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The MAKASI empowerment randomized intervention and depression and loneliness among sub-Saharan immigrants living in the greater Paris area

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Abstract

Purpose

The MAKASI intervention aimed to empower sub-Saharan African immigrants living in precarious situations in the Paris metropolitan area. Because there are factors specifically related to immigration that may increase the risk for common mental disorders, the present study aimed to examine participants' levels of depression and loneliness and analyze the effect of the intervention on depression and loneliness.

Methods

The MAKASI study was designed as a stepped-wedge randomized intervention trial. Study participants were recruited through an outreach program led by a nongovernmental organization and randomly assigned to two groups, with an intervention delay of three months between groups. Both groups were assessed for six months after inclusion and the effect of the intervention on depression and loneliness was assessed using generalized linear mixed models. The study was conducted from 2018 to 2021 and we took in consideration whether being interviewed during one of the Covid-19 confinement had an effect on the results.

Results

A total of 821 subjects participated in the Makasi study. High levels of depression and loneliness were found in the study population. We found no effect of the intervention on depression [95%CI 0.77 to 2.40]. Similarly, no effect of the intervention was found on loneliness [95%CI 0.87 to 2.54].

Conclusions

The intervention we tested did not appear to improve the level of depression and loneliness among participants. However, the high prevalence of mental and emotional problems in the study population suggests a public health crisis among immigrants in the greater Paris area.

Clinical Trial Registration Number:

Trial registration [Clinicaltrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT04468724), NCT04468724 (July 13, 2020)

Introduction

According to the latest World Migration report [1], there were about 272 million immigrants worldwide in 2020, meaning that 3.5% of the world's population was living in a country different from their country of origin. In France, immigrants represent 10.3% of the population [2], 1.7% of the country's population comes from a sub-Saharan African country [3]. Arriving in a new country can present many challenges in a person's life, such as disconnection from existing social networks. In addition, cultural barriers and lack of welcoming policies can hamper integration in the new country and contribute to psychological difficulties [4]. All of these factors can be exacerbated by exposure to vulnerability factors in pre, peri, and post-immigration periods [4, 5].

Depression is one of the most common and treatable mental disorders, characterized by lack of energy, depressed mood, sadness, insomnia and inability to enjoy life [6, 7]. In France, the prevalence of depression is estimated to range between 8 and 10% within the general population [8]. The prevalence of depression in the immigrant population widely varies from 5 up to 75%, depending on the group of interest and methodology of assessment [9, 10]. Among sub-Saharan African immigrants living in Paris, 24% of women and 18% of men who visited healthcare facilities between 2012 and 2013 reported symptoms of depression or anxiety in the ANRS-Parcours study conducted with 2468 participants [11].

Apart from the most well-known risk factors for depression observed in the general population, such as unemployment, low educational level, and being a woman [12–14], there are factors specifically related to immigration that may increase the risk for common mental disorders. Discrimination, uncertainty about legal and administrative procedures in the host country, separation from family members and existing support networks [4, 11], acculturation stress, risk of sexual violence [15], low socioeconomic status [9], housing instability, and food insecurity [16] are some of the factors that may be experienced by immigrants, all of which are associated with increased risk for depression.

Loneliness, in turn, is the perceived discontent with the quantity and/or quality of relationships in a person's life [17]. It is also seen as a cognitive and emotional response to the lack of significant social interactions. Research on loneliness has gained particular attention after this condition was declared an "epidemic of modern times" because factors associated with contemporary lifestyles, for instance, delayed marriage, lower fertility rates, increased single households, and social media use, can exacerbate subjective social isolation [18–20].

Although there is a widespread perception that people are becoming increasingly lonely, there is little evidence of prevalence trends, and further longitudinal research in this area is needed. Persistent loneliness can have significant negative effects on a person's life, namely lower self-esteem, cognitive impairment, increasing harmful habits such as smoking, higher care utilization, lower treatment adherence, and even higher mortality [18–20]. Chronic loneliness can also trigger a high stress response over prolonged periods of time, leading to increased blood pressure and cortisol levels [21].

Loneliness is also highly contextual and shares several risk factors with depression [22]. Reduced social integration, unemployment, low educational attainment, and low socioeconomic status are all factors related to increased loneliness [17]. Studies dating back to the 1980s accounted for loneliness as one of

the symptoms of depression. After this initial moment, evidence emerged stating that loneliness was an independent risk factor of depression and now a bidirectional relationship has been demonstrated [22]. This association means that depression may affect a person's level of loneliness, and at the same time loneliness may be related with the development of depression.

The MAKASI intervention, a randomized clinical trial with a stepped-wedge design, was developed after a high burden of human immunodeficiency virus (HIV) infections was identified among sub-Saharan African immigrants in Paris [11, 23]. The intervention aimed to improve empowerment in sexual health and reduce social and health vulnerabilities. Because mental and emotional health problems constitute barriers in promoting sexual health and engaging in healthy behaviors [24], a secondary objective of the MAKASI empowerment intervention was to examine participants' levels of depression and loneliness throughout the study.

The intervention, based on Ninacs model of individual empowerment, consisted in a 30-minute motivational interview that utilized techniques to assist the individual in identifying and prioritizing their social and health requirements [23, 25]. Additionally, there was an evaluation of the individual's expressed needs to determine a suitable referral location. In the study, empowerment was defined as "a psychosocial process that promotes the participation and agency of individuals, organizations, and communities to improve control over their own health" [23].

In the present study, we provide descriptive analysis of participants' mental and emotional health related outcomes and test whether this sexual health empowerment intervention improved participants' levels of depression and loneliness. Because the study was conducted between 2018 and 2021, in additional analyses we tested whether the COVID-19 pandemic modified the effect of the intervention.

