



## Bridging the knowledge gap of biomedical HIV prevention tools among sub-saharan african immigrants in France. Results from an empowerment-based intervention

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### ABSTRACT

**Introduction:** Biomedical HIV prevention tools are available in France to prevent new infections. However, evidence suggests a lack of knowledge of these tools among sub-Saharan African immigrants, who are particularly affected by HIV due to social hardship, an indirect factor of HIV acquisition. We analysed the impact of an empowerment-based intervention on the knowledge of treatment as prevention (TasP), pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP) in a population of precarious sub-Saharan African immigrants.

**Methods:** Data were collected throughout the MAKASI project. Following an outreach approach, participants were recruited in public places based on their precarious situations and followed for six months (0, 3, 6 months) between 2018 and 2021. Participants were randomized into two groups and received an empowerment intervention sequentially (stepped wedge design). We used random-effects logistic regression models to evaluate the intervention effect on the knowledge of biomedical HIV prevention tools. [ClinicalTrials.gov](https://clinicaltrials.gov) Identifier: NCT04468724.

**Results:** The majority of the participants were men (77.5%), and almost half of them had arrived in France within 2 years prior to inclusion (49.3%). At baseline, 56% of participants knew about TasP, 6% knew about PEP and 4% knew about PrEP. Receiving the intervention increased the odds of knowing about PEP (aOR = 2.02 [1.09–3.75];  $p < 0.026$ ). Intervention effects were observed for TasP and PrEP only after 6 months. We found significant time effects for PEP (at 3 months, aOR = 4.26 [2.33–7.80];  $p < 0.001$ ; at 6 months, aOR = 18.28 [7.39–45.24];  $p < 0.001$ ) and PrEP (at 3 months, aOR = 4.02 [2.10–7.72];  $p < 0.001$ ; at 6 months, aOR = 28.33 [11.16–71.91];  $p < 0.001$ ).

**Conclusions:** We showed that the intervention increased the knowledge of biomedical HIV prevention tools. The effect of the intervention was coupled with an important time effect. This suggested that exposure to the intervention together with other sources of information contributed to increased knowledge of biomedical HIV prevention tools among precarious sub-Saharan African immigrants.

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## 1. Introduction

Immigrants from sub-Saharan Africa are particularly affected by HIV in France. In 2021, there were an estimated 5013 new HIV-positive cases, 32% of which involved people born in sub-Saharan Africa (Santé Publique France, 2022), whereas the latter account for less than 2% of the population living in France (Insee, 2023). Among sub-Saharan African immigrants, it is estimated that 91.5 per 10,000 women and 77.6 per 10,000 men may be infected with HIV without knowing their status. These estimates are much higher than those observed in the general population: 0.9 per 10,000 women and 1.6 per 10,000 men (Marty et al., 2018).

In France, HIV prevention is based on a combination of HIV prevention tools such as HIV screening, condom use and biomedical tools: post-exposure prophylaxis (PEP), pre-exposure prophylaxis (PrEP) and treatment as prevention (TasP) (CNS, 2021). PEP was adopted in France as an HIV prevention tool in 1998 and is a combination of antiretroviral drugs taken by HIV-negative people who have been exposed to HIV. PEP should be taken within 48 h of exposure and then daily for up to one month (Ministère des solidarités et de la santé and Direction générale de la santé, 1998). PrEP, available in France since 2016, is an antiretroviral drug taken by HIV-negative people before potential exposure to the virus to reduce the risk of HIV acquisition (Molina et al., 2015, 2017). TasP refers to the fact that people living with HIV on antiretroviral therapy who achieve and maintain an undetectable viral load beyond six months do not transmit HIV to their sexual partners (Vernazza & Bernard, 2016). In 2010, the French experts recommended to treat all HIV infected people in order to reduce new transmissions (Yeni, 2010). The prevention campaigns including TasP as a prevention tool appeared in 2016, particularly among men who have sex with men (MSM) (Lydié et al., 2017).

The prescription of these prevention tools, which are all reimbursed by public health insurance, including the national scheme for undocumented immigrants, is recommended by the French health authorities for populations exposed to HIV (CNS, 2021). This prevention already seems to be successful since national surveillance data show that between 2013 and 2018, the number of HIV-positive diagnoses decreased among people born in France but there have been mixed trends among those born abroad: French-born MSM (−16%), French-born heterosexuals (−22%), MSM born abroad (+38%), heterosexual men born abroad (−14%) and a stability among heterosexual women born abroad (Santé Publique France, 2019).

To the extent that testing and condom use rates did not vary in these population groups (Larsen et al., 2017; Lydié, 2007), the decline in new infections among people born in France could be partly explained, on the one hand, by the good knowledge and use of biomedical HIV prevention tools, particularly by MSM (Billioti de Gage et al., 2022; Velter et al., 2022) and, on the other hand, by the lack of knowledge and use of these tools among other populations exposed to HIV infection, particularly people born in sub-Saharan Africa living in precarious situations (Carillon & Gosselin, 2020; Coulibaly et al., 2023; Hadj et al., 2017).

The lack of knowledge of these prevention tools among immigrants from sub-Saharan Africa in precarious situations is a major concern in the prevention of HIV in France. Indeed, the ANRS Parcours study estimated that at least 35% of people from sub-Saharan Africa followed up for HIV infection in France were infected after migration (Desgrées du Loû et al., 2015). Social and administrative precariousness experienced after arrival in France was an indirect factor of exposure to HIV infection, as it increased the risk of transactional or occasional sex (Desgrées du Loû et al., 2016) and the risk of sexual violence (Pannetier et al., 2017).

With biomedical HIV prevention tools that offer the possibility of managing one's own protection without having to negotiate with one's sexual partner, it is possible to reduce the risk of HIV infection among people who have either non-consensual sex with a condom or unprotected sex. However, this option requires that people be informed of the

existence of these tools so that they can ask for them. The knowledge gap was identified as one of the main barriers to PrEP uptake (Cordel et al., 2022; Mwaturura et al., 2021). Therefore, access to information is an important step towards the use of HIV prevention tools. Consequently, improving the knowledge of these tools among sub-Saharan African immigrants in precarious situations in France through prevention activities is a major challenge in the HIV prevention process and should be tailored to sociocultural circumstances of the target group.

