

SHORT COMMUNICATION

Facilitators and barriers of women's participation in HIV clinical research in Switzerland: A qualitative study

Nelly Courvoisier¹ | Chiara Storari¹ | Saphir Lesage¹ | Lucie Vittoz¹ |
Charlotte Barbieux² | Isabelle Peytremann-Bridevaux¹ | Ingrid Gilles¹ |
Alexandra Calmy²

¹Center for Primary Care and Public Health (Unisanté), Department of Epidemiology and Health Systems, University of Lausanne, Lausanne, Switzerland

²HIV/AIDS Unit, Department of Infectious Diseases, Geneva University Hospitals, Geneva, Switzerland

Correspondence

Ingrid Gilles, Centre for Primary Care and Public Health (Unisanté), Department of Epidemiology and Health Systems, University of Lausanne, 10 route de la Corniche, 1010 Lausanne, Switzerland.
Email: Ingrid.gilles@unisante.ch

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Abstract

Objectives: Women are underrepresented in most HIV clinical trials in Western countries, but their participation remains crucial as the lack of information on sex- and gender-specific effects may hinder the safety and efficacy of antiretroviral treatments. The aim of this study was to identify barriers to and facilitators of women's participation in HIV clinical trials in Switzerland.

Methods: We conducted semi-structured interviews among 20 women with HIV to explore factors associated with non-participation in clinical trials. The interviewer presented to participants a clinical trial's description and discussed it with them. Lexicometric analysis on transcribed interviews identified three themes and eight sub-themes related to the pros and cons of participation in HIV clinical trials.

Results: Participants evoked mainly decision-making drivers, concerns for women living with HIV and treatment side-effects. They highlighted the need for extensive information provided by trusted healthcare professionals on the research process as central to the decision to enrol in HIV clinical trials. Familial responsibilities were clearly identified as barriers to their participation, but not pregnancy. Additional preoccupations were other health concerns and comorbidities and the consequences of stopping ongoing antiretroviral treatments.

Conclusions: To overcome the barriers to the participation of women living with HIV in clinical research in Western countries, healthcare professionals and researchers should increase women's research literacy by involving them in the study design and by tailoring clinical trials to their social roles and health concerns. Trust in professionals is a facilitator of enrolment of women living with HIV that should be maintained.

KEYWORDS

gender perspective, HIV clinical trial, HIV women, people living with HIV, qualitative research

Nelly Courvoisier, Chiara Storari are co-first authors.

Ingrid Gilles, Alexandra Calmy are co-last authors.

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INTRODUCTION

Most HIV clinical trials in Western countries lack adequate participation of women, despite the fact that they represent one-half of all people living with HIV worldwide [1,2]. This situation is potentially worrisome as the safety and efficacy of treatments may vary according to biological and social factors associated with sex and gender (e.g. sex hormones or metabolism, access to healthcare institutions) [3,4]. Past research with a focus on barriers to and facilitators of participation of people living with HIV in HIV research emphasized the underlying role of positive and trusting relationships with healthcare professionals, altruistic attitudes, and expectations of personal benefits (e.g. reduction of treatments, hope of being cured) in facilitating their participation in clinical trials [5,6]. By contrast, negative attitudes towards research and perceived or actual health risks, as well as socioeconomic and cultural contexts, were described as barriers to participation [7–10].

The main explanation given by researchers for the underrepresentation of women in HIV clinical trials is possible pregnancy and the potential risks to the foetus with a change or interruption of treatment [5]. However, beyond this argument, few studies have formally investigated the barriers and facilitators related to the enrolment of women living with HIV in such trials [6]. To our knowledge, this is particularly the case in European countries, with little consideration given to the women's own discourse. The aim of this study was to explore the knowledge gap related to women's underrepresentation and to approach the issue of participation in clinical trials by women living with HIV from their perspective. More specifically, we investigated the specific perceptions of women living with HIV on HIV research in order to determine the main drivers of participation or not in HIV clinical trials. We also explored the issue of pregnancy as a barrier to participation.

METHODS

Study design

We conducted a qualitative study using in-depth semi-structured interviews with women living with HIV under treatment at the HIV Unit of Geneva University Hospitals (Switzerland) between December 2020 and March 2021. Best practices for qualitative research requirements were followed (Supplemental content 1: COREQ checklist in Appendix S2).

