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Immigrants' health empowerment and access to health coverage in France: A stepped wedge randomised controlled trial

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ABSTRACT

Throughout Europe, migration-related health inequalities are mirrored by large inequalities in health coverage. There is a need to develop novel strategies to secure access to health insurance for immigrants in Europe, in order to meet the shared Sustainable Development Goal of universal health coverage. We evaluated the impact of an original health-related empowerment intervention on access to health coverage among vulnerable, mostly undocumented immigrants in France.

As part of the MAKASI study, we adopted an outreach approach and developed a community-based intervention with and for immigrants from sub-Saharan Africa living in precarious conditions in the Greater Paris area. This participatory intervention was grounded in the theory of individual empowerment. Using a stepped wedge randomised design, we first conducted a robust evaluation of the effect of the intervention on access to health coverage at three and six months post-intervention. We then investigated whether the intervention effect was mediated by a health empowerment process.

Between 2018 and 2021, a total of 821 participants – 77% of whom were men – were recruited in public spaces and followed up for six months. Participants had been living in France for four years on average, 75% of them had no residence permit, and 44% had no health coverage at the time of inclusion. The probability of accessing health coverage increased by 29 percentage points at six months post-intervention ($p < 0.01$). This improvement was partially mediated by a health empowerment process, namely a reinforcement of participants' knowledge of and capacity to access available social and health resources.

A health empowerment intervention largely improved access to health insurance among vulnerable immigrants in France. Our findings may be transferred to other settings where immigrants are entitled to health insurance. This study offers promising perspectives – beyond information provision and direct referral – to reduce migration-related inequalities in health coverage.

1. Introduction

Studies on the health of immigrants in Europe have consistently documented (i) a selection effect of immigrants, who tend to arrive in the host country in better health than their native-born counterparts (i.e., *healthy immigrant effect*) (Moullan and Jusot, 2014), (ii) greater exposure of immigrants to psychosocial risks in the host country, more frequent psychological disorders, and lower access to health services (Hargreaves et al., 2019; Lebano et al., 2020; Rechel et al., 2013), and (iii) a progressive deterioration in the health status of immigrants in the host country (i.e., *unhealthy assimilation*) (Bousmah et al., 2019). The COVID-19 pandemic and the excess morbidity and mortality observed

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among migrant and ethnic minority groups, in particular undocumented immigrants (Hayward et al., 2021), have further highlighted their vulnerability to infection and poor clinical outcomes (Kumar et al., 2021).

Such migration-related health inequalities are mirrored by large inequalities in coverage of essential health services throughout Europe (Aldridge et al., 2017; Hübner et al., 2023; Legido-Quigley et al., 2019). Despite being legally entitled to healthcare rights – albeit with large variations in policies between and within countries (Ingleby et al., 2019) –, immigrants living in precarious conditions, in particular undocumented immigrants, largely lack health coverage. The most common causes include legal and administrative barriers, financial difficulties, lack of language and cultural knowledge to navigate the social and healthcare system, exposure to discrimination, refusal of care, or fear of being reported and eventually deported (Lebano et al., 2020), France being no exception (Larchanché, 2012; Médecins du Monde, 2022; Vignier et al., 2018).

An estimated 7.0 million immigrants lived in France in 2021 (defined as persons who were born non-French outside France and currently live in France), representing 10.3% of the total population (INSEE, 2023). Among them, 848,000 (i.e., 12.2%) were from West and Central Africa. Some immigrant groups – including those from sub-Saharan Africa – have experienced worsening living conditions in the last two decades, which accentuated the deterioration of their health status with the length of stay in France (Hamel and Moisy, 2015), making it a major public health concern.

In France, statutory refugees, asylum seekers, and all other documented immigrants are entitled to the regular French national health insurance. In 2000, France introduced the State Medical Aid (SMA, *Aide Médicale de l'État* in French), a national free health insurance programme for undocumented immigrants (individuals without a residence permit for more than three months) (André and Azzedine, 2016; Gabarro, 2012). To benefit from the SMA, undocumented immigrants must provide proof of identity, of continuous residence in France for at least three months, and of low financial resources (i.e., less than about €10,000 per year for a single person). SMA beneficiaries can access most health services on the same basis as other residents (including emergency care, ambulatory care, hospitalisations and surgery, and prescribed drugs reimbursed by the French national health insurance), the cost of which is covered at 100% without advance payment. Applications for the SMA must be renewed annually. A total of 403,144 individuals benefited from the SMA in 2022 (Cnam, 2023).

However, the mere existence of such schemes does not guarantee access and use by eligible individuals. The French Interior Minister recently declared that between 600,000 and 700,000 individuals lived in France without a residence permit in 2021 (Décugis et al., 2021), although this number is difficult to estimate. The Premier Pas survey conducted in 2019 in France revealed that only 51% of undocumented immigrants eligible for the SMA were actually covered, the length of stay in France being the main determinant of uptake (Dourgnon et al., 2022). These alarmingly low coverage rates appear to be even lower among immigrants living in precarious conditions, as those seen in the Médecins du Monde healthcare, advice and referral centres (CASO) at the national level in France, with 81% of eligible individuals not covered by any kind of health insurance in 2021 (Médecins du Monde, 2022).

Immigrants need better access to healthcare regardless of their legal status, first and foremost for ethical reasons related to the right for everyone to receive the care they need. Other reasons include improving allocative efficiency by avoiding overcrowding of emergency services, and protecting the entire population by controlling the spread of communicable diseases (Dourgnon et al., 2022).