Methods

Study Design

The MAKASI intervention is a community-based project designed as a stepped-wedge randomized trial aiming to improve empowerment in the area of sexual health [26–28]. Study participants were recruited via an outreach program led by a non-governmental organization (NGO) involved in providing HIV and hepatitis B rapid testing to individuals from sub-Saharan Africa living in the greater Paris area (Afrique Avenir). Owing to the stepped-wedge design, participants were divided into a) an immediate and b) a deferred intervention group. Randomization was performed by inclusion day, each day assigned corresponding either to the immediate or deferred intervention group.

One advantage of the stepped-wedge design is the possibility of offering the intervention to both groups [26]. Because MAKASI participants are immigrants living in precarious situations, this design was chosen for ethical reasons, in order to provide the intervention to all participants.

As shown in Fig. 1, participants in the immediate intervention group received the intervention just after providing consent and answering the first MAKASI study questionnaire at baseline. Participants in the deferred intervention group started the study as controls and received the intervention after answering the second study questionnaire, three months after inclusion. Both study groups were followed for six months after recruitment with two additional assessments.

The MAKASI intervention 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).

Participants

MAKASI study participants were immigrants from sub-Saharan Africa living in the metropolitan area of Paris. After completing a rapid HIV test at the Afrique Avenir association's truck, candidates were invited to participate in the study if their test result was negative (otherwise they were referred to specialized infectious disease care). Selection criteria included: being 18 years or older, being born in sub-Saharan Africa, having a negative HIV rapid test result and meeting at least one of the following vulnerability criteria: having unstable housing, being unemployed, experiencing food insecurity in the previous month (going a full day without eating a meal due to lack of money), being undocumented or having a short stay residence permit (< 1 year), experiencing violence, having no health insurance, and not knowing where to go to see a doctor [23].

Figure 2 shows the enrollment procedure; 2117 potential participants were identified through Afrique Avenir outreach activities; 1799 were invited to participate in the intervention, and 1221 accepted to participate. After withdrawal of individuals without valid consent forms, 821 participants were randomly assigned to one of the two study groups: 406 to the immediate and 415 to the deferred intervention group. Some respondents were lost between accepting to participate and the enrollment period because they could not or would not wait to speak with the social worker responsible for enrolling them in the study and obtaining written consent.

Intervention

The intervention, primarily aiming to improve participants' sense of empowerment with regard to their sexual health, was designed by a multidisciplinary team and pilot tested to adapt the study protocol (Trial registration Clinicaltrials.gov, NCT04468724) [23]. It consisted of a motivational interview conducted by trained professionals. The idea behind the intervention was to understand each participant's needs and work with him/her to develop strategies to reduce their social and health needs. The intervention included: a personal sexual health assessment; information about the French healthcare system; referral to a social worker or partner NGO to address healthcare, housing, immigration or other social issues.

The intervention was implemented at 11 transit places such as train stations and metro exits[1] known for their high immigrant population in Paris and suburbs, between April 2018 and September 2021 (illustrative map of intervention sights in appendix). Questionnaires at baseline, 3 months and 6 months after inclusion were used to assess participants' sociodemographic characteristics, level of empowerment, sexual and reproductive health behaviors and mental and emotional health. Due to the special circumstances of the Covid-19 pandemic, follow-up questionnaires were conducted by phone between March 2020 and September 2021. A ten euros voucher was given to participants after answering each of the three study questionnaires.

Study Outcomes

The outcomes of interest in this study were two indicators of mental health and well-being: participants' a) depression and b) loneliness. Depression was assessed using the PHQ-9 [6] a screening, diagnosis and monitoring instrument that measures the presence of nine major symptoms of depression based on the Diagnostic and Statistical Manual of Mental Disorders (DSM-V) [29, 30]. Each of the nine questions is scored on a scale that takes the values: 0 (not at all), 1 (several days), 2 (more than half the days) and 3 (almost every day). The total score varies from 0 to 27: PHQ-9 score of 5, 10, 15 and 20 represents mild, moderate, moderately severe, and severe symptoms of depression, respectively [6]. As supported by previous literature [29,31], a cut-off of 10 and above was used which is consistent with moderate to severe depression.

The second outcome of interest in our analyses was loneliness, assessed by a single question about the frequency of feelings of loneliness with four potential answers: "never," "from time to time," "often", and "very often." This variable was dichotomized and participants who stated feeling lonely "often" or "very often" were considered as being lonely.

Statistical Methods

Participants' sociodemographic characteristics at baseline were described using frequencies and percentages. Pearson's Chi-squared and Fisher's exact test were performed to determine bivariate differences between the two study groups.

The effect of the MAKASI intervention on depression and loneliness was tested based on the intention-to-treat principle using generalized linear mixed models (GLMM) with a logit link, in which the incorporation of random effects allows to account for within-participant correlation [32, 33]. After confirming the choice of a GLMM model as the most appropriate statistical approach [32], we tested the effect of the intervention on participants' levels of depression and loneliness using a dichotomous variable. The intervention variable was coded as follows: 0 = participant has not yet received the intervention; and 1 = participant has received the intervention. We controlled for the study group (a binary variable taking the values: 1 = Immediate intervention group; 2 = Deferred intervention group) and the observation period

(variable taking the values: 1 = baseline, 2 = 3 months after inclusion and 3 = 6 months after inclusion). Logistic models provided estimates of the intervention effect via an odds ratio.

Multivariable regression models were adjusted for the period before and during the Covid-19 pandemic. The period from April 19, 2018 until March 16, 2020 was considered as prior to the Covid-19 pandemic; the period from March 17, 2020, date of the first lockdown in France, until September 24, 2021, date of the last assessment, was considered as being during the Covid-19 pandemic. Because other known risk factors for depression and loneliness, such as sex and age, were not significantly associated with the outcomes in the baseline measures of the study, they were not included in the regressions performed.

All statistical analyses were performed using RStudio version 1.4.1717.

[1] Intervention sites in Paris greater area: Rosa Parks, Marcadet, Château Rouge, Flandres, Montreuil, Aubervilliers, Sevran Beaudottes, Saint Denis, Sarcelles, Pierrefitte-Stains and Gare de Grigny.