Health empowerment interventions have been described as promoting access to HIV prevention information and resources (Brody et al., 2019). Some empowerment-based interventions aimed at HIV prevention have shown good results in terms of safer sex, sexual communication and knowledge about HIV prevention tools (Romero et al., 2006; Swendeman et al., 2009; Wilson et al., 2019). To our knowledge, no empowerment-based intervention has been developed in France for sub-Saharan African immigrants in precarious situations. The MAKASI empowerment intervention was implemented in this context in the greater Paris area with immigrants from sub-Saharan Africa in precarious situations to reduce their exposure to HIV infection (Gosselin et al., 2019). The intervention consisted of a motivational interview based on Ninacs' theory of individual empowerment (Ninacs, 2002, 2003). Empowerment was defined in the study as "a psychosocial process that promotes the participation and agency of individuals, organizations, and communities to improve control over their own health" (Gosselin et al., 2019). This intervention, in which issues related to knowledge of TasP, PEP, and PrEP were addressed, provided a rare opportunity to analyse the effect of such an intervention on improving the knowledge of biomedical HIV prevention tools among immigrants from sub-Saharan Africa in precarious situations. This study therefore aimed to evaluate the effect of the MAKASI empowerment-based intervention on the knowledge of biomedical HIV prevention tools.

## 2. Methods

### 2.1. The MAKASI study

#### 2.1.1. Trial design

The MAKASI study was conducted between 2018 and 2021 in the greater Paris area to reduce social vulnerability and improve the sexual health empowerment of immigrants from sub-Saharan Africa in precarious situations. This study was based on an outreach approach and used a stepped wedge cluster randomized trial (SW-CRT) design (Hemming et al., 2018) in which participants received the intervention sequentially over two three-month periods (Fig. 1). Participants recruited in the immediate intervention sequence received the intervention immediately after the baseline survey (M0), and those recruited in the deferred intervention sequence received the intervention three months after recruitment once they completed the three-month survey (M3). The participants in the deferred intervention sequence received the intervention at the same places where they were enrolled. This design was chosen for ethical reasons because it allowed all participants to receive the same intervention with a three-month lag, and it also enabled a robust impact evaluation (Hemming et al., 2015). For the impact evaluation, the same participants were surveyed repeatedly over six months: at baseline (M0), three months (M3) and six months (M6). At each survey, participants completed a face-to-face questionnaire that was administered in French or English. The questionnaires included questions on sociodemographic characteristics, living conditions, sexual activity, and knowledge of biomedical HIV prevention tools.

This study was approved by the Committee for Persons' Protection (Comité de protection des personnes, ID RCB 2018-A02129-46) and the French Data Protection Authority (Commission Nationale de l'Informatique et des Libertés, CNIL, déclaration n°2215270); the protocol is registered on [Clinicaltrials.gov](https://clinicaltrials.gov) (NCT04468724).

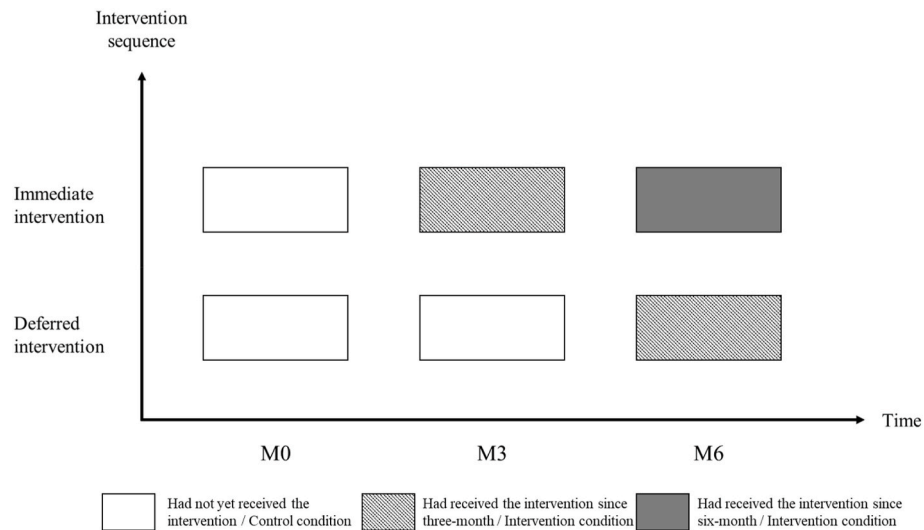


Fig. 1. MAKASI study design.

### 2.1.2. Participants eligibility and inclusion

Participants were recruited at public places where the association Afrique Avenir carries out its rapid HIV testing and health outreach activities, such as public transportation station exits and markets. Eligible participants were born in sub-Saharan Africa, aged 18 years or older, HIV negative (participants received a rapid HIV screening test before the intervention), and met at least one of the following criteria: (i) unstable housing, (ii) unemployed, (iii) experienced food deprivation in the past month (going a full day without eating a meal due to lack of money), (iv) social isolation (not having someone in France to rely on in time of hardship), (v) undocumented or short-term residence permit, (vi) experienced violence, (vii) no health insurance coverage, and (viii) did not know where to go to see a doctor. All participants provided written informed consent and received a €10 voucher at each survey (M0-M3-M6).

### 2.1.3. The empowerment intervention

The MAKASI project was developed by different stakeholders: researchers, members of the Arcat and Afrique Avenir associations and the Arcat association's peer group, a group made up of people from sub-Saharan Africa living with HIV who had experienced precarious situations when they arrived in France. All of these stakeholders were involved in implementing the intervention and developing and testing the questionnaires. The intervention (motivational interview) was led by social workers from the associations Afrique Avenir and Arcat. These associations are established in the greater Paris area for several years and well known by health authorities and the study population. The Afrique Avenir association runs daily community-based screening and prevention campaigns for hepatitis, HIV/AIDS and other sexually transmitted infections. Arcat is a long-standing association fighting HIV/AIDS, hepatitis and discrimination. Both intend to defend the social and health rights of immigrants. The social workers recruited to conduct the intervention were from sub-Saharan Africa and had a background in social psychology and social work. To implement the intervention, they also received two-days initial training in motivational interviewing (Miller & Rollnick, 2016) and ongoing training under the supervision of the trainer, a social psychologist.

The intervention consisted of a single 30-min motivational interview that included three components: (i) listening and building trust, (ii) active referral to partner facilities, and (iii) personalized sexual health assessment and counselling (Appendix Fig. A.1.). During this interview conducted in vans or tents, the social worker had to listen to the participants, identify their needs and help to prioritize them. Then, the social worker could offer a referral to health and social services

appropriate to participants' needs. This referral could include an appointment by phone for the respondent, a referral letter, and a referral map to access the facility. The social worker shared information about HIV prevention and available health and social resources to which they might be entitled with the participant. Collective weekly discussions were organised to review each week's activities and find solutions to the challenges of implementing the intervention. The intervention is described in more detail elsewhere (Gosselin et al., 2019).