Ensuring equitable access to health coverage is therefore a major challenge from a public health and societal perspective – calling for the need for information-based interventions about health entitlements. Moreover, as public health interventions are more effective when the individuals and communities directly concerned are involved in the process (Roura et al., 2021; Rustage et al., 2021), it appears necessary to develop interventions with community-based organisations and vulnerable immigrants themselves to fully understand their specific needs (Genovese et al., 2023; Orcutt et al., 2020). Community-based participatory approaches have the potential to address migration-related health inequalities by reaching socially disadvantaged immigrant groups who tend to be excluded from both healthcare systems and health surveys. With the ability to draw on their community's own knowledge and experience and help build a trusting relationship, community actors are key to reaching and engaging vulnerable immigrants from sub-Saharan Africa in health prevention programmes in France (Gosselin et al., 2020a). Last but not least, empowerment-based interventions for and with immigrants have received growing attention due to their capacity to address specific health needs and achieve better outcomes than information provision alone (Desgrées du Loû and Gosselin, 2021).

Based on this evidence, we conducted in 2018–2021 the MAKASI study with immigrants from sub-Saharan Africa living in precarious conditions in the Greater Paris area, most of whom were undocumented. This population is particularly affected by social hardship and tends to be excluded from the French healthcare system due to a lack of health coverage and limited access to healthcare and prevention (Gosselin et al., 2020a). A particular focus was given to sexual health since previous studies showed that sub-Saharan African immigrants in France were particularly exposed to sexual risks and disproportionally affected by the HIV epidemic, with high levels of post-migration HIV acquisition (Gosselin et al., 2020b).

We adopted an evidence-based outreach approach and developed an original health-related empowerment intervention offered in public spaces by mobile teams of health mediators and social workers from two community-based organisations (Gosselin et al., 2019). In the present study, we evaluated the impact of the intervention on access to health coverage. We further sought to determine whether an empowerment process was at play in the impact of the intervention on access to health coverage.

2. The MAKASI study

The MAKASI study built on the theory of individual empowerment proposed by Ninacs (2008, 2003) – empowerment defined as a psychosocial process enabling individuals to strengthen their capacity to decide and act on important aspects of their lives – including health – and to influence their environment (Ninacs, 2008; Wallerstein, 1992).

The health empowerment intervention consisted of a single, personalised 30-min individual interview conducted by health mediators and social workers, based on the principles of motivational interviewing (Miller and Rollnick, 2013) and linked to active counselling (Gosselin et al., 2019). Motivational interviewing is a structured, person-centred method for enhancing intrinsic motivation to change. First mobilised in interventions aimed at reducing addictive behaviours, motivational interviewing has been increasingly used in a wide range of health and social care settings (Frost et al., 2018). More specifically, the intervention was built according to three main dimensions: (i) listening and building a trusting relationship, (ii) helping the participants assess and prioritise their social and health needs, and (iii) active referral and navigation to the services that can best meet the participants' health needs (by means of referral letters, proactive calls, bilingual handouts, or customised neighbourhood maps).

Building on the theoretical framework developed by Ninacs (2008, 2003) adapted to the sexual health context, the intervention was designed to improve four components of individual empowerment measured by validated scores (Ravalihasy et al., 2021): i) participation (capacity to express sexual health needs), ii) competencies and skills (capacity to understand and use healthcare information and disease prevention messages), iii) self-esteem (perceived control at the individual level), and iv) critical awareness (knowledge of health and social

resources).

In addition to reinforcing the participants' capacity to act on health matters (i.e., their health empowerment), the intervention aimed at improving their access to health coverage and their knowledge of biomedical HIV prevention tools, and ultimately at reducing their exposure to sexual risks and improving their health.

In summary, the intervention: (i) was designed based on the conceptual framework of individual empowerment, (ii) aimed at improving the participants' health empowerment (i.e., empowerment as a result), and (iii) aimed at improving other outcomes, in particular through an empowerment process (i.e., empowerment as a process). Considering empowerment as both a result and a process is in line with Ninacs' theory (2008, 2003), and contrasts with the large majority of studies on sexual health which tend to assess empowerment only as a result (Coulibaly et al., 2022).

The present study seeks to determine whether the intervention improved the participants' access to health coverage, and whether a health empowerment process partly contributed to the impact of the intervention on access to health coverage. The critical awareness dimension of health empowerment specifically involves the immigrants' knowledge of and capacity to access available health and social resources, and therefore any improvement in this dimension is assumed to lead participants to claim their rights to health coverage.

3. Methods

3.1. A stepped wedge cluster randomised trial

3.1.1. Trial design

The MAKASI study, whose protocol was validated in a pilot study (Gosselin et al., 2019), used a stepped wedge cluster randomised design (Hemming et al., 2018; Hussey and Hughes, 2007). Participants were included into clusters according to the day on which they were recruited by our mobile teams of health mediators and social workers. The same participants were followed over six months, in a closed cohort design. The evaluation was based on data collected through face-to-face questionnaires administered at baseline (Month 0) and then at M3 and M6.

The intervention was rolled out sequentially over two three-month periods (Fig. 1). Clusters were randomly allocated to two sequences: those in the *immediate intervention* sequence received the intervention directly after answering the M0 questionnaire, while those in the *delayed intervention* sequence received the intervention three months later (directly after answering the M3 questionnaire). Therefore, even though all participants were to be interviewed at M0, M3 and M6, the sequence to which they were randomly allocated dictated the timing with which they would switch to the *intervention condition*. For each participant, the *intervention condition* determines the time since exposure to the intervention, with three modalities: (i) not having received the intervention yet, (ii) having received the intervention three months ago, or (iii) having received the intervention six months ago.