Results

Descriptive results

In total, 821 subjects participated in the Makasi intervention, 406 in the immediate intervention group and 415 in the deferred intervention group. From study baseline to the third month after inclusion 43% of participants were lost to follow-up both in the immediate and deferred intervention groups, leaving the immediate and deferred intervention groups with 224 and 234 participants, respectively. Six months after inclusion, 151 participants from the immediate intervention group and 122 from the deferred intervention group answered study questionnaires. There was one missing value on the lonely variable and the intervention impact on this outcome was analyzed with 820 study participants.

Table 1 shows the baseline characteristics of participants by intervention group. The study population consisted of 77% men and 23% women; 42% of study participants were aged between 30 and 39 years and 61% were from West Africa; 40% of participants migrated to France to find work and 40% due to threats in their home country; 52% had secondary education and 49% lived in France for less than two years; 13% lived in France for more than 7 years. Seventy five percent of study participants were undocumented and approximately 15% had a residence permit of less than one year; 45% reported food insecurity during the month preceding the study and 66% had moderate to severe depression (PHQ-9 \geq 10). Sixty three percent of participants in the immediate intervention group and 56% in the deferred group felt lonely at baseline ($p = 0.034$).

Table 1

Sociodemographic characteristics of 821 participants of the MAKASI intervention; between the immediate and deferred intervention groups at baseline (N and %), MAKASI project, 2018–2021, Paris (N = 821).

Characteristic	Total (N = 821)	Immediate intervention group ¹ (n = 406, %)	Deferred intervention group ¹ (n = 415, %)	Chi2 or Fisher p- value ²
Sex				> 0.9
Men	636 (77%)	314 (77%)	322 (78%)	
Women	185 (23%)	92 (23%)	93 (22%)	
Age				0.3
18–29	253 (31%)	118 (29%)	135 (33%)	
30–39	343 (42%)	180 (44%)	163 (39%)	
40+	225 (27%)	108 (27%)	117 (28%)	
Region of birth				> 0.9
West Africa	502 (61%)	247 (61%)	255 (61%)	
Central Africa	292 (36%)	146 (36%)	146 (35%)	
Eastern and Southern Africa	27 (3.3%)	13 (3.2%)	14 (3.4%)	
Reason for coming to France				0.2
Find work, try one's luck	328 (40%)	154 (38%)	174 (42%)	
Join a family member	73 (8.9%)	32 (7.9%)	41 (9.9%)	
Studies	41 (5.0%)	16 (3.9%)	25 (6.0%)	
Medical reasons	27 (3.3%)	15 (3.7%)	12 (2.9%)	
Threatened in his/her home country	331 (40%)	180 (44%)	151 (36%)	

Characteristic	Total (N = 821)	Immediate intervention group¹ (n = 406, %)	Deferred intervention group¹ (n = 415, %)	Chi2 or Fisher p- value²
Others	21 (2.6%)	9 (2.2%)	12 (2.9%)	
Level of Education				0.7
None/Primary	244 (30%)	120 (30%)	124 (30%)	
Secondary	425 (52%)	206 (51%)	219 (53%)	
Superior	152 (19%)	80 (20%)	72 (17%)	
Length of stay in France				0.15
1–2 years	405 (49%)	216 (53%)	189 (46%)	
2–3 years	88 (11%)	43 (11%)	45 (11%)	
3–7 years	221 (27%)	100 (25%)	121 (29%)	
7 years and more	107 (13%)	47 (12%)	60 (14%)	
Legal status				0.2
Undocumented	612 (75%)	297 (73%)	315 (76%)	
Permits < 1 year (incl. Asylum seekers)	122 (15%)	71 (17%)	51 (12%)	
Permits ≥ 1 year	61 (7.4%)	26 (6.4%)	35 (8.5%)	
10-y residence permit or French nationality	21 (2.6%)	9 (3%)	12 (3%)	
Others	5 (0.6%)	3 (0.7%)	2 (0.5%)	
Food insecurity				0.083
No	444 (54.1%)	207 (51%)	237 (57.1%)	
Yes	366 (44.6%)	193 (47.5%)	173 (41.7%)	

Characteristic	Total (N = 821)	Immediate intervention group ¹ (n = 406, %)	Deferred intervention group ¹ (n = 415, %)	Chi2 or Fisher p- value ²
Missing	11 (1.3%)	6 (1.5%)	5 (1.2%)	
Moderate to severe depression				
No	279 (34%)	132 (33%)	147 (35%)	0.4
Yes	542 (66%)	274 (67%)	268 (65%)	
Lonely				
No	334 (40.7%)	150 (37%)	184 (44.4%)	0.034*
Yes	486 (59.2%)	256 (63%)	230 (55.4%)	
Missing	1 (0.1%)		1 (0.2%)	
**P < 0.05				
**P < 0.01				

The following figures show the prevalence of moderate to severe depression (PHQ-9 \geq 10) and loneliness in the immediate and deferred intervention groups during the MAKASI intervention observation period.

Figure 3 shows the prevalence of moderate to severe depression (PHQ-9 \geq 10) in the immediate and deferred intervention groups with respective p-values from chi-square tests examining between group prevalences at each observation period. In the immediate intervention group, the prevalence was 67% at baseline, 70% three months after inclusion, and 66% six months after inclusion. In the deferred intervention group, the respective figures were 65%, 64%, and 67%. There was no statistically significant difference in prevalence between the immediate and deferred intervention groups at any of the observed time periods (p-value = 0.42 at baseline; p-value = 0.17 at three months; and p-value = 0.96 at six months).

Figure 4 presents the prevalence of loneliness throughout the study observation periods with the respective p-values from chi-square tests between group prevalences at each observation period. The immediate intervention group had a prevalence of 63% at baseline, 70% three months after inclusion and 56% six months after inclusion. In the deferred intervention group, prevalence rates were respectively 55%, and 58% at the third and sixth month assessments. There was a statistically significant difference in prevalence rates of loneliness at baseline (p-value = 0.03) and three months after enrollment (p-value =

0.01). Six months after the intervention there was no statistically significant difference between groups (p-value = 0.84).

