https://doi.org/10.1093/fampra/cms054.
43. Jolly K, Lip GY, Taylor RS, Mant JW, Lane DA, Lee KW, Stevens AJ, Brum Steering Committee T. Recruitment of ethnic minority patients to a cardiac rehabilitation trial: the Birmingham rehabilitation uptake Maximisation (brum) study [ISRCTN72884263]. BMC Med Res Methodol. 2005;5(1):18. https://doi.org/10.1186/1471-2288-5-18.
44. Sheikh A, Halani L, Bhopal R, Netuveli G, Partridge MR, Car J, Griffiths C, Levy M. Facilitating the recruitment of minority ethnic people into research: qualitative case study of south asians and asthma. PLoS Med. 2009;6(10):e1000148. https://doi.org/10.1371/journal.pmed.1000148.
45. Fisher JA, Kalbaugh CA. Challenging assumptions about minority participation in us clinical research. Am J Public Health. 2011;101(12):2217–22. https://doi.org/10.2105/AJPH.2011.300279.
46. Wendler D, Kington R, Madans J, Wye GV, Christ-Schmidt H, Pratt LA, Brawley OW, Gross CP, Emanuel E. Are racial and ethnic minorities less willing to participate in health research? PLoS Med. 2005;3(2):e19. https://doi.org/10.1371/journal.pmed.0030019.
47. Collister D, Song C, Ruzycki SM. Fostering diversity in clinical trials: need for evidence and implementation to improve representation. BMJ Med. 2024;3(1). https://doi.org/10.1136/bmjmed-2024-000984.
48. Treweek S, Pitkethly M, Cook J, Fraser C, Mitchell E, Sullivan F, Jackson C, Taskila TK, Gardner H. Strategies to improve recruitment to randomised trials. Cochrane Lib. 2018. https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.MR000013.pub6/full.
49. Novas C. The political economy of hope: patients' organizations, science and Biovalue. BioSocieties. 2006;1(3):289–305. https://doi.org/10.1017/S1745855206003024.
50. Beckmann N. Responding to medical crises: aids treatment, responsibilisation and the logic of choice. Anthropol Med. 2013;20(2):160–74. https://doi.org/10.1080/13648470.2013.800805.
51. Marsland R. (Bio)Sociality and HIV in Tanzania: finding a living to support a life. Med Anthropol Q. 2012;26(4):470–85. https://doi.org/10.1111/maq.12002.
52. Fassin D. The biopolitics of otherness: undocumented foreigners and racial discrimination in French public debate. Anthropol Today. 2001;17(1):3–7. https://doi.org/10.1111/1467-8322.00039.
53. Persson A, Newman C. Potency and vulnerability: troubled 'selves' in the context of antiretroviral therapy. Soc Sciamp Med. 2006;63(6):1586–96. https://doi.org/10.1016/j.socscimed.2006.04.001.
54. Ware NC, Idoko J, Kaaya S, Biraro IA, Wyatt MA, Agbaji O, Chalamilla G, Bangsberg DR. Explaining adherence success in Sub-Saharan Africa: an ethnographic study. PLoS Med. 2009;6(1):e1000011. https://doi.org/10.1371/journal.pmed.1000011.
55. Kingori P. The 'empty choice': a sociological examination of choosing medical research participation in resource-limited Sub-Saharan Africa. Curr Sociol. 2015;63(5):763–78. https://doi.org/10.1177/0011392115590093.

Publisher's Note