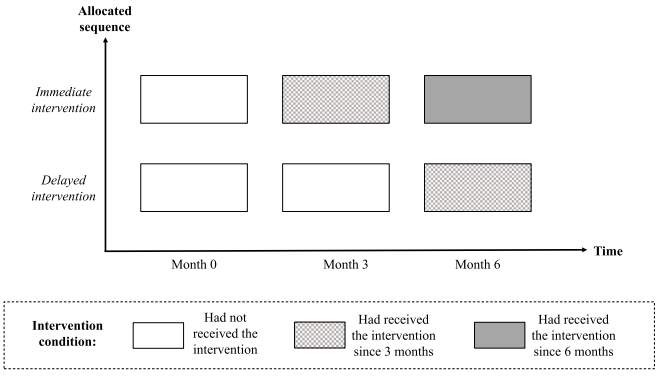

Fig. 1. Diagram of the MAKASI stepped wedge cluster randomised trial.

This design arose from extended discussions between the research teams, community-based organisations and peer groups. In addition to enabling robust impact evaluation (Hemming et al., 2015), it was considered the most ethical way to evaluate the intervention as it allowed us to offer the intervention to all identified people with social or health needs.

Trial Registration: ClinicalTrials.gov Identifier: NCT04468724.

3.1.2. Participants

Participants were recruited in public spaces in the Greater Paris area, such as markets and metro and suburban train stations (see Appendix A in the Supplementary Material for a map of the 11 recruitment locations), by mobile teams of health mediators and social workers from two community-based organisations (Afrique Avenir and Arcat). In addition to the routinely offered health counselling and rapid HIV testing, persons who visited the mobile units (vans or tents) were systematically offered a rapid assessment of their social and health needs. Eligibility criteria for inclusion in MAKASI were being 18 years or older, being born in sub-Saharan Africa, having a negative rapid HIV test result, and meeting at least one of the following vulnerability criteria: being undocumented or having a short-term residence permit, having unstable housing, experiencing food insecurity, being unemployed, experiencing violence, having no medical insurance, or not knowing where to go to see a doctor. All participants provided written informed consent and received a €10 voucher for their participation in each survey wave.

3.1.3. Sample size

To detect a 10-point difference in the primary outcomes between the *control* and *intervention conditions* with 80% power and a type I error rate of 0.05, a minimum sample size of 336 participants per allocated sequence was required. The final sample included 406 and 415 participants in the *immediate* and *delayed intervention* sequence, respectively.

3.1.4. Randomisation

Eligible participants were randomly assigned to clusters based on the day of presentation. The random allocation sequence was generated by the research team and concealed from the community-based organisations until the beginning of each daily recruitment session.

3.1.5. Outcome

Our primary outcome was access to health coverage, namely a binary variable for whether the participant had health coverage (i.e., had either the State Medical Aid or the French national health insurance) at each survey wave.

3.2. Methodology

3.2.1. Descriptive analysis

First, we provided descriptive statistics on the evolution of access to health coverage over the six-month follow-up, by calculating frequencies and percentages at each follow-up visit. We used chi-square tests to assess the significance of percentage differences in the outcome between both sequences. Analyses were further stratified by gender.

3.2.2. Impact evaluation

To evaluate the impact of the MAKASI intervention on access to health coverage, we used a multivariable random-effects probit model which controls for unobserved heterogeneity at the participant level (i.e., unmeasured time-invariant individual attributes influencing access to health coverage) (Wooldridge, 2020). Standard errors, clustered at the participant level, were robust to within-panel autocorrelation. The econometric model is described in detail in Appendix B. Detailed definitions of all variables used in the present study are provided in Appendix C.

In stepped wedge cluster randomised trials, where all participants receive the intervention but at different times, the impact of the intervention under evaluation is assessed by the above-defined *intervention condition* which measures the participants' exposure to the intervention (Hemming et al., 2018). This is our main explanatory variable of interest, which we constructed as a three-category variable according to the time since exposure to the intervention. Had we used a binary *intervention condition* variable, we would have implicitly assumed that the intervention effect was the same regardless of the time since the intervention was delivered (Hemming et al., 2018). We instead assumed that the intervention effect accumulated over time – in a non-linear fashion – by using this three-category *intervention condition* variable: (i) not having received the intervention yet, (ii) having received the intervention three months ago, or (iii) having received the intervention six months ago.

As necessary to estimate unbiased intervention effects within a stepped wedge design, we also controlled for: (i) the allocated sequence (a binary variable for whether the participant has been allocated to the *immediate* or *delayed intervention* sequence), to account for any systematic differences that may persist between the two randomly allocated sequences, and (ii) the survey wave (categorical time effects), to allow for the confounding effect of time which is by definition associated with exposure to the intervention (Hemming et al., 2015).

Apart from the *intervention condition*, the allocated sequence and time effects, all other variables included in the final models were identified using backward stepwise selection to avoid collinearity and over-adjustment (Heinze et al., 2018). First, we tested for associations between each variable and outcome using univariable regressions. We included all variables with a significance of $p < 0.2$ in a multivariable model. Then, starting with the variable that had the highest global p-value, we iteratively removed each variable with a significance of $p \geq 0.10$ from the multivariable model.

The following variables (time-varying or measured at baseline) were retained in the multivariable model: gender, age, the share of lifetime spent in France, the region of birth, and whether the participant had stable housing. Because age and the number of years spent in France are highly correlated, we used the share of lifetime spent in France (i.e., the participants' number of years since immigration divided by their age) as a measure for the length of stay in France, as previously proposed (Bousmah et al., 2019).