Intervention Effects

Table 2 shows the effect of the intervention on depression and loneliness. We found no effect of the intervention on depression [95%CI 0.77 to 2.40]. These results were consistent whether the assessment took place before or during the Covid-19 pandemic [95%CI 0.62 to 1.29]. Similarly, we found no effect of the intervention on loneliness [95%CI 0.87 to 2.54]. This was consistent whether participants were assessed before or during the Covid-19 pandemic [95%CI 0.73 to 1.42].

Table 2

Effect of the MAKASI sexual health empowerment intervention on depression (PHQ-9 > 10) and loneliness, results from generalized linear mixed models. MAKASI project, 2018–2021, Paris (N = 821).

	Intervention effect	Time frame (ref = Baseline)		Study group (ref = Deferred group)	Assessed during the Covid-19 pandemic (ref = No)
		3 months	6 months	Immediate intervention group	Yes
Outcome	OR (95% CI)	OR (95% CI)	OR (95% CI)	OR (95% CI)	OR (95% CI)
Depression (N = 821)	1.36 (0.77–2.40)	0.92 (0.61–1.37)	0.80 (0.41–1.56)	1.11 (0.77–1.61)	0.89 (0.62–1.29)
Loneliness (N = 820)	1.48 (0.87–2.54)	1.05 (0.72–1.54)	0.57 (0.30–1.08)	1.34 (0.96–1.86)	1.02 (0.73–1.42)
*P < 0.05					
**P < 0.01					

Table 3

Factors associated with depression (PHQ-9 ≥ 10) and loneliness amongst MAKASI study participants at baseline assessment. N = 821 for depression and N = 820 for loneliness (Odds ratio and 95% confidence interval), MAKASI project, 2018–2021, Paris

	Depression N = 821 (100%)		Loneliness N = 820 (100%)	
	Odds Ratio	95% CI	Odds Ratio	95% CI
Sex				
Men	1		1	
Women	0.99	0.71–1.40	0.87	0.63–1.22
Age (years)				
18–29	1		1	
30–39	1.31	0.93–1.86	1.28	0.92–1.79
40+	0.77	0.53–1.12	0.84	0.59–1.21
Reason for coming to France				
Find work, try one's luck	1		1	
Join a family member	0.99	0.58–1.69	1.26	0.75–2.13
Studies	0.6	0.31–1.16	0.83	0.43–1.58
Medical reasons	1.04	0.45–2.38	0.85	0.39–1.86
Threatened in his/her country	1.12	0.81–1.54	1.38	1.01–1.89*
Others	0.69	0.28–1.69	1.05	0.43–2.56
Level of education				
None/Primary	1		1	
Secondary	0.87	0.62–1.21	0.67	0.48–0.93*
Superior	0.68	0.45–1.04	1.01	0.66–1.55
Length of stay in France				
1 to 2 years	1		1	
2 to 3 years	1.05	0.64–1.74	0.73	0.46–1.16
3 to 7 year	0.64	0.46–0.9*	0.66	0.47–0.92*
7 years and more	0.77	0.49–1.2	0.61	0.4–0.94*

	Depression N = 821 (100%)		Loneliness N = 820 (100%)	
Legal status				
Undocumented	1		1	
Permits < 1 year (incl. Asylum seekers)	1.06	0.7–1.61	1.01	0.68–1.5
Permits ≥ 1 year	0.41	0.24–0.69*	0.88	0.52–1.5
10-y residence permit or French nationality	0.64	0.26–1.54	0.33	0.13–0.82*
Other	1.91	0.21– 17.23	0.16	0.02–1.48
Food insecurity				
No	1		1	
Yes	2.57	1.89–3.5*	2.15	1.61–2.87*
Type of housing				
Hosted by a charity	1		1	
Hosted by family/friends	0.73	0.42–1.26	0.97	0.59–1.61
Personal dwelling	0.49	0.28–0.87*	0.77	0.46–1.31
Nowhere to go/ experiencing homelessness	1.96	0.91–4.22*	2.44	1.23–4.86*
Missing value	0.68	0.22–2.08	0.97	0.33–2.84
Experience of violence during migrating				
No	1		1	
Yes	1.86	1.33–2.62*	1.4	1.03–1.92*
Occupation				
Student	1		1	
Informal and part time jobs	1.68	0.6–4.71	1.03	0.37–2.9
Full time	0.95	0.32–2.79	0.66	0.22–1.97
Unemployed	2.32	0.86–6.27	1.26	0.46–3.43
Has a stable partner				
No	1		1	
Yes	0.73	0.55–0.98*	0.56	0.42–0.74*

	Depression N = 821 (100%)		Loneliness N = 820 (100%)	
French proficiency				
Yes	1		1	
No	0.62	0.44–0.86*	0.58	0.42–0.81*
* P-value < 0,05				

Discussion

Within the Makasi study, consisting of immigrants from sub-Saharan countries living in precarious situations, we found very high levels of depression and loneliness at baseline. Testing the effect of the proposed empowerment intervention, conducted between 2018 and 2021, we found no evidence of a positive effect on participants' levels of depression nor loneliness. These results are contrary to the expected findings, as previous interventions based on an empowerment approach have shown to be effective in reducing mental and emotional distress [34, 35]. The high levels of depression at study baseline may in part explain why our intervention did not succeed in improving mental health. In future studies in this population, interventions of higher intensity, or involving a broader mobilization of the community, would be worth examining.

Depression

The high share of participants with moderate to severe depression at study baseline among MAKASI study participants (66%) is consistent with prior research conducted among immigrants and refugees, where this proportion has been estimated to be as high as 75% [4, 10]. Considering that the PHQ-9 has been validated and recommended for use in different cultural and ethnic groups [10, 36], we consider it a reliable instrument for determining the presence of depression.