### 2.1.4. Randomization and sample size

The intervention impact was evaluated through a stepped wedge cluster randomized trial in which the unit of randomization was the day of intervention. Depending on the day participants were recruited, they were either included in the immediate intervention or in the deferred intervention sequence (Fig. 1). This randomization was conducted by a member of the research team on a monthly basis, and social workers were informed only on the day of the intervention to avoid bias.

Assuming 80% power and a two-sided alpha of 0.05, a minimum sample size of 281 participants per sequence with a risk difference of 0.12 was sufficient to show a difference in percentages between the two intervention sequences.

## 2.2. Statistical analysis

### 2.2.1. Outcome variables

The purpose of this research was to study the impact of the MAKASI intervention on knowledge of the main biomedical HIV prevention tools TasP, PEP and PrEP. The questions for each of these indicators were: "I believe that someone who has HIV and is taking his or her treatment well does not transmit it during sex" (TasP); "Have you ever heard of post-exposure treatment (or emergency treatment) which taken very quickly AFTER sex prevents HIV transmission?" (PEP); and "Have you ever heard of pre-exposure prophylaxis (PrEP), a treatment to be taken BEFORE sex without a condom, which protects against HIV?" (PrEP). Each variable was binary and coded 0 = does not know and 1 = knows. All the questions were pre-tested in a pilot study (Gosselin et al., 2019). During the intervention, the same questions were asked at baseline and at each follow-up visit (i.e., at M0, M3 and M6).

### 2.2.2. Descriptive analysis

First, we performed a descriptive analysis of the participants' characteristics at baseline (M0) using chi-square tests to check the balance between intervention sequences. The variables used included sex; age; level of education; oral French proficiency; region of birth; reasons for

coming to France; duration of stay in France; type of housing; occupational status; experience of food deprivation during the last month; administrative status; experience of violence (other than sexual violence); health insurance coverage; knowing where to go to see a doctor; having someone to rely on in time of hardship; having a stable partner; sex with an occasional partner in the last 3 months; transactional sex in the last 3 months, i.e., unwanted sex in exchange for money, papers, or other goods; and experience of forced sex.

Then, we provided descriptive statistics of the evolution of the levels of knowledge of biomedical HIV prevention tools at each follow-up survey (M0-M3-M6) by intervention sequence (immediate group vs deferred group). Chi-square tests were used to assess the significance of observed differences by sequence at each follow-up survey. Additional analysis stratified by sex is provided in Appendix Fig. A.2.

### 2.2.3. Impact evaluation

To evaluate the effect of the intervention on the knowledge of biomedical HIV prevention tools, we used a multivariable random-effects logistic regression model (Wooldridge, 2020). A robust standard error clustered at the participant level was estimated to take into account within-panel autocorrelation. The main explanatory variables in the analysis are the intervention condition (or intervention effect) and the follow-up time variables. The intervention condition variable was used to capture the intervention effect. As suggested by Hughes and Hussey (Hughes & Hughes, 2007), this variable was an explanatory binary variable (0 = control condition vs 1 = intervention condition) (Fig. 1). With this variable, the intervention effect was assumed to be the same regardless of the time since the intervention was delivered. This variable was our main explanatory variable in the Model 1. Other studies have proposed considering a nonlinear effect of the intervention that may be different over time since the intervention was delivered (Hughes et al., 2015; Li et al., 2021). We used a second intervention effect variable, which is a categorical variable (0 = control condition vs 1 = three months' post-intervention vs 2 = six months' post-intervention) to test the hypothesis of a nonlinear intervention effect in the Model 2 (Fig. 1).

As suggested in the literature in order to estimate an unbiased intervention effect (Hemming et al., 2015, 2017; Hussey & Hughes, 2007), we included in all analysis a categorical follow-up time variable to separate the intervention effect from the time effect since inclusion. The time variable corresponded to the survey waves (M0; M3; M6). We also included in our models all variables related to participants' characteristics that were significantly associated with each outcome in bivariate regressions ( $p \geq 0.10$ ), except for sex and oral French proficiency, which were systematically maintained in the analysis even if the  $p$  values in the bivariate analysis were not significant. These variables were maintained in the analysis to control for potential sex differences and the fact that the language proficiency can influence the participants' understanding of the survey items (Vujcich et al., 2021). Variables checked included participants' characteristics listed in the descriptive analysis (Section 2.2.2) and the following: children; mental health status using the Patient Health Questionnaire (PHQ-9) developed by Kroenke et al. (2001); social workers who delivered the intervention; and ability to express needs to a social or health professional during referral. Bivariate analysis results are provided in Appendix Table A.1.

We performed a robustness analysis by estimating a nonparametric test that fit the stepped wedge cluster randomized trial (Thompson et al., 2019). This analysis involved a Monte Carlo permutation test to estimate a  $p$  value and confidence intervals adjusted for the study design and sample size. We performed the test on Model 1, with 2500 permutations, since the test can only be performed using a binary intervention condition variable (Appendix Table A.2.).

To test and take into account potential attrition bias in the estimations, we conducted a first analysis of all participants using a longitudinal Heckman sample selection model (Heckman, 1976) and a second analysis restricted to participants who completed all follow-up surveys

using a random-effects logistic regression model. For the Heckman sample selection model, we jointly estimated two models: 1 = selection model and 2 = outcome model. This analysis is relevant when the correlation either between the residuals or between the random effects in the selection model and the outcome model is statistically significant. A significant correlation means that the outcome model estimated alone is likely to produce biased estimates, and a non-significant correlation indicates that the outcome model estimates are not biased when presented alone. These analysis were performed using the `cmp` package in Stata (Roodman, 2011). Since the correlation between the selection and outcome models was not significant in all analysis, we kept the results in the appendices as a sensitivity analysis (Appendix Tables A.3, A.4. and A.5.). The results from the analysis performed on the restricted sample are available in Appendix Table A.6. All analysis were presented and discussed collectively with input from all the stakeholders involved in the project. All analysis were performed with Stata 17 (StataCorp. 2021. *Stata Statistical Software: Release 17*. College Station, TX: StataCorp LLC).

## 3. Results

### 3.1. Descriptive analysis results

#### 3.1.1. Participant flow

From April 2018 to December 2020, out of the 2117 participants eligible for the MAKASI intervention, 1799 (85%) received an offer to participate, 1221 (58%) agreed to participate, and 846 (40%) participants were included. After exclusion of participants with a large number of missing values, the final sample included 821 participants (Fig. 2). Of those included, 458 (56%) were surveyed at M3. Of these, 273 (60%) were surveyed at M6.

The description of the characteristics of eligible participants depending on their inclusion status showed that those included in this study were more often men (77.5% vs. 66.4%;  $p < 0.001$ ), had arrived in France in the two years preceding the study (49.3% vs. 30.8%;  $p < 0.001$ ) and were more often in a precarious situation: unemployed (69.5% vs. 59.1%;  $p < 0.001$ ); without a residence permit (74.5% vs. 47.5%;  $p < 0.001$ ) and without any health insurance coverage (44.5% vs. 25.3%;  $p < 0.001$ ) (Appendix Table A.7.).