Additionally, we used a Heckman selection model on longitudinal data, that is, a regression-based approach to test for and, if found to correct for selection bias due to non-random attrition (Wooldridge, 2020). The intervention effect estimate may indeed be biased due to loss to follow-up, an issue which we expected to be important given the cumulative forms of precarity faced by participants, who had to change their address or telephone number frequently. Implementing the Heckman selection model involved jointly estimating (i) trial retention (i.e., a binary time-varying variable for whether the participant was lost to follow-up or remained in the trial at each follow-up point) by a random-effects probit model, and (ii) access to health coverage by a random-effects probit model, in a full maximum-likelihood framework and using the '*cmp*' Stata command (Roodman, 2011). Using a Heckman selection model would be needed when the correlation between either the residuals or the random effects in the selection (trial retention) and outcome (access to health coverage) equations is statistically significant. Otherwise, using a standard (one-equation) model would not produce biased intervention estimates due to selection.

Variables retained in the trial retention equation included the allocated sequence, time since inclusion in the trial, whether the participant was interviewed during a Covid-19 lockdown, gender, age, the share of lifetime spent in France, the level of formal education, oral proficiency in French, as well as two commonly used variables which satisfy the exclusion restrictions (i.e., variables likely to influence trial retention but not access to health coverage): the month of survey (accounting for seasonal variation) and the interviewer identity (which was randomly assigned) (Bärnighausen et al., 2011).

All things considered, the *intervention condition* variable is likely to capture the unbiased effect of having received the intervention on the participants' access to health coverage.

We assessed the magnitude of the effects by calculating predicted probabilities and average marginal effects conditional on trial retention, assuming that the random effect is zero across participants.

Finally, we assessed the robustness of our findings by re-estimating the intervention effect using a nonparametric alternative, namely a permutation test for stepped wedge cluster randomised trials (Thompson et al., 2019), with 1000 permutations. This allowed us to calculate the p-value and confidence interval (CI) for the intervention effect without making any distributional assumptions. This test, however, can only be performed using a binary *intervention condition* variable.

3.2.3. Mediation analysis

Our last objective is to investigate whether the effects of the intervention on access to health coverage at three and six months post-intervention were mediated by a health empowerment process. We are interested in one specific dimension of health empowerment, namely the knowledge of social and health resources.

Health empowerment was measured using a validated score (Ravalihasy et al., 2021), with higher values corresponding to higher levels of empowerment in terms of knowledge of social and health resources.

This involved using a mediation model with a multicategorical *intervention condition* variable (Hayes and Preacher, 2014). More specifically, we jointly estimated health empowerment (random-effects linear model conditional on the *intervention condition* and other covariates) and access to health coverage (random-effects probit model conditional on health empowerment, the *intervention condition*, and other covariates) by the maximum-likelihood seemingly unrelated regression (SUR) estimator (Roodman, 2011).

Apart from the *intervention condition*, the allocated sequence and time effects, the health empowerment model was adjusted for gender, the level of formal education, oral proficiency in French, the main reason for migration, and depression severity measured by the 9-item Patient Health Questionnaire (PHQ-9) (Kroenke et al., 2001).

After having estimated the mediation model, we calculated the indirect intervention effects (i.e., the intervention effects on access to health coverage at three and six months post-intervention that are mediated through health empowerment). Following Valeri and Vanderweele (2013), standard errors and percentile CIs for indirect effects were obtained via bootstrapping (with 1000 replications).

Finally, we calculated the proportion mediated (Vanderweele and Vansteelandt, 2010), which is the proportion of the total intervention effects that was mediated by reinforcement of participants' knowledge of and capacity to access available social and health resources.

All analyses were performed using Stata/SE Release 16 (StataCorp LP, College Station, TX).

4. Results

4.1. Descriptive results

4.1.1. Participant flow

A total of 2117 persons were assessed for eligibility through the outreach activities of the two community-based organisations, on which 821 eligible participants were randomised into the two sequences (406 and 415 participants in the *immediate* and *delayed intervention* sequence, respectively). The flowchart of the study is shown in Appendix D. Participants were recruited between April 2018 and December 2020. Each participant was followed up for six months, and the last follow-up ended in July 2021.

As expected, attrition rates were high, with only 55.8% of participants remaining at M3 (458 of 821) and 33.3% at M6 (273 of 821). A full description of missing data over follow-up, overall and stratified by

allocated sequence and gender, is provided in Appendix E. There was no significant difference between the two sequences at any time point in the incidence of missing data.

4.1.2. Participant characteristics

Table 1 provides baseline descriptive statistics of all variables retained in the multivariable regressions, overall and by allocated sequence. There was no significant difference between both sequences at baseline, except for a significantly higher average share of lifetime spent in France in the *delayed intervention* sequence – but with a small difference in magnitude (0.127 versus 0.106, p = 0.031) –, and a significantly higher percentage of participants without stable housing in the *immediate intervention* sequence (71.9% versus 68.6%, p = 0.041).

Overall, 77.5% (636/821) of participants were men, 29.7% (244/821) had primary education or less, and 22.5% (185/821) were not proficient in French. The mean age was 34.8 (SD 8.8) years. Participants spent on average 11.7% (SD 13.6) of their lifetime in France, corresponding to a mean length of stay of 4.3 years. The majority of participants were from West Africa (61.1%, 502/821), and the main reasons for migration were economic or educational (44.9%, 369/821) or related to threats in the country of origin (40.3%, 331/821). Nearly three-quarters of them had no residence permit (74.5%, 612/821), and more than two-thirds had no stable housing (68.6%, 563/821). The mean PHQ-9 score amounted to 12.0 (SD 5.4), indicating a high prevalence of depressive symptoms in this population, with 66.0% (542/821) of participants having symptoms of moderate to severe depression (PHQ-9 score ≥10).