Although there is strong evidence that immigrants are more likely to suffer from mental health problems compared with non-immigrants, access to mental health care remains a challenge for this group [9, 11, 12, 37, 38]. There is a persistent disparity in access to care, between first-generation immigrants and non-immigrants, even in countries where healthcare is free and guaranteed by law, such as France [11].

There is limited evidence regarding the effectiveness of empowerment interventions aiming to decrease symptoms of depression among immigrants who experience socioeconomic disadvantage. A meta-analysis of randomized controlled trials found that psychosocial interventions have a significant impact on reducing depression among asylum seekers and refugees. In the aforementioned study, strategies that focus on the relationship between individuals' social circumstances and their thoughts, emotions, and behaviors are referred to as psychosocial interventions [39].

A randomized controlled trial conducted in Germany found that a value-based counseling (VBC) intervention proved effective in improving migrants', including refugees, depression symptoms. VBC interventions consist of three to five sessions divided in two components: first, developing a narrative of the participants' life story in order to understand their current life situation; second, focusing on their present situation and co-developing ways of improving their daily functionality. In the study, participants that received the intervention were less likely to make use of mental health care in the three months following the intervention [40].

Depression is related to multiple factors, and the MAKASI intervention, which consisted of a one-time interview and referral, may not have been sufficient to have a noticeable effect on participants' mental health. Although the study showed positive results in facilitating access to health coverage [41], participants were still living in extremely precarious situations which may have prevented improvement of their depression levels.

Moreover, lower levels of empowerment have been associated with depression and poor quality of life in the literature [42]. Considering that depression affects perceived control over life choices, a fundamental aspect of feeling empowered [43], we hypothesize that participants with high levels of depression may not benefit from the intervention in terms of their mental health.

Another hypothesis explaining our results stems from the response shift theory [44]. According to this theory, a participant's response, particularly in terms of subjective constructs, depends on his/her current assessment of his/her own reality at a given time. In other words, the meaning of a particular construct is time-dependent, and as participants have different life experiences, they construct a new understanding of it [45].

Given the passage of time, experiences, possible reflections mediated by the intervention and its various assessments during the follow-up period, there might be a variance between participant's target construct (loneliness and depression) and its measurement [45]. This variance may happen due to a change in a person's internal scales (recalibration), a change in the person's values (reprioritization), or a redefinition of the target construct (reconceptualization) [44].

Because depression was assessed by a sum score composed of nine subjective questions, the lack of intervention effect could be explained by the occurrence, throughout the follow-up period, of one of the three processes described above. Lastly, it must be underlined that the mental health system is very inadequate in France at the moment. In particular, it is very difficult to find mental health professionals to refer immigrants to.

Further research should be conducted to understand the extent to which this may have influenced the present results.

Loneliness

We found that 59% of participants in the MAKASI study felt lonely often or very often at the time of the baseline assessment. An earlier 2014 study that included immigrants living in the United Kingdom found similar results, with 58% of respondents reporting feeling lonely [46]. Other studies have previously shown that immigrants have higher levels of loneliness compared to the native population, which tend to decrease with time and integration in the host country [5, 47].

There is limited evidence of the effectiveness of interventions to reduce perceived social isolation among immigrants and previous results are often mixed. A randomized controlled trial, designed for older Chinese immigrants living in Canada showed significant reduction in loneliness after an eight week peer support intervention. The intervention group received home visits and telephone calls to provide emotional support, problem-solving support and community resource sharing [48].

Another intervention, designed to decrease loneliness by preventing social isolation, showed a significant impact on older Japanese migrants. The intervention consisted of four encounters that promoted a group-based educational, cognitive, and social support program. The focus on improving community knowledge and interacting with other participants and community "gatekeepers" proved to be an efficient strategy and participants maintained lower levels of loneliness in the sixth month follow-up after the intervention [49].

In the present study, we found no effect of the intervention on reducing loneliness. Loneliness is considered an adaptive emotion that motivates people to form meaningful relationships and avoid suffering [20]. However, developing individual strategies to avoid loneliness is time-consuming, and the duration of the MAKASI study follow-up may not have been sufficient to observe an improvement in participants' levels of perceived social isolation.

Covid-19

Recent studies have shown that depression rates increased during the Covid-19 pandemic [16, 50], especially among marginalized groups, including immigrants. In a subgroup of 100 MAKASI participants who participated in a nested-study during Covid lockdown in 2020, we found an increase in depression symptoms associated with worsening food insecurity and unemployment [51].

Research findings on loneliness during the Covid 19 pandemic show rather contradictory results. One study conducted in four European countries, including France, reported an increase in loneliness, particularly among young adults and people with a history of mental illness [52]. A second study found no increase in loneliness during this period and reported that participants perceived more support from others during Covid-19-induced social distancing [53].

In the present analysis, we did not find an association between being assessed during the pandemic and the levels of depression and loneliness. A possible explanation is that participants were more likely to be

taken in by a charity or friends and family during the Covid-19 lockdown than to be homeless, which had an impact on social isolation and possibly on participants' levels of loneliness and depression.

Limitations And Strengths

Our study presents some limitations worth mentioning. First, the MAKASI intervention was not primarily designed to tackle depression and loneliness, which might partly explain our negative findings. It may be that the intervention was not powerful enough to improve participants' mental health, particularly considering the elevated levels of depression at study baseline. Second, blinding participants and data collectors was not possible. Blinding in randomized control trials may prevent bias in participant allocation, assessment, or adherence [54]. However, given the training and the use of a closed-ended questionnaire, information bias is probably not a major concern in this study. Third, a significant proportion of participants were lost to follow-up, which could affect the results considering the impact of differential attrition on results [54]. Fourth, there was a high proportion of men in the MAKASI intervention, which precludes generalization of the results to women. It would be important to better understand why recruitment of sub-Saharan African women was challenging. Some hypotheses are that they are less willing to talk about their sexual and reproductive health in public spaces; that there are fewer women in the type of public spaces where the intervention was conducted; and that these women are more likely to be responsible for household chores and harder to reach on the street [23]. Strengths of our study include the provision of a culturally adapted intervention that allowed the collection of mental health related data in an understudied population. Also, the study's longitudinal design, which allowed us to collect data from participants at different time points and understand factors associated with depression and loneliness over time. In addition, data were collected in real time, reducing the possibility of recall bias [54].