Participants and recruitment

Eligible participants were cis-gender women living with HIV, either included in the Swiss HIV Cohort Study (SHCS)

network in Geneva or supported by a local association [Groupe sida (santé) Genève], aged > 18 years, receiving stable antiretroviral therapy (ART) and fluent in French. Members of the research teams of the HIV Unit of Geneva University Hospitals and the Groupe sida (santé) Genève recruited participants, provided information on the study, scheduled appointments and obtained informed consent to participate 72 h before the interview. Of the 40 patients screened and invited to participate to the study, 20 patients accepted to participate. Recruitment stopped when researchers reached data saturation. Interviewers did not have access to patients' names or medical information. Ethical approval was granted by the Ethics Committee of the Canton of Geneva (reference 2020-02286).

Data collection and analysis

Three researchers (all three women; one PhD and one master's degree in social psychology, and one master's degree in health psychology) specialized in carrying out qualitative interviews conducted the interviews, which lasted approximately 90 min, and followed an interview guide developed on the basis of the published literature on barriers to and facilitators of participation in HIV clinical trials. After discussing women's views on HIV and research, the interviewer presented a clinical trial vignette (Supplemental content 2: vignette in Appendix S3) that described a fictitious clinical trial of a therapeutic vaccine. The hypothesis of the trial (e.g. duration, possible side-effects, potential benefits and consequences on current treatment), as well as inclusion/exclusion criteria and safety aspects of the trial were explained. Participants were asked about their attitude towards their potential participation in the trial and the way in which they would decide to participate (i.e. motivations, barriers, necessary additional information). They were also invited to express in general the pros and cons of their participation in HIV clinical trials, independently of the vignette. Finally, women were asked to express their opinion on the underrepresentation of women in HIV clinical trials in general. Interviewers then asked participants whether pregnancy would be a barrier to their own participation in such trials, or if, from their point of view, they thought that this could be the case for other women living with HIV.

Due to COVID-19 restrictions, interviews ($n = 18$) were conducted either face to face in the HIV Unit in Geneva, applying rules of distancing and hygiene recommended by the cantonal medical authorities. To identify barriers to and facilitators of the participation of women living with HIV in HIV clinical trials, a lexicometric analysis was performed by two researchers experienced in the use of IRaMuTeQ software (v.0.7

alpha 2, 2008–2014 Pierre Ratinaud; Toulouse, France), a computer-assisted qualitative data analysis program specifically dedicated to conducting lexicographic content analysis and allowing the identification of recurring themes and their connections using word or expression co-occurrences [11]. Following the Reinert method [12], texts were partitioned into elementary contextual units (i.e. sentences), which served as units for the analysis. Two hierarchical descending classifications of words by elementary contextual units were carried out to generate a classification of words in thematic classes, including a tree graph showing the associations between these classes in the texts. Each extracted thematic class was associated with a typical vocabulary and extracts. Once the classification was completed, the researchers identified and labelled the classes according to the typical words and extracts. Analyses of connections between classes were performed using a tree graph and a factor analysis of correspondence. Each researcher first conducted their analysis separately and then all researchers discussed the results together to reach a consensus.

RESULTS

All participants were treated with ART and all had undetectable viral load. Fifteen were HIV-positive for more than 10 years, median age was 48 years, eight had already participated in HIV research, 14 had children, nine were of African origin, one was from South America and 10

were from Europe (Supplemental content 3: participants' characteristics in Appendix S1).

Lexicographic analysis

Lexicographic analysis identified eight sub-themes grouped into three main themes: (1) decision-making drivers; (2) living with HIV; and (3) treatments and side-effects. Figure 1 presents themes, sub-themes, typical vocabulary and extracts. Barriers and facilitators of the involvement of women living with HIV in HIV clinical trials derived from the eight sub-themes are summarized in Table 1.