Table 1
Baseline summary statistics, overall and by allocated sequence.

	All participants (n = 821)	*Immediate intervention* (n = 406)	*Delayed intervention* (n = 415)	p-value[a]
Outcome				
Had health coverage? (ref.: No)				
Yes	457 (55.7%)	215 (53.0%)	242 (58.3%)	0.122
Explanatory variables retained in the multivariable regressions				
Gender (ref.: Man)				
Woman	185 (22.5%)	92 (22.7%)	93 (22.4%)	0.932
Level of formal education (ref.: Primary)				
Secondary and higher	577 (70.3%)	286 (70.4%)	291 (70.1%)	0.919
Oral proficiency in French (ref.: Fluent)				
No proficiency/ Elementary	185 (22.5%)	91 (22.4%)	94 (22.7%)	0.935
Age (years)	34.8 (8.8)	34.7 (8.5)	34.9 (9.1)	0.752
Share of lifetime spent in France	0.117 (0.136)	0.106 (0.123)	0.127 (0.147)	0.031
Region of birth				
West Africa	502 (61.1%)	247 (60.8%)	255 (61.4%)	0.968
Central Africa	292 (35.6%)	146 (36.0%)	146 (35.2%)	
Southern & Eastern Africa	27 (3.3%)	13 (3.2%)	14 (3.4%)	
Main reason for migration				
Economic or educational reasons	369 (44.9%)	170 (41.9%)	199 (48.0%)	0.120
Family reasons	73 (8.9%)	32 (7.9%)	41 (9.9%)	
Medical reasons	48 (5.8%)	24 (5.9%)	24 (5.8%)	
Threats	331 (40.3%)	180 (44.3%)	151 (36.4%)	
Administrative status				
Had no residence permit	612 (74.5%)	297 (73.2%)	315 (75.9%)	0.059
Had a short-term residence permit (less than one year)	127 (15.5%)	74 (18.2%)	53 (12.8%)	
Had a long-term residence permit (one year or more)	82 (10.0%)	35 (8.6%)	47 (11.3%)	
Had stable housing? (ref.: Yes)				
No	563 (68.6%)	292 (71.9%)	271 (65.3%)	0.041
Depression severity (PHQ-9 score)	12.0 (5.4)	12.1 (5.5)	11.9 (5.3)	0.678
Health empowerment score	9.6 (2.1)	9.6 (2.1)	9.7 (2.2)	0.946
Interviewed during a Covid-19 lockdown? (ref.: No)				
Yes	15 (1.8%)	7 (1.7%)	8 (1.9%)	0.828

Notes: Values are presented as mean (SD) or n (%).
Abbreviations: n = number of observations; PHQ-9 = Patient Health Questionnaire-9; SD = standard deviation.
[a] T-test (for continuous variables) and chi-square test (for categorical variables) for between-arm mean and percentage differences, respectively.

Regarding our main outcome, results showed that only 55.7% (457/821) of participants had health coverage at inclusion. Fig. 2 shows the evolution of access to health coverage by allocated sequence over follow-up (gender-specific evolutions are provided in Appendix F). The participants' access to health coverage largely improved over follow-up, with 71.1% and 65.2% of participants having health coverage at M6 in the *immediate* and *delayed intervention* sequences, respectively.

4.2. Impact evaluation results

The full table of results is provided in Appendix G. The estimated correlation coefficient between the random effects in the selection (trial retention) equation and the outcome (access to health coverage) equation is positive and significant (0.144; p < 0.10), indicating the presence of unobserved time-invariant individual attributes influencing retention in the trial which are positively correlated with unobserved time-invariant individual attributes influencing access to health coverage. Hence, a model of access to health coverage that would not correct for selection bias due to attrition would yield biased and inconsistent estimates – justifying the use of a Heckman selection model.

To ease the interpretation of the results, we present in Fig. 3 plots of the average marginal effects of all covariates on the probability of retention in the trial (Panel A) and on the probability of access to health coverage (conditional on retention) (Panel B).

Trial retention was not associated with the allocated sequence. Women, participants of younger age, those who have spent a higher share of their lifetime in France, those with a higher level of formal education, and those who were not proficient in French were all more likely to be lost to follow-up. Not surprisingly, time since inclusion in the trial was positively associated with being lost to follow-up. However, having been (or planned to be) interviewed during a COVID-19 lockdown was positively associated with trial retention, partly because interviews were conducted by telephone during these periods. Finally, the

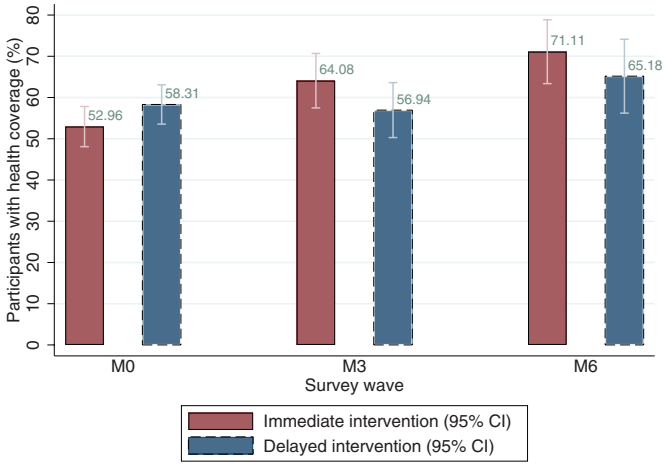

Fig. 2. Evolution of access to health coverage over follow-up by allocated sequence (MAKASI trial, n = 821).