#### 3.1.2. Participants' characteristics at baseline

Participants' characteristics at baseline by intervention sequence show that the randomization process went overall well since the differences in the main sociodemographic characteristics are mostly not significant (Table 1). However, there were some exceptions. The deferred intervention sequence had a higher proportion of employed individuals (34.5% vs. 26.4%;  $p < 0.01$ ), individuals with a long-term residence permit (11.3% vs. 8.6%;  $p = 0.059$ ) and individuals who had experienced violence (32.5% vs. 25.1%;  $p < 0.01$ ).

Overall, in the three months preceding recruitment, 31.1% of participants had sex with an occasional partner. During the last sexual intercourse with an occasional partner, 52.7% of the respondents used a condom. Nearly 1.7% of the participants had transactional sex (sex in exchange for housing, papers, or money) and 2.5% had forced sex, with no significant differences between sequences (Table 1).

#### 3.1.3. Knowledge levels of biomedical HIV prevention tools over follow-up surveys by intervention sequence

At inclusion, TasP was known by more than one in two participants in the two sequences, and PEP and PrEP were known by only approximately one in twenty participants. Different trends were observed between sequences over follow-up (Fig. 3). At M3, the only significant difference between sequences was regarding PEP knowledge. There was a 10 percentage point difference between the knowledge levels observed in the immediate and deferred intervention sequences (28% vs. 18%;  $p < 0.02$ ). This difference was maintained at M6 (64% vs. 46%;  $p < 0.006$ ). A significant difference between the sequences regarding TasP

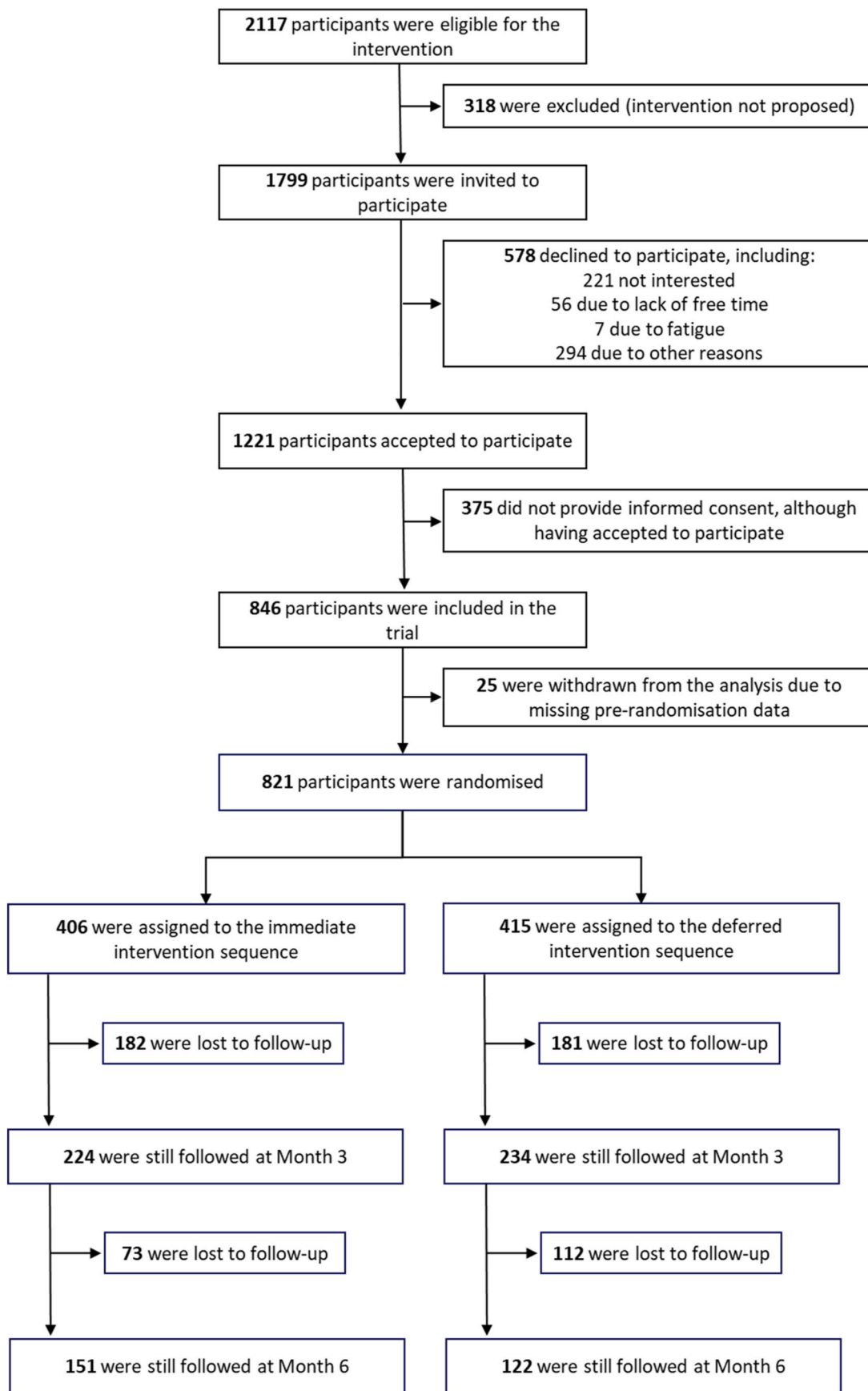


Fig. 2. Inclusion and follow-up flow chart.