Conclusions

Immigrants from sub-Saharan Africa face many difficulties when settling in France [11]. The lack of legal documentation, stable housing and nutritional security contribute to high levels of depression and loneliness in this population. The intervention we tested did not appear to improve levels of depression and loneliness among participants. Nonetheless, we observed a high prevalence of mental and emotional problems in the study population, indicating a public health crisis in the immigrant population living in Paris greater area that requires attention.

This study brings evidence that immigrants' mental and emotional health need to be specially focused through mental health support, as well as through social and political interventions, as the determinants of depression and loneliness appear to be related to structural factors that could be addressed through a more inclusive and integral immigration policy.

Declarations

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Authors' contributions: ADDL was responsible for securing the funding for the study. ADDL and MM designed the study. ADDL, AG, KC, MQB and AR collected and prepared the data. BGT, MQB and KC conducted statistical analysis. BGT conducted the literature review and wrote the first draft of the paper. All authors have read and approved the manuscript.

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Competing Interests: All authors declare that they have no competing interests concerning the present study.

Ethical approval: The MAKASI study was performed in line with the principles of the Declaration of Helsinki. This study 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, ID RCB 2018-A02129-46). Written informed consent was obtained from all participants.

Consent to participate: Informed consent was obtained from all individual participants included in the study.

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Figures

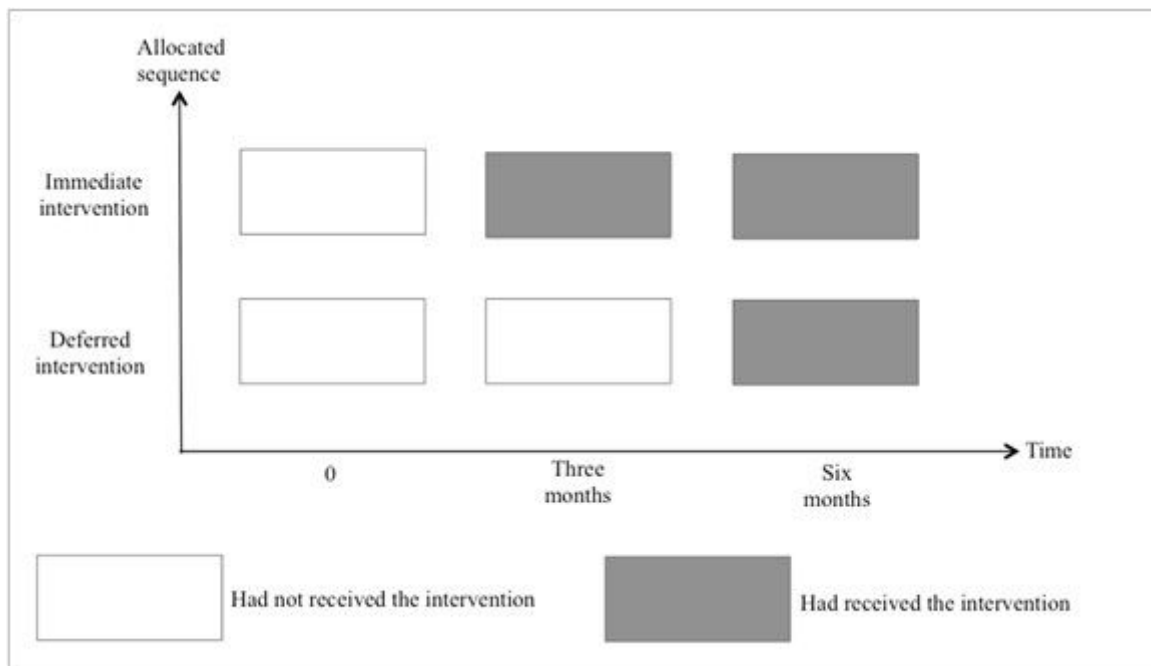


Figure 1

MAKASI intervention: a stepped wedge design. Participants entered in either the immediate or deferred intervention group. Both groups were assessed at baseline, and every three months, for six months after recruitment. MAKASI project 2018-2021, Paris