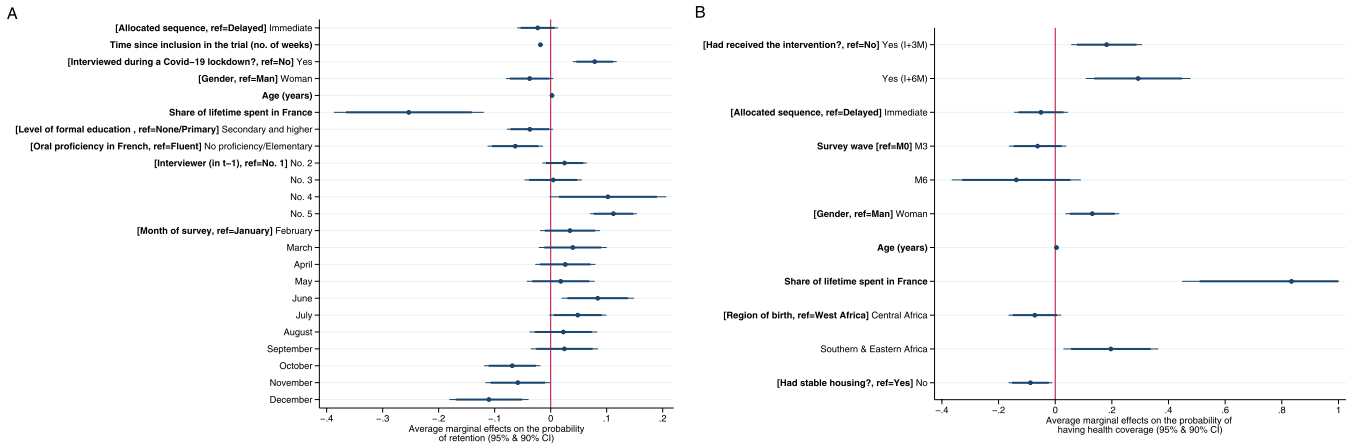

Fig. 3. Impact evaluation results: average marginal effects. **Panel A:** Average marginal effects on the probability of retention in the trial. **Panel B:** Average marginal effects on the probability of access to health coverage (conditional on trial retention).
Notes: Upper CI limit for the share of lifetime spent in France in the outcome equation is truncated for readability (upper 95% CI is 1.220). I = intervention; CI=Confidence interval.

probability of retention was the highest during summer and the lowest during autumn, and was influenced by the interviewer's identity in the preceding survey wave.

Regarding our main outcome, there was no systematic difference in access to health coverage between the two sequences – which was expected since participants were randomly allocated to either the *immediate* or the *delayed intervention* sequence. There was also no effect of time since inclusion in the trial on the participants' access to health coverage. As for the *intervention condition* – the main variable of interest –, the results revealed a significant effect of the intervention, which accumulated over time since exposure. The probability of accessing health coverage increased by 18.2 percentage points three months after having received the intervention (from 56.5% pre-intervention to 74.7%, $p < 0.01$), and by 29.3 percentage points six months after having received the intervention (from 56.5% pre-intervention to 85.8%, $p < 0.01$). The 11.1 percentage-point increase in the probability of accessing health coverage between three and six months post-intervention was also significant (from 74.7% to 85.8%, $p < 0.10$).

Results for the other covariates indicated that the probability of accessing health coverage was 13.1 percentage points higher for women (i.e., 74.1% versus 61.0% for men, $p < 0.01$), 19.7 percentage points higher for participants from Southern and Eastern Africa compared with those from West Africa (i.e., 85.3% versus 65.7%, $p < 0.05$), and 8.7 percentage points lower for participants without stable housing (i.e., 61.2% versus 70.0% for those with stable housing).

Lastly, results highlighted an increasing probability of accessing health coverage both with age (+0.4 percentage points for every 1-year increase in age, $p < 0.10$) and with the length of stay in France (independent of age, $p < 0.01$). The estimated relationships between predicted probabilities of accessing health coverage and both age and the length of stay in France are further depicted in Appendix H. The results revealed a non-linear relationship between the length of stay in France and access to health coverage. The lower the share of lifetime spent in France, the higher the increase in the probability of accessing health coverage with the length of stay. For instance, at the sample average of 11.7% of lifetime spent in France, a 10 percentage-point increase in the share of lifetime spent in France was associated with an 8.0 percentage-point increase in the probability of accessing health coverage (from 65.2% to 73.2%, $p < 0.01$). On the other hand, for patients who already spent half of their lifetime in France, a 10 percentage-point increase in their share of lifetime spent in France was associated with a 3.6 percentage-point increase in the probability of accessing health coverage (from 89.9% to 93.4%, $p < 0.01$).

To assess the robustness of our main finding, we calculated the p-value and CI for the intervention effect using a nonparametric permutation test for stepped wedge cluster randomised trials. The intervention effect estimate was significantly different from zero ($p = 0.010$, two-sided 95% CI for the p-value = [0.005; 0.018]), providing robust evidence that the intervention did improve the participants' access to health coverage.

4.3. Mediation analysis results

Lastly, we investigated the extent to which the intervention effect was mediated by a health-related empowerment process. The regression results for the mediation analysis are provided in Appendix I. Participants who received the intervention six months ago, men, participants with a higher formal education level, those who were fluent in French, those for whom the main reason for migration was economic or educational (compared with family-related), and those with a lower score of depression severity were all more likely to have a higher health empowerment score.