**Table 1**  
Characteristics of the study population at baseline, by intervention sequences (N = 821).

	Deferred (N = 415) % (n)	Immediate (N = 406) % (n)	All (N = 821) % (n)	p
<b>Sociodemographic characteristics</b>				
<b>Sex</b>				
<b>Men</b>	77.6 (322)	77.3 (314)	77.5 (636)	0.93
<b>Women</b>	22.4 (93)	22.7 (92)	22.5 (185)	
<b>Age (years)</b>				
<b>18–29</b>	32.5 (135)	29.1 (118)	30.8 (253)	0.32
<b>30–39</b>	39.3 (163)	44.3 (180)	41.8 (343)	
<b>40 +</b>	28.2 (117)	26.6 (108)	27.4 (225)	
<b>Educational level</b>				
<b>None/Primary</b>	29.9 (124)	29.6 (120)	29.7 (244)	0.67
<b>Secondary</b>	52.8 (219)	50.7 (206)	51.8 (425)	
<b>Superior</b>	17.3 (72)	19.7 (80)	18.5 (152)	
<b>Oral French proficiency</b>				
<b>Fluent</b>	77.3 (321)	77.6 (315)	77.5 (636)	0.93
<b>No/can manage</b>	22.7 (94)	22.4 (91)	22.5 (185)	
<b>Region of birth</b>				
<b>Western Africa</b>	61.4 (255)	60.8 (247)	61.1 (502)	0.85
<b>Central, Eastern and Southern Africa</b>	38.6 (160)	39.2 (159)	38.9 (319)	
<b>Main reason for coming to France</b>				
<b>Find work/study</b>	48.0 (199)	41.9 (170)	44.9 (369)	0.12
<b>Join a family member</b>	9.9 (41)	7.9 (32)	8.9 (73)	
<b>Medical reasons and other</b>	5.8 (24)	5.9 (24)	5.8 (48)	
<b>Threatened in their country</b>	36.4 (151)	44.3 (180)	40.3 (331)	
<b>Duration of stay in France (years)</b>				
<b>1–2</b>	45.5 (189)	53.2 (216)	49.3 (405)	0.09
<b>3–6</b>	36.4 (151)	31.3 (127)	33.9 (278)	
<b>7 +</b>	18.1 (75)	15.5 (63)	16.8 (138)	
<b>Living conditions (eligibility criteria)</b>				
<b>Occupational status</b>				
<b>Unemployed</b>	65.5 (272)	73.6 (299)	69.5 (571)	0.01
<b>Employed (informal/formal/student)</b>	34.5 (143)	26.4 (107)	30.5 (250)	
<b>Experienced food deprivation during the last month</b>				
<b>No</b>	58.3 (242)	52.0 (211)	55.2 (453)	0.06
<b>Yes</b>	41.7 (173)	48.0 (195)	44.8 (368)	
<b>Housing type</b>				
<b>Associations</b>				
<b>Housed by family/friends</b>	8.9 (37)	9.4 (38)	9.1 (75)	0.33
<b>Own housing</b>	48.0 (199)	50.5 (205)	49.2 (404)	
<b>No stable housing</b>	31.8 (132)	26.4 (107)	29.1 (239)	
<b>No stable housing</b>	11.3 (47)	13.8 (56)	12.5 (103)	
<b>Administrative status</b>				
<b>Undocumented</b>	75.9 (315)	73.2 (297)	74.5 (612)	0.059
<b>Short-term residence permit (&lt;1 year)</b>	12.8 (53)	18.2 (74)	15.5 (127)	

**Table 1 (continued)**

	Deferred (N = 415) % (n)	Immediate (N = 406) % (n)	All (N = 821) % (n)	p
<b>Long-term residence permit (1 year and +, including French nationality)</b>	11.3 (47)	8.6 (35)	10.0 (82)	
<b>Health insurance coverage</b>				
<b>No Health insurance coverage</b>	41.7 (173)	47.3 (192)	44.5 (365)	0.09
<b>State Medical Aid (SMA)</b>	30.1 (125)	23.6 (96)	26.9 (221)	
<b>Health insurance coverage (HIC)</b>	28.2 (117)	29.1 (118)	28.6 (235)	
<b>Knows where to go to see a doctor</b>				
<b>No</b>	24.3 (101)	27.1 (110)	25.7 (211)	0.36
<b>Yes</b>	75.7 (314)	72.9 (296)	74.3 (610)	
<b>Have someone close to rely on in time of hardship</b>				
<b>No</b>	46.5 (193)	49.3 (200)	47.9 (393)	0.42
<b>Yes</b>	53.5 (222)	50.7 (206)	52.1 (428)	
<b>Experienced violence (other than sexual violence) (beatings, etc.)</b>				
<b>No</b>	67.5 (280)	74.9 (304)	71.1 (584)	0.01
<b>Yes</b>	32.5 (135)	25.1 (102)	28.9 (237)	
<b>Sexual activity</b>				
<b>Had sex with an occasional partner in the last 3 months</b>				
<b>No</b>	71.8 (298)	66.0 (268)	68.9 (566)	0.07
<b>Yes</b>	28.2 (117)	33.9 (138)	31.1 (255)	
<b>Condom use at last sexual intercourse with an occasional partner (n = 408)</b>				
<b>No</b>	46.1 (94)	48.5 (99)	47.3 (193)	0.62
<b>Yes</b>	53.9 (110)	51.5 (105)	52.7 (215)	
<b>Had transactional sex in the last 3 months (n = 814)</b>				
<b>No</b>	98.1 (407)	98.5 (393)	98.3 (800)	0.64
<b>Yes</b>	1.9 (8)	1.5 (6)	1.7 (14)	
<b>Had forced sex since they left their country of origin (n = 811)</b>				
<b>No</b>	97.6 (403)	97.5 (388)	97.5 (791)	0.93
<b>Yes</b>	2.4 (10)	2.5 (10)	2.5 (20)	

Source: Makasi study, 2018–2021.

and PrEP was observed at M6. Knowledge levels of these two prevention tools were higher in the immediate intervention sequence than in the deferred intervention sequence: 63% vs. 50%;  $p < 0.03$  for TasP and 61% vs. 43%;  $p < 0.005$  for PrEP.

### 3.2. Impact of the intervention on the knowledge of biomedical HIV prevention tools

#### 3.2.1. Main analysis

The results are presented in Table 2. In Model 1, for TasP, we did not observe any significant intervention effect (aOR = 1.13 [0.71–1.81];  $p = 0.59$ ) or a significant follow-up time effect (at M3: aOR = 0.99 [0.68–1.43];  $p = 0.94$ ; at M6: aOR = 1.03 [0.59–1.82];  $p = 0.91$ ). In Model 2, we did not observe an effect three months after the intervention (aOR = 1.20 [0.75–1.94];  $p = 0.44$ ). However, six months after the intervention, the odds of knowing about TasP seemed to be increasing (aOR = 2.21 [0.95–5.12];  $p \leq 0.06$ ), regardless of the p value at the limit of significance. The odds of knowing about TasP were low among participants with no oral French proficiency compared to those who were orally fluent in French (aOR = 0.39 [0.27–0.57];  $p < 0.001$ ). Furthermore, we noticed a positive significant effect of social workers on the