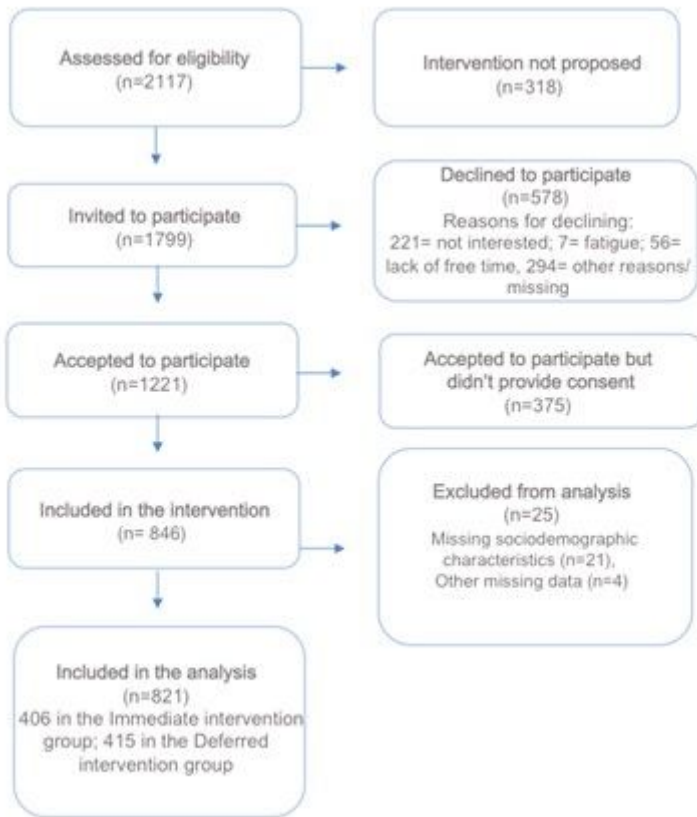


Figure 2

MAKASI participants flowchart, 2018-2021, Paris

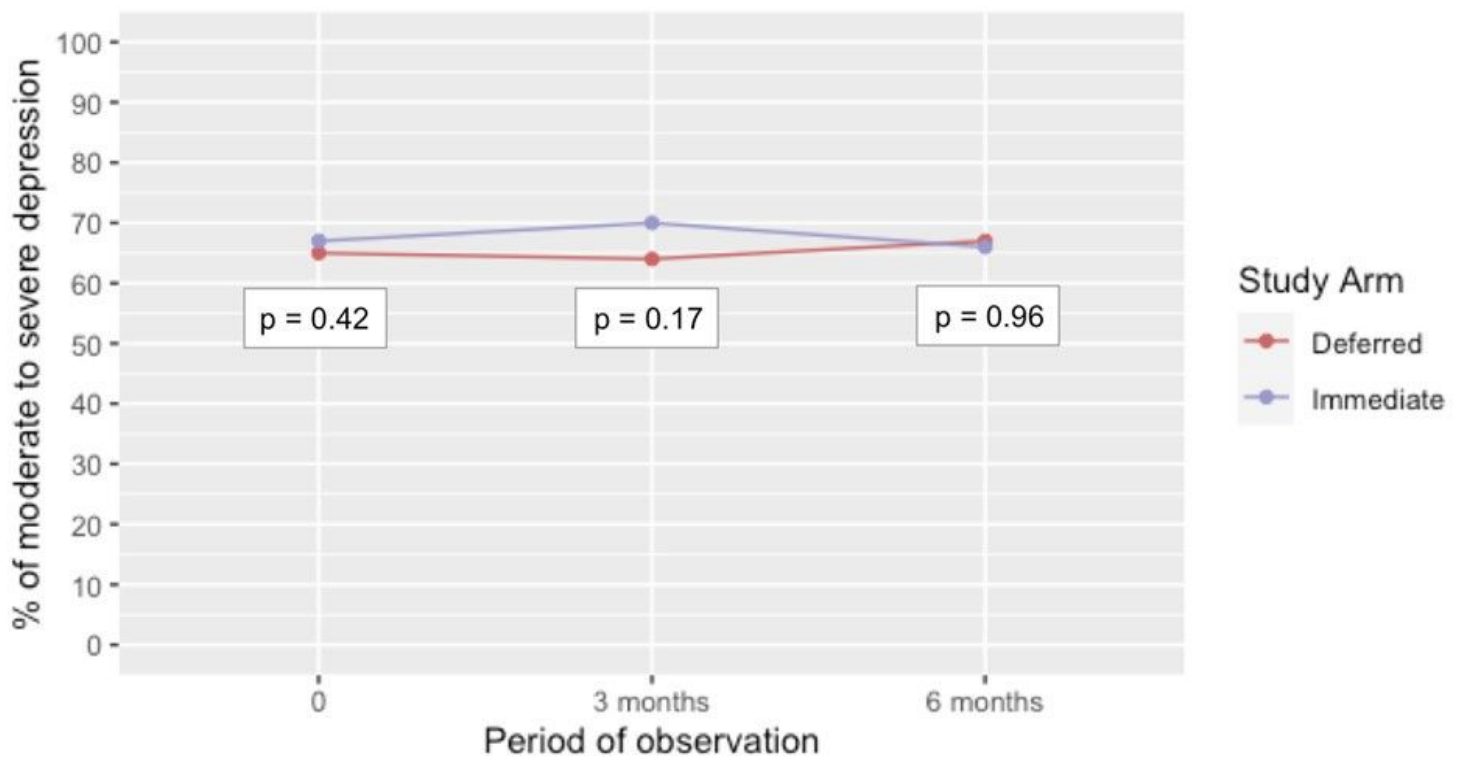


Figure 3

Prevalence of moderate to severe depression (PHQ-9 \geq 10) in immediate and deferred intervention groups and p-values from chi-square tests. Periods of observation were at baseline, three and six months after inclusion. MAKASI project, 2018-2021, Paris.