Decision-making drivers

This was composed of three sub-themes. First, participants established their criteria to decide about participation. These concerned having enough information on HIV clinical trials and having a positive attitude towards the clinical trial proposed. This sub-theme was the one with the highest amount of classified text, thus indicating that the need for information and the capacity to imagine and understand the trial were significant considerations regarding any potential participation. The second sub-theme was specifically related to information provided by healthcare professionals who were their reference point to access information. Participants also mentioned the fundamental

Themes	Sub-themes	Typical words	Excerpts
Decision-making drivers (33.6%)	Criteria for decision-making (16.4%)	Information; really; to think; case; impression; to feel; to participate; interest; trial; risk; health; some; finally; that; maybe; I.	"Interest may be generated, and this I think, is achievable with information, by actually paying attention to what is happening" "One has to be already in a mindset that will take in this information as, yes, I want to say, useful".
	Information from professionals (9.1%)	Doctor; to ask; question; nurse; patient; to talk; to explain; trust; problem; to discuss; to understand; him; everything; never; why; with.	"That is why I will never do something without asking my doctor" "Because before participating, I need to ask a lot of questions to understand, I would like that they explain clearly so that I understand correctly".
	Pregnancy & gender differences (8.1%)	Woman; pregnant; man; to protect; to propose; to answer; to decline; situation; age; research; (sexual) relations; less; more.	"It would be good if research succeeded in finding a medicine so that seropositive women would not need to change their current treatment... I know that when I was pregnant, I had to change my treatment and this disturbed me" "For me, not planning a pregnancy isn't a reason to decline, because if one has to avoid it during one year... for me there is no problem".
Living with HIV (27%)	Accepting the disease (15.8%)	Life; to live; people; disease; VIH; to go on; friend; mother; young; courage; to know; husband; to love; to cure; his; me; to want; because.	"Research has improved medicines a lot... the proof is in front of you, and people almost don't die from AIDS now" "To live with this disease, this sword of Damocles above your head, and to say to oneself to take this risk, under such conditions as today I feel secure...".
	Social roles attributed to women (11.2%)	Child; family; son; to count on; to think about; to care; home; women; test; health; the will; always; my; their; she.	"I think that women are busy with children and have no time to do that" "It is not only my mother, but the whole family who counts on me, and also my children" "As women we nonetheless have responsibilities, as family, towards children, towards all that it implies".
	Side-effects (7.6%)	Fever; to react; body; pain; nausea; side effect; to inject; guarantee; thing; cure; muscular; to accept; none; bad; what; how.	"I risk vomiting or having fever or muscular pain" "Perhaps the vaccine will react in your whole body because it enters the blood and that's it"
Treatments and side-effects (39.3%)	Health concerns (16.3%)	To take; medicines; to give; decision; to sleep; big; morning; habit; alone; to stay; to wait; day; to heal; moment; myself; ours; that is; good.	"The first time I took medicines I had strong nausea" "So he gave me a prescription with the pills I wanted, Do you realize it?" "Some took I don't remember how many medicines everyday; at least three, two or one"
	ARTs interruptions (15.4%)	Month; to stop; times; treatment; vaccine; medicine; year; injection; to take; to change; day; epoch; example; to try; hospital; to start; first; three; five; two; every; during; when.	"Then, I don't know. To stop taking the treatment for 5 months, not 3, but 5 months..." "In that case, if I should stop my medicines in the meantime, I don't know what would happen" "Should we stop triple therapy during the trial?"

FIGURE 1 Themes, sub-themes, typical words and excerpts from the lexicometric analysis. Percentages correspond to the proportion of text included in the analysis

TABLE 1 Barriers and facilitators derived from the semi-structured interviews for each of the eight sub-themes

Sub-themes	Barriers	Facilitators
Criteria to decide about participation	<ul style="list-style-type: none"> Negative attitude towards research and the trial 	<ul style="list-style-type: none"> Sufficient information on HIV research Personal information related to the trial proposed Positive attitude towards research and the trial
Information from professionals	<ul style="list-style-type: none"> Negative relationship or past experience with HIV healthcare professionals 	<ul style="list-style-type: none"> Trust in healthcare professionals Healthcare professionals perceived as resources for information
Pregnancy and gender differences	<ul style="list-style-type: none"> Researchers recruiting more men than women 	<ul style="list-style-type: none"> Research tailored for specific life periods, such as pregnancy
Accepting the disease		<ul style="list-style-type: none"> Hope of being cured of HIV Perception of research results as improving quality of life
Social roles attributed to women	<ul style="list-style-type: none"> Familial responsibilities (role of care) 	<ul style="list-style-type: none"> Flexibility in organization of the trial Instrumental support (access to childcare services, transportation) Implication of women in early phases of development of research
Side-effects	<ul style="list-style-type: none"> Side-effects impacting everyday life (familial responsibilities, professional life) 	<ul style="list-style-type: none"> Past experiences of coping with side-effects
Health issues	<ul style="list-style-type: none"> Preoccupations with other health concerns impacting more on everyday life than HIV (e.g. chronic obstructive pulmonary disease, back pain) Compatibility of treatments for comorbidities with the trial 	<ul style="list-style-type: none"> Consideration of health concerns other than HIV by researchers and healthcare professionals
Antiretroviral treatment (ART)	<ul style="list-style-type: none"> Preoccupation with the consequences of stopping ART 	<ul style="list-style-type: none"> Less frequent intake of trial treatment compared with current ART