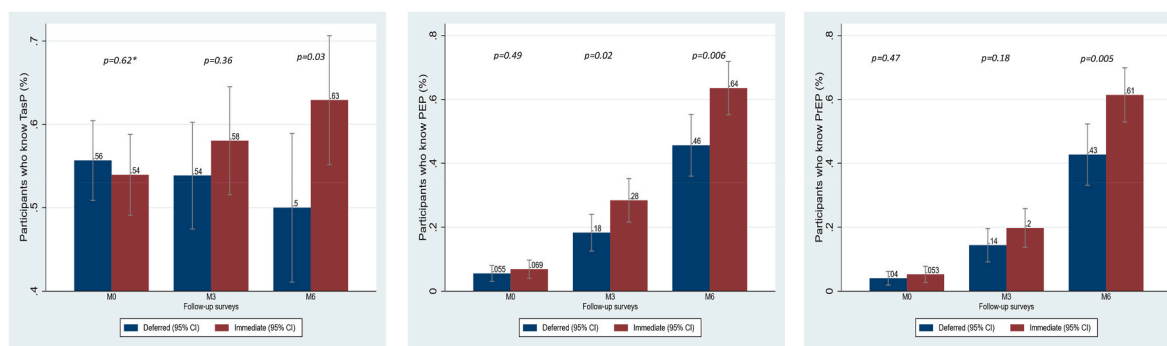


Fig. 3. Proportion of participants who know biomedical HIV prevention tools at each follow-up survey

\*p: chi-square test for percentage differences between sequences at each follow-up survey. Source: Makasi study, 2018–2021

odds of knowing about TasP (Table 2).

The intervention increased the odds of knowing about PEP (aOR = 2.02 [1.09–3.75];  $p \leq 0.02$ ). The p value and confidence interval (CI) calculated using a nonparametric permutation test provided robust evidence of this intervention effect (aOR = 2.02;  $p = 0.025$ ; two-sided 95% CI for the p value = [0.019–0.032]). The odds of knowing about PEP increased over time since the first survey. At M3, the odds of knowing about PEP were 4.26 (95% CI = [2.33–7.80];  $p < 0.001$ ), and at M6, they were 18.28 (95% CI = [7.39–45.24];  $p < 0.001$ ). We found in Model 2 that three months after the intervention, the odds of knowing about PEP increased (aOR = 2.26 [1.19–4.28];  $p \leq 0.01$ ). These odds were also higher and significant six months after the intervention (aOR = 5.79 [2.12–15.79];  $p \leq 0.001$ ). The odds of knowing about PEP were also higher for participants with children (aOR = 1.75 [1.12–2.73];  $p \leq 0.01$ ) and those with a long-term residence permit (aOR = 2.22 [1.06–4.66];  $p \leq 0.03$ ) than for those without children and undocumented participants.

Regarding PrEP, the intervention did not significantly increase the odds of knowing about PrEP (aOR = 1.41 [0.71–2.78];  $p = 0.32$ ). Nevertheless, with regard to the effect of time spent between follow-up surveys, we noticed that the odds of knowing about PrEP increased at M3 (aOR = 4.02 [2.10–7.72];  $p < 0.001$ ) and at M6 (aOR = 28.33 [11.16–71.91];  $p < 0.001$ ). In Model 2, we found that there was no intervention effect three months after the intervention (aOR = 1.59 [0.79–3.19];  $p = 0.18$ ). However, the odds of knowing about PrEP increased considerably six months after the intervention (4.76 [1.67–13.57];  $p \leq 0.003$ ). We also found that participants who were able to express their needs to a social or health worker during referral were more likely to know about PrEP (aOR = 3.66 [1.36–9.83];  $p \leq 0.01$ ). The same trends were observed for those who did not need or have the opportunity to express their needs to a social or health worker (aOR = 3.27 [1.15–9.32];  $p \leq 0.02$ ).

### 3.2.2. Sensitivity analysis

All sensitivity analysis confirmed the above results. The Heckman sample selection models that accounted for attrition, the permutation tests, and the analysis restricted to the sample of participants who completed all follow-up surveys showed similar results (Appendix Tables A.2., A.3., A.4., A.5. and A.6.). For example, the analysis of the restricted sample showed that the odds of knowing about PEP were higher in the intervention condition (aOR = 2.49 [1.13–5.52];  $p \leq 0.02$ ) and increased over follow-up time (at M3: aOR = 2.88 [1.20–6.95];  $p \leq 0.018$  and at M6: aOR = 12.34 [3.92–38.87];  $p < 0.001$ ) (Appendix Table A.6.).

## 4. Discussion

This research aimed to evaluate the effect of the MAKASI empowerment-based intervention on the knowledge of biomedical HIV prevention tools. Our analysis highlighted several points. TasP was

relatively well known (55%) at baseline, while PEP and PrEP were very poorly known (6% and 5%, respectively). The intervention increased the odds of knowing about PEP. The knowledge level increased from 9% in the control condition (combined knowledge level at M0 in the immediate intervention sequence and at M0 and M3 in the deferred intervention sequence) to 44% in the intervention condition (combined knowledge level at M3 and M6 in the immediate intervention sequence and at M6 in the deferred intervention sequence). We observed an increase in the odds of knowing about TasP and PrEP six months after the intervention under the assumption of a nonlinear effect of the intervention. Our results also showed a significant time effect: at the end of the follow-up, knowledge levels of biomedical HIV prevention tools were high for PEP (46% in the deferred intervention sequence and 64% in the immediate intervention sequence) and PrEP (43% in the deferred intervention sequence and 61% in the immediate intervention sequence).

The effect of the intervention appeared slightly smaller than the effect of the follow-up time. Several elements linked to the implementation of the intervention could explain this result. First, the intervention was carried out within a population that suffered multiple dimensions of precariousness. As shown in previous studies, while precarious living conditions may be an indirect factor of exposure to HIV infection, sexual health is not the first priority due to those precarious situations (Desgrées du Loué et al., 2017; Lert, 2017). This point was shared by the social workers who delivered the intervention. They reported that the participants' main needs were access to social resources (residence permits, housing, employment) and health resources (health coverage) rather than sexual health.

Second, the important follow-up time effect on the knowledge of PEP and PrEP could reflect the prevention activities conducted by the Afrique Avenir association. Indeed, during routine screening and outreach activities conducted by the associations' health mediators, the issue of PEP and PrEP was addressed with a specific focus on PrEP, independently of the MAKASI intervention. Finally, awareness campaigns on HIV prevention tools through video clips posted on social networks were initiated by several actors in the fight against HIV in the greater Paris area, including the association Afrique Avenir and "Vers Paris Sans Sida" (Afrique Avenir and Vers Paris sans Sida, 2019; AIDES, 2021; CRIPS ÎLE-DE-FRANCE, & Ikambéré, 2021). The effect of time may therefore have resulted in the participants' exposure to other prevention campaigns, including those of the Afrique Avenir association.