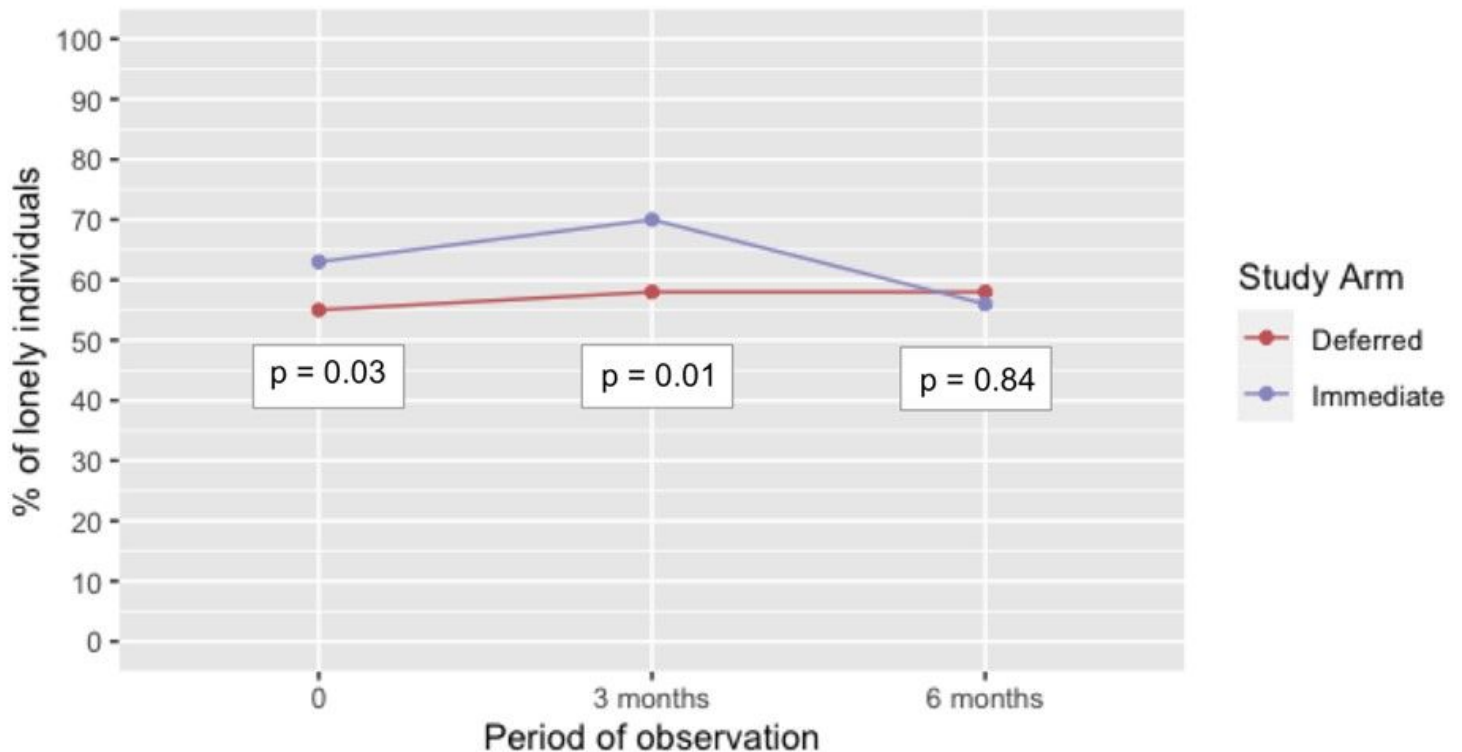


Figure 4

Prevalence of lonely individuals in immediate and deferred intervention groups and p-values from chi-square tests. Periods of observation were at baseline, three and six months after inclusion, MAKASI project, 2018-2021, Paris.

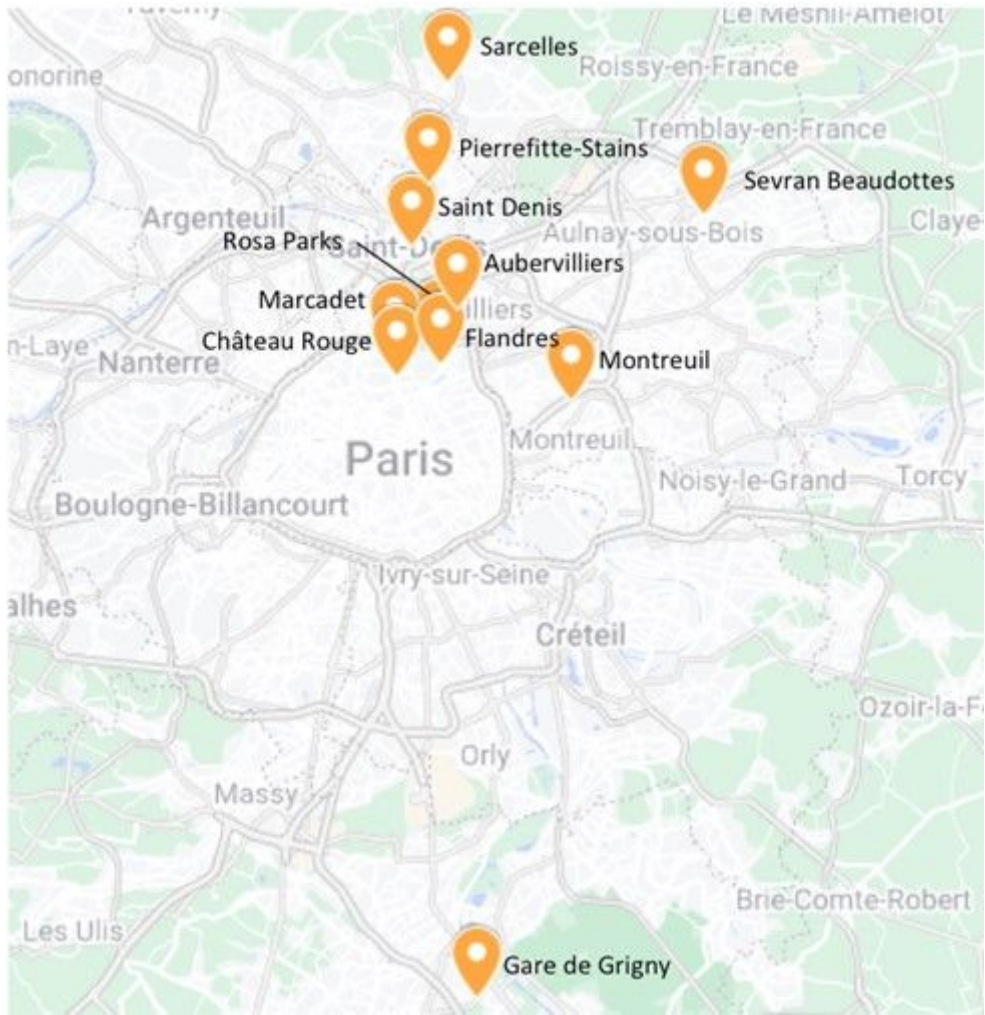


Figure 5

Makasi intervention sights in Paris greater area. Intervention was delivered in: Rosa Parks, Marcadet, Château Rouge, Flandres, Montreuil, Aubervilliers, Sevrans Beaudottes, Saint Denis, Sarcelles, Pierrefitte-Stains and Gare de Grigny. (Map created with the Google My Maps tool).