role of trust both in research and in the professionals to whom they would refer. In a third sub-theme, participants discussed the issue of pregnancy and trial participation, as well as related gender specificities. Pregnancy as a barrier was rarely spontaneously expressed during interviews. Indeed, participants perceived pregnancy as a potential barrier to HIV clinical trial participation for women in general, without identifying it as a strong barrier for themselves. Some stated that participation was limited in time and that it would be conceivable for a woman to postpone pregnancy plans for this period. Others were confident in the fact that frequent controls during the trial would prevent pregnancy-related problems. Finally, participants also expressed the view that underrepresentation could simply be due to the fact that women are less likely than men to be proposed for participation in these trials.

Living with HIV

This broad theme included two sub-themes. The first related to HIV as a terminal illness and socially overwhelming, which they needed to deal with. Participants explained the importance of accepting the disease in

order both to move forward despite HIV and to overcome HIV effects. Scientific research was perceived as one of the elements that allowed them to keep going: first, because some participants had personally experienced improvements in their everyday life due to research; and second, because research carries the hope of healing. The second sub-theme concerned the role of women in society in general and of women living with HIV in particular. Parental responsibilities, as well as the central role participants played in their extended family, were identified as barriers to enrolment in HIV clinical trials. Constraints associated with participation (presented as consuming time and energy) were perceived as conflicting with their family role. In particular, side-effects were considered a major risk for not being able to assume their familial responsibilities.

Treatments and side-effects

This was divided into three sub-themes. The first clearly referred to the side-effects of HIV treatments, either in general or linked to the vignette. In fact, participants questioned their physical reaction to the vaccine. Whereas they

were used to experiencing side-effects and had a clear view on how to cope with them, side-effects remained an aspect to consider carefully in the decision-making process related to participation. The second sub-theme referred to general health issues and treatment for conditions other than HIV. Several participants complained about the fact that some care providers placed too much emphasis on HIV and neglected other health issues. In addition, they questioned their eligibility to participate in HIV trials due to comorbidities. Finally, the third sub-theme was related to ART. Participants related the history of their current ART and expressed the burden of remaining such a long-term treatment, while some women even expressed the need to have pauses during ART. They then linked new long-acting treatment administered by injection as proposed in the vignette to their current ART in terms of frequency of dosing. Thus, reduction of dosing appeared to be a clear benefit of participation in such a trial. However, despite that benefit, women expressed worry about the potential health consequences of interrupting their current treatment for several months.

DISCUSSION

Underrepresentation of women in clinical trials is a concern in many areas of medicine [13,14], not only HIV research. Several policies and guidelines have been developed to increase women's participation in clinical research, without resulting in significant documented improvements overtime [13,15]. This study investigated barriers and facilitators to engagement in HIV clinical trials of women living with HIV in Switzerland through their own discourse.

The women interviewed seemed to be particularly unfamiliar with research on HIV. Even those who had participated in clinical trials in the past had difficulties in explaining the aim of the research they had participated in. In fact, we found no differences in the perceptions of research between women who had already participated in clinical trials and those who had not. This suggests that the research process remains unclear even when explained to participants. Therefore, our results highlight that providing information is not sufficient but must be accompanied by an effort by researchers to make research familiar to participants. Together with the central role of healthcare providers, this need for a clear understanding of research by women living with HIV is a recurrent finding in the literature on research acceptability [8,16]. To address this need, researchers should increase women's research literacy [17,18]. As developed in community-based strategies [19], this can be achieved by soliciting the active involvement of the women living with HIV community to help

document specific information needed to make a decision on participation. In line with patient and public involvement approaches, including women living with HIV in pretrial preparation would have the following benefits: (1) increase awareness among women living with HIV of the active role they can play in HIV treatment development; (2) increase understanding of the relevance of trials to patients, thus making it a valued part of self-care; and (3) allow women to obtain updated information on HIV [2,20].