We also observed that the odds of knowing about biomedical tools increased among participants with children, participants with a long-term residence permit and those who were able to express their needs to social and health professionals during referral. These results may highlight that the intervention improved the knowledge among participants who were already settled in France and potentially more attentive to prevention messages. This may also indicate that the intervention contributed to creating a pathway to prevention knowledge by referring

**Table 2**

Effect of the MAKASI empowerment intervention on the knowledge of biomedical HIV prevention tools. Results of the random effects regression models.

	TasP				PEP				PrEP			
	Model 1*		Model 2**		Model 1*		Model 2**		Model 1*		Model 2**	
	aOR [95% CI]	<i>p</i>	aOR [95% CI]	<i>p</i>	aOR [95% CI]	<i>p</i>	aOR [95% CI]	<i>p</i>	aOR [95% CI]	<i>p</i>	aOR [95% CI]	<i>p</i>
<b>Intervention effect</b>												
Control condition	ref											
Intervention condition/3 months post Intervention	1.13 [.71–1.81]	0.59	1.20 [.75–1.94]	0.44	<b>2.02</b> [1.09–3.75]	<b>0.02</b>	<b>2.26</b> [1.19–4.28]	<b>0.01</b>	1.41 [.71–2.78]	0.32	1.59 [.79–3.19]	0.18
6 months post Intervention			<b>2.21</b> [.95–5.12]	<b>0.06</b>			<b>5.79</b> [2.12–15.79]	<b>0.001</b>			<b>4.76</b> [1.67–13.57]	<b>0.003</b>
<b>Follow-up surveys</b>												
M0	ref											
M3	.99 [.68–1.43]	0.94	.95 [.66–1.39]	0.80	<b>4.26</b> [2.33–7.80]	<b>0.000</b>	<b>4.07</b> [2.24–7.38]	<b>0.000</b>	<b>4.02 [2.10–7.72]</b>	<b>0.000</b>	<b>3.77</b> [1.98–7.15]	<b>0.000</b>
M6	1.03 [.59–1.82]	0.91	.69 [.34–1.41]	0.31	<b>18.28</b> [7.39–45.24]	<b>0.000</b>	<b>9.88</b> [3.78–25.81]	<b>0.000</b>	<b>28.33</b> [11.16–71.91]	<b>0.000</b>	<b>13.50</b> [5.10–35.79]	<b>0.000</b>
<b>Sex</b>												
Men	ref											
Women	.83 [.57–1.20]	0.33	.82 [.56–1.19]	0.29	1.12 [.68–1.87]	0.65	1.04 [.62–1.74]	0.87	.98 [.56–1.73]	0.94	.92 [.52–1.62]	0.77
<b>Oral French proficiency</b>												
Fluent	ref											
No/can manage	<b>.39 [.27–.57]</b>	<b>0.000</b>	<b>.39 [.27–.57]</b>	<b>0.000</b>	.79 [.48–1.30]	0.355	.80 [.49–1.30]	0.36	.95 [.57–1.59]	0.83	.98 [.59–1.62]	0.92
<b>Duration of stay in France (years)</b>												
1–2									ref			
3–6									1.50 [.93–2.42]	0.09	1.57 [.98–2.53]	0.06
7 +									.87 [.387–1.97]	0.74	.92 [.41–2.06]	0.83
<b>had children</b>												
No												
Yes					<b>1.75</b> [1.12–2.73]	<b>0.01</b>	<b>1.77</b> [1.13–2.77]	<b>0.01</b>	1.50 [.92–2.43]	0.10	1.54 [.95–2.51]	0.07
<b>Health insurance coverage</b>												
No Health insurance coverage												
State Medical Aid (SMA)					1.05 [.66–1.67]	0.83	1.06 [.66–1.67]	0.81	1.31 [.78–2.22]	0.30	1.36 [.81–2.28]	0.25
Health insurance coverage (HIC)					1.18 [.71–1.97]	0.52	1.12 [.67–1.87]	0.67	1.17 [.67–2.02]	0.58	1.09 [.62–1.93]	0.75
<b>Occupational status</b>												
Unemployed												
Employed(informal/formal/student)	1.29 [.97–1.71]	0.08	1.29 [.97–1.71]	0.075	.82 [.56–1.19]	0.29	.82 [.56–1.20]	0.30	.92 [.61–1.37]	0.67	.90 [.60–1.35]	0.61
<b>Housing type</b>												
Associations					.63 [.29–1.33]	0.22	.74 [.35–1.56]	0.42				
Housed by family/friends					1.09 [.68–1.74]	0.71	1.11 [.69–1.77]	0.66				
Own housing												
No stable housing					.77 [.33–1.79]	0.53	.74 [.32–1.72]	0.48				
<b>Administrative status</b>												
Undocumented												
Short-term residence permit (<1 year)					.66 [.42–1.04]	<b>0.07</b>	.61 [.39–.97]	<b>0.03</b>				
Long-term residence permit (1 year and +, including French nationality)					<b>2.22</b> [1.06–4.66]	<b>0.03</b>	<b>2.23</b> [1.06–4.71]	<b>0.03</b>				
<b>Have someone close to rely on in time of hardship</b>												
No												
Yes	1.15 [.87–1.53]	0.32	1.14 [.86–1.51]	0.35								
<b>Knows where to go to see a doctor</b>												
No												
Yes									.99 [.55–1.79]	0.97	.95 [.52–1.72]	0.86
<b>Experienced violence (other than sexual violence) (beatings, etc.)</b>												
No												

(continued on next page)



Table 2 (continued)

	TasP		PEP		PrEP			
	Model 1*	Model 2**	Model 1*	Model 2**	Model 1*	Model 2**		
Yes					1.33 [.83–2.13]	0.23	1.41 [.88–2.24]	0.15
Have been able to express needs to a social or health professional								
No								
Yes					<b>3.66 [1.36–9.83]</b>	<b>0.01</b>	<b>4.41 [1.63–11.93]</b>	<b>0.003</b>
No need/opportunity					<b>3.27 [1.15–9.32]</b>	<b>0.02</b>	<b>3.87 [1.36–11.03]</b>	<b>0.01</b>
Social workers								
1	1.72 [.76–3.88]	0.19	1.67 [.73–3.80]	0.22				
2								
3	<b>2.09 [1.36–3.21]</b>	<b>0.001</b>	<b>2.08 [1.35–3.20]</b>	<b>0.001</b>				
4	<b>1.96 [1.39–2.75]</b>	<b>0.000</b>	<b>1.94 [1.38–2.73]</b>	<b>0.000</b>				
Had stable partner								
No								
Yes	1.25 [.95–1.66]	0.11	1.26 [.96–1.67]	0.09				
Had sex with an occasional partner in the last 3 months								
No					1.04 [.64–1.70]	0.87	1.08 [.67–1.75]	0.74
Yes					.95 [.55–1.66]	0.86	1.00 [.58–1.73]	0.98
Had transactional sex in the last 3 months								
No								
Yes	<b>.55 [.32-.94]</b>	<b>0.03</b>	<b>.56 [.32-.96]</b>	<b>0.03</b>	1.49 [.75–2.95]	0.25	1.59 [.79–3.20]	0.19
Number of observations	1498				1207		1197	

Model 1: Intervention effect is measured with a binary variable where 0 = control condition and 1 = intervention condition.