The results seem to indicate that the intervention effect on access to health coverage operated partly through an empowerment process in terms of knowledge of social and health resources. We indeed found that (i) the *intervention condition* six months post-intervention significantly affected health empowerment, (ii) the *intervention condition* three and six months post-intervention significantly affected access to health coverage (as previously found), and (iii) health empowerment significantly affected access to health coverage.

The mediating role of health empowerment was confirmed by estimating the indirect intervention effects at three and six months post-intervention. The path diagram in Fig. 4 provides the coefficients, as well as the direct, indirect, and total effects estimated from Model 3. The indirect effect three months after having received the intervention was not significantly different from zero (0.005, 90% bootstrap percentile CI [−0.074; 0.099]). Nonetheless, we found a significant indirect effect six months after having received the intervention (0.104, 90% bootstrap percentile CI [0.007; 0.346]). Hence, significant mediation was established at six months post-intervention only.

The proportion mediated six months after having received the intervention was estimated to be 12.1%. Hence, 12.1% of the total intervention effect at six months post-intervention was mediated by reinforcement of participants' knowledge of and capacity to access available social and health resources.

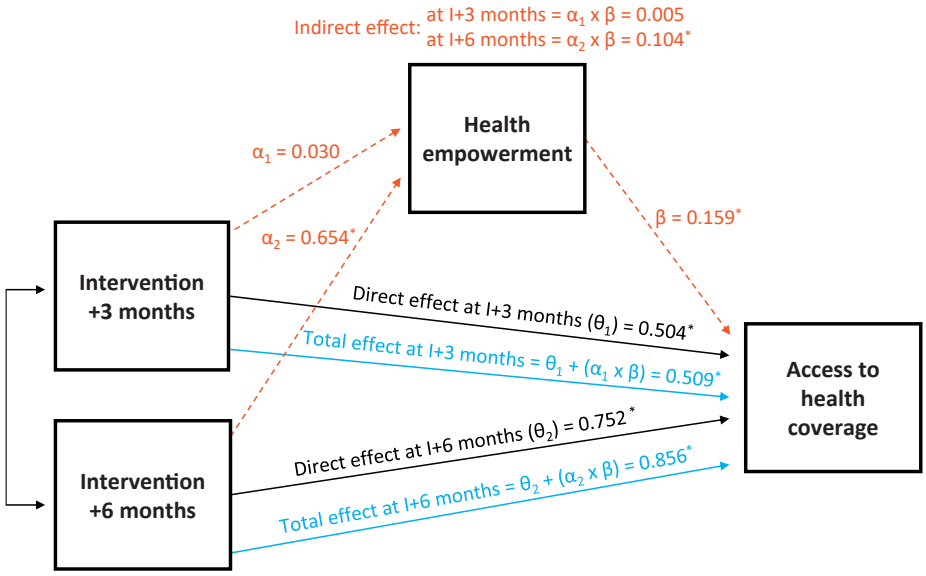

Fig. 4. Estimated coefficients from the mediation analysis: path diagram.
Notes: * = statistical significance of at least 90%. I=Intervention.

5. Discussion

5.1. A large impact of the intervention on access to health coverage

Our findings indicate that the intervention largely improved the participants' access to health coverage, with an increase of 18.2 percentage points three months after having received the intervention, and of 29.3 percentage points six months after having received the intervention. As a result, the probability of accessing health coverage – which was as low as 56.5% at the time of inclusion in the study – amounted to 85.8% six months after having received the intervention.

Overall, our results are consistent with those from previous studies on the factors influencing undocumented immigrants' uptake of the SMA in France, in particular the Premier Pas survey conducted in 2019 (Dourgnon et al., 2019). As in Premier Pas, we showed that the uptake of the SMA was higher among women and increased with the number of years since arrival in France (Dourgnon et al., 2022). The length of stay in France was of particular importance as it was identified as the most important determinant of SMA take-up. After five or more years of residence in France, 35% of the undocumented immigrants interviewed in Premier Pas still did not have the SMA (Jusot et al., 2019). In this respect, our findings are all the more important in that they show that an empowerment-based intervention can significantly reduce the long delays that have been observed for immigrants to obtain health coverage. Our results are therefore encouraging as they indicate that a significant improvement can be achieved in a short period of time: the probability of accessing health coverage increased by almost 30 percentage points only six months after having received the MAKASI intervention, independent of the length of stay in France.

5.2. The mediating role of health empowerment

We sought to explain whether the observed improvement in the participant's access to health coverage was rooted in an empowerment process. Interestingly, the intervention – which consisted of a single interview – had an effect which accumulated over time. Explaining this pattern was of particular importance, as it may have been partly due to reinforcement of the participants' capacity to act on health matters.

Our methodology of impact evaluation ensured that the intervention effect estimate was independent of any underlying temporal effect (which is by definition confounded with the *intervention condition*). This was all the more important since the community-based organisations involved in the study were already providing health counselling as part of their routine activities.

Nevertheless, the health empowerment intervention encompassed several dimensions, one of which was an active referral and navigation to the services that can best meet the participants' health needs (including the SMA and national health insurance management services). Such referral and navigation were likely to account for a large part of the intervention effect.

Additionally, there may have been a lagged effect due to delays between the moment participants decided to claim their right to health insurance, the initiation of the administrative procedure, and its validation by the French national health insurance (CPAM), thus causing the intervention effect to not necessarily materialise within the first three months post-intervention.