Other barriers identified were concrete and anchored in gender stereotypes attributed to women, especially the role of care within the family context and in their preoccupations with health concerns other than HIV. The participation of women living with HIV in HIV clinical trials was presented as potentially in conflict with familial responsibilities and treatment for other conditions. Women feared that trials required time and energy that they would usually devote to their family and, more importantly, that potential strong side-effects linked to trials could compromise their ability to assume these responsibilities. This is consistent with research suggesting that women downplay considerations regarding their own health because of their 'primary care roles in their families' [18]. They feared also that interactions between trial treatments and those they take for other health concerns would compromise their participation in the trial or the efficacy of other treatments, or both. These aspects highlight that recruitment into research studies needs to be more sensitive to the circumstances of participants' everyday life. This could be overcome by ensuring a certain flexibility and by adapting to a woman's personal organization or health needs (e.g. by providing childcare services or transportation arrangements or discussing other treatments) [16,21]. However, we believe that a more comprehensive strategy of integrating research into the everyday life of all participants would benefit the enrolment of both men and women.

Although prospective pregnancy was cited among the excluding conditions of the fictitious trial vignette, it is striking that among participants of child-bearing age, none spontaneously expressed prospective pregnancy as a reason for underrepresentation of women in general in HIV clinical trials. This confirms the literature on women's enrolment in HIV research, which reports that pregnancy issues are not among the strongest barriers according to women [1]. When evoked, it was often linked to cultural aspects or social roles attributed to women [22]. This is particularly interesting, as investigators and sponsors in HIV clinical research, as in other fields of medicine [13,14], frequently avoid recruiting women of childbearing age to protect them and their babies from possible complications [13]. As the involvement of women of childbearing age in research is necessary [13,22,23], associating women

and proposing research protocols tailored to their specific needs, either in general or during specific life episodes, represent a crucial step towards increasing their participation in HIV trials and should be endorsed by all those planning phase 3 studies in HIV research.

Strengths and limitations

The main strength of this study is that it complements the understanding of barriers to and facilitators of participation in HIV clinical trials by women living with HIV from a European perspective. However, the following limitations must be considered in interpreting the results. First, our study focused on cis-gender women attending a Swiss HIV consultation. Generalization of our results to all women living with HIV, especially those belonging to minority or vulnerable groups, is limited. Nevertheless, our findings are coherent with studies conducted among the latter groups. Second, the median age of our sample was 48 years, which is close to the median age of the SHCS (51 years), but implies that less than half of the women interviewed were or might be concerned about a potential pregnancy. The fact that the participants did not spontaneously mention pregnancy might be related to this limitation. Although our finding is consistent with some current research, further studies should be conducted to specifically explore the perceptions of women of childbearing age compared with older women regarding pregnancy as a barrier to participation in clinical studies. Third, the trial proposed in our study focused on a vaccine curing HIV. Some participants expressed their concerns about vaccine safety, also in relation to the controversy around COVID-19 vaccines. Studies presenting clinical trials on other treatments, such as dosing frequency, could be considered in order to confirm the central role of the research literacy theme.

CONCLUSIONS

Women living with HIV are not very familiar with HIV research and they clearly expressed the need for personalized and accurate information about HIV clinical trials, combined with a consideration of the social roles they endorse in everyday life and other health concerns. Pregnancy and anxiety over the baby's health as an obstacle to women's inclusion in research do not appear to be a major barrier. Involving women living with HIV in the study design and tailoring HIV clinical trials according to their social roles and actual health concerns would facilitate their enrolment in HIV clinical trials.

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AUTHOR CONTRIBUTIONS

IG, IPB and AC designed the study. CS, SL, LV and CB contributed to the acquisition and transcription of interviews. IG, CS and NC performed the analyses and drafted the manuscript. All authors gave final approval for all aspects of work, ensuring its accuracy.

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SUPPORTING INFORMATION

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