Model 2: Intervention effect is measured with a categorical variable where 0 = control condition, 1 = three-months post intervention and 2 = six-months post intervention.

Source: Makasi Study, 2018–2021.

some participants to health professionals who can also provide information on biomedical HIV prevention tools.

Our results can be understood through the concept of empowerment. Indeed, several authors have emphasized that empowerment is achieved by improving people's knowledge (Ninacs, 2002, 2003; Spencer et al., 2008; Zimmerman, 1995). According to William Ninacs, individual empowerment involves the acquisition of individual skills and knowledge. This knowledge enables the individual to make choices in relation to their personal life. Similarly, Zoe Peterson highlighted that sexual health empowerment is a dynamic and multidimensional process. It is a dynamic process because it is almost never completed and there is no culmination that sets the final stage of an empowered person. It is also multidimensional because it is a combination of many components (Peterson, 2010). Based on this idea, sexual health empowerment may take time to achieve. This may explain why we observed only a nonlinear intervention effect for TasP and PrEP. In addition, as shown in previous studies (Gomez et al., 1999; Romero et al., 2006; Swendeman et al., 2009), improving participants' knowledge of biomedical HIV prevention tools contributes to their empowerment as it broadens their knowledge and, beyond that, offers them the possibility of choosing prevention tools suited to their situation (Dehne et al., 2016; Lert, 2017, p. 36).

Overall, our results showed that exposure to the MAKASI intervention helped to fill an important gap in the HIV prevention cascade by making biomedical HIV prevention tools known to sub-Saharan African immigrants in precarious situations. Hence, the levels of knowledge observed at the end of this study were close to those observed among men who have sex with men who are also highly exposed to HIV in France (The EMIS Network, 2019; Velter et al., 2022). To the extent that the prescription of these tools has increased among certain groups of immigrants (Cordel et al., 2022), we may hypothesize that this improvement in knowledge can have an impact on the effective use of these tools. However, we could not further explore this issue in this study.

There are some limitations to this analysis that should be mentioned. The intervention involved two sequences, immediate and deferred intervention sequences. Individuals were recruited from the same sites, and although randomization was performed daily to avoid sequence contamination, we cannot rule out this possibility, which often occurs in interventions that aim to improve knowledge (Howe et al., 2007; Magill et al., 2019). In Model 2, it is possible that there was a collinearity between the effect observed six months after the intervention and the effect of follow-up time at M6. However, the different adjustments made and the consistency observed between the results of the different models suggested that this possible collinearity is negligible. In addition, attrition was an important issue. The loss of participants between waves was approximately 40% (44% between M0 and M3 and 40% between M3 and M6). To account for potential biases due to attrition, we implemented a Heckman model to correct for selection (Heckman, 1976). The results from the Heckman selection model did not indicate the presence of attrition bias. All our analysis converged and confirmed the robustness of the results presented. Since the participants were in precarious situations, with high mobility and often changing their telephone numbers, a retention rate of more than 50% is a great achievement (Gomez et al., 1999). This study enrolled more men (77.5%), which may be related to i) the lower presence of women in public spaces in general (Franck & Paxson, 1989) and ii) the fact that it may be difficult for women to discuss sexual health issues in public spaces, as reported by MAKASI social workers and in line with other studies on street-based HIV interventions (Fernández-Balbuena et al., 2014).

This study showed that social and health empowerment interventions can reach and disseminate sexual health knowledge to populations in precarious situations that are exposed to HIV. This study also showed that exposure to such an intervention has its own effect, in addition to the effect of time linked to different sources of information. This study thus sheds light on the effectiveness of other HIV prevention

campaigns carried out in the greater Paris area, either for sub-Saharan African immigrants in precarious situations or for other populations.

## 5. Conclusions

Our study revealed that the MAKASI social and health empowerment intervention had a heterogeneous effect on the knowledge of biomedical HIV prevention tools among immigrants from sub-Saharan Africa living in precarious situations in the greater Paris area. An intervention effect was clearly observed after the intervention for PEP and only after 6 months for TasP and PrEP. Although the effects of the MAKASI empowerment intervention may seem rather small, they highlight the fact that a simple one-shot intervention, i.e., an interview conducted on the street in an outreach approach, has encouraging results. The important follow-up time effect observed suggests that exposure to the MAKASI intervention and potentially to other sources of information (mainly Afrique Avenir association campaigns) increased the knowledge about these tools. Thus, knowledge of biomedical HIV prevention tools broadens the possibility of choosing tools that are suited to different life situations. At the same time, the issue of the effective use of these tools by targeted populations is raised. This is left for further research.

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## Ethical statement

The MAKASI project was approved by the French Data Protection Authority (Commission Nationale de l'Informatique et des Libertés, CNIL, declaration n°2215270) and the Committee for Persons' Protection (Comité de Protection des Personnes, CPP, Sud-Ouest et Outre-Mer, ID RCB 2018-A02129-46). All participants provided written informed consent.

## Author statement

The MAKASI research project was conducted by a group that included researchers from three research laboratories and workers from two associations. The listed authors made substantial contributions to the conception of the work; the acquisition, analysis and interpretation of data for the work. All authors fully meet the ICMJE criteria for authorship.

## CRedit authorship contribution statement

**Karna Coulibaly:** Conceptualization, Methodology, Formal analysis, Data curation, Visualization, Writing – original draft, Writing – review & editing. **Marwân-al-Qays Bousmah:** Methodology, Validation, Writing – review & editing. **Andrainolo Ravalihasy:** Methodology, Data curation, Validation, Writing – review & editing. **Corinne Taéron:** Project administration, Data collection, Writing – review & editing. **Romain Mbiribindi:** Project administration, Data collection, Writing – review & editing. **Jean-Noël Senne:** Methodology, Writing – review & editing. **Flore Gubert:** Project administration, Methodology, Writing – review & editing. **Anne Gosselin:** Project administration, Supervision, Conceptualization, Methodology, Writing – review & editing. **Annabel Desgrées du Loû:** Funding acquisition, Project administration, Supervision, Conceptualization, Methodology,

Validation, Writing – review & editing.

## Declaration of competing interest

All authors report no conflict of interest.

## Data availability

Data will be made available on request.

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## Appendix A. Supplementary data

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