Hence, a mediation analysis allowed us to formally test whether the intervention effect operated partly through a health empowerment process. This can be viewed as disentangling the intervention effect into a direct effect mostly related to active referral and an indirect effect via health empowerment.

While the effect at three months post-intervention seems to have been mainly driven by active referral, results revealed that a significant share of the intervention effect at six months post-intervention (although rather small, namely 12%) was mediated by reinforcement of participants' knowledge of and capacity to access available social and health resources. We can hypothesize that the mediated effect would have been larger had we proposed a more substantial intervention (e.g., longer and repeated over time).

These results are in line with the theory of empowerment in the sense that it is a dynamic process that takes time to materialise into action (Ninacs, 2003, 2008). Offering something that is "of great value" to the individuals concerned is also a structuring factor for the realisation of the empowerment process (Ninacs, 2003). Previous qualitative evidence highlighted that for most undocumented immigrants who applied for the French SMA, obtaining health coverage was not only viewed as a means of accessing care, but also as a means of being recognised "as an existing, deserving individual residing on the French territory" (Larchanché, 2012).

5.3. Study strengths and limitations

The MAKASI study was the first, to our knowledge, to develop a health empowerment intervention among immigrants from sub-Saharan Africa living in precarious conditions in France. Our community- and evidence-based participatory intervention was grounded in the theory of individual empowerment. This, together with an outreach strategy in public spaces, has enabled us to engage a hard-to-reach population. Although not representative of sub-Saharan African immigrants in France as a whole, the MAKASI population is nevertheless representative of the population of sub-Saharan African immigrants living in precarious conditions in France (Gosselin et al., 2020a).

From a methodological standpoint, we conducted a robust evaluation of the impact of the MAKASI intervention, controlling for the effects of time and other demographic and socioeconomic factors associated with access to health coverage, accounting for unobserved heterogeneity, and correcting for potential selection bias due to attrition. We assessed the robustness of the results by estimating the intervention effect using a nonparametric alternative.

We nonetheless acknowledge several limitations to this study. First, we adopted a context-sensitive approach in the Greater Paris area which may limit the generalizability of the results.

Second, we unintentionally recruited a high proportion of men in the study (77.5%), an overrepresentation that has persisted since the pilot study (Gosselin et al., 2019), and which may be due to the greater difficulty for women to discuss sexual health issues in public spaces, and more generally to the lower presence of women in urban public spaces (Franck and Paxson, 1989).

Third, the low trial retention rate was an issue. The sample size would have been substantially reduced had we performed a complete case analysis (since only 273 participants remained until the end of the six-month follow-up period), and this removal of cases would have led to a loss of statistical power. We rather employed a Heckman selection model that allowed us to use all the information available over follow-up for the 821 participants. Furthermore, our method not only addressed the issue of missing data due to attrition, but also helped correct the selection bias due to attrition (i.e., the fact that the selection process was influencing the estimation of the impact of the intervention on access to health coverage). Nevertheless, finding ways to improve adherence to interventions targeted to immigrants in precarious situations remains a major challenge from a public health perspective.

At the methodological level, our random-effect models incorporated unobserved heterogeneity with the strong assumption that omitted variables were uncorrelated with the explanatory variables in the model. However, as the *intervention condition* has been randomly assigned across sequences, the estimated impact of the intervention is unlikely to be strongly biased. The possibility of within-cluster contamination is also a common issue in stepped wedge cluster randomised trials (Hemming et al., 2018). Nonetheless, our cluster randomisation according to the day of recruitment is likely to prevent contamination between allocated sequences: interaction between participants from different allocated sequences (which were seen on different days) was less likely than with other types of cluster-randomisation units.

Finally, we have considered empowerment from an individual perspective, although the concept of empowerment has also a strong collective dimension (Ninacs, 2003, 2008), which ought to be appraised in future intervention research with immigrants in precarious situations.

6. Conclusions

Our study responds to the recent call for creating an evidence base of immigrant-inclusive policies in Europe (Blanchet, 2022; James et al., 2022), including strategies to secure access to health coverage and healthcare for undocumented immigrants (Trummer, 2022).

We showed that an original empowerment-based intervention can largely improve access to health insurance coverage among vulnerable, mostly undocumented immigrants from sub-Saharan Africa in France – a necessary precondition for halting the deterioration in their health status with the length of stay in France. Although such interventions do not remove the structural barriers faced by vulnerable immigrants, they can nevertheless contribute to reducing their social vulnerability by providing better access to healthcare.

Beyond information provision and direct referral, we demonstrated that a significant proportion of the improvement in access to health coverage was triggered by the participants' strengthened capacity to act in health matters. Participants were more likely to claim health rights. Therefore, we believe our findings offer promising perspectives to effectively reduce migration-related inequalities in health coverage.

We believe our findings may be transferred to other communities or settings. This would require tailoring the health empowerment intervention to the people and communities who would be directly concerned, as well as to the specific features of the legal and healthcare system where the intervention would be implemented. Although European countries have committed to achieving universal health coverage, there are large variations between and within countries in health policies on entitlement to healthcare coverage for immigrants (Ingleby et al., 2019; Legido-Quigley et al., 2019).

Exploring the potential for scaling up such an intervention at the national level is an interesting avenue for future research. Further work is also needed to investigate whether better access to health coverage in this population eventually contributes to improving health service utilisation and ultimately health outcomes.

The MAKASI Study Group

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Data sharing statement

Data are included in the Supplemental Digital Content. Data requests will be reviewed internally and will be available subject to a written proposal and a signed data sharing agreement.

Declaration of competing interest

All authors report no conflict of interest.

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Supplementary data

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