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RESEARCH ARTICLE

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Sustained impact of motivational interviewing on reducing vaccine hesitancy among postpartum mothers: A randomized control trial, Southeastern France, 2021 to 2022

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ABSTRACT

Parental vaccine hesitancy (VH) remains a significant public health challenge in France, despite mandatory childhood vaccination policies. Motivational interviewing (MI) has shown promise in reducing VH and increasing vaccination intentions. This study aimed to evaluate the sustained impact of an MI-based intervention on VH and vaccination intentions among postpartum mothers in Southeastern France. We conducted a randomized controlled trial (RCT) in two maternity wards in Southeastern France between November 2021 and April 2022. A total of 733 mothers were randomly assigned to receive either a MI session delivered by trained midwives or an educational leaflet. We used the Parent Attitudes about Childhood Vaccines questionnaire to assess VH (0–100 score) and a single question to measure vaccination intentions (1–10 score). Data on VH and vaccination intentions were collected pre-intervention (T0), immediately post-intervention (T1), and seven months later on average (T2). Linear regression models adjusted on potential confounders and Heckman's two-step selection method were used to analyze the data. Seven months post-intervention, we observed a reduction in VH scores (10.1/100 points, $p < .0001$) and an increase in vaccination intention scores (0.8/10 points, $p = .01$) compared to the control group. The impact of MI was consistent across different perceived financial situations. Our findings demonstrate that MI has a sustained effect in reducing VH and increasing vaccination intentions among postpartum mothers. MI should be considered as a key strategy to strengthen and sustain vaccine confidence. Further research is needed to test the impact of MI interventions among other under-vaccinated populations, such as pregnant women.

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KEYWORDS
Childhood vaccination; vaccine hesitancy; vaccine intention; motivational interviewing; randomized-controlled trial

Introduction

In 2018, the French Ministry of Health extended childhood vaccination mandates for children born after 2018 from three vaccines to eleven. Despite an important increase of childhood vaccination coverage, it remains below the 95% target for most vaccines.[1,2] Moreover, an average delay of 6 months in vaccination intake persisted for measles, mumps and rubella (MMR) at 36 months of age among the 2019 birth cohort.[3] These delays, associated with suboptimal vaccination coverage may increase the risk for outbreaks in France.[4]

Vaccine hesitant parents comprise parents who refuse or delay certain vaccines, or accept them but with doubts.[5,6] In 2016, vaccine hesitancy was estimated at 46% among parents in France.[7] While education and information interventions are widely used in attempt to address parental lack of knowledge and/or concerns toward vaccination, there is low to moderate evidence of their efficacy on parents' intention to vaccinate their children.[8,9] Therefore, innovative and individual approaches are needed to reduce the wide scope of vaccine hesitancy among parents and increase parents' intention to vaccinate their children.

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Two psychologists, Miller and Rollnick, developed motivational interviewing (MI) in the 1990s, defining it as "*a directive, client-centered counselling style for eliciting behaviour change by helping clients to explore and resolve ambivalence.*"[10–12] Since 2017, the ministry of health in Quebec has started to roll out the EMMIE program (Entretien Motivationnel en Maternité pour l'Immunization des Enfants) offering information sessions on childhood immunization to parents in maternity wards after birth based on MI techniques adapted to vaccination.[13,14] Each session is adapted to the level of vaccine hesitancy, the needs and potential questions of parents. The EMMIE program was implemented after the PromoVaQ study demonstrated that a MI-based intervention decreased mothers' VH by 40%, increased vaccine intention by 12% and increased, 7 months later, infant vaccination coverage by 6%.[11,15–18] Recent analyses of the EMMIE programme have shown a similar order of magnitude impact on VH and vaccine intention.[19]

In 2021, we adapted this programme to the French setting and implemented a randomized controlled trial (RCT) in two maternity wards in Southeastern France.[20] The primary objective was to provide evidence that, in the French context of childhood vaccination mandates, MI on immunization, offered by midwives to mothers in maternity wards (MI group) before discharge, could significantly reduce VH and increase their intentions to get their child vaccinated, compared to receiving an educational leaflet (control group). The study protocol included three measurement points: one before intervention (T0), an immediate post-intervention assessment (T1), with results previously reported,[20] and a last assessment seven months later (T2). Right after the intervention at the maternity ward (T1), mothers' VH decreased by 33% and intention to vaccinate their infant at 2 months increased by 8% in the group receiving MI, corresponding to a net VH decrease of 5.8/100 points and a net intention to vaccinate increase of 0.6/10 point. The effect on VH and vaccine intention was larger in mothers with a high level of initial VH ((≥50/100, representing 26% of mothers) and low level of education (for VH only).[20]

This article presents the results of this trial seven months on average after the intervention and compare between both groups (MI and control): 1) the evolution of VH scores, 2) mothers' intentions to vaccinate their infants, and 3) the influence of education level and perceived financial situation on these evolutions.

Methods

Trial design and procedure

We described in details the design, eligibility criteria, recruitment method, and study procedure in a previous publication.[20] Briefly, we implemented a parallel-arm, multicentre randomized controlled trial with individual randomization, comparing the impact of MI intervention with standard information about vaccine (educational leaflet about vaccination) as the control (ClinicalTrials.gov: number NCT05093452). The two maternity wards who participated in the study were located in Southeastern France (Saint-Joseph Hospital in Marseille serving a mixed and less-affluent population and Sainte-Musse Hospital in Toulon serving a more affluent population). Three midwives were trained to perform MI, to recruit eligible mothers in the study and to randomly assign participants to both groups. Midwives delivered MI to participants in the MI group in individual sessions lasting between 10 and 30 min.[20]

Eligible mothers recruited to participate to the study (aged 18 or over, speaking French and living in one of the two districts of the study area), gave birth at one of the two maternity wards, provided their written consent to participate in the study, and were included after birth and before discharge from the maternity ward.

Initial recruitment took place from November 2021 to April 2022; for the follow-up survey, participants who had given their consent at inclusion were contacted again seven months later on average (five to twelve) between July and December 2022. We estimated a sample size of 550 participants in each group, at initial inclusion, to allow the measurement of the impact of the intervention (20% difference before and after and between groups) both in immediate and 7-month terms, taking into account an attrition of 20% at follow-up. At follow-up, mothers were first reached by e-mail containing a link to an online questionnaire. In case of no response, we sent two reminders by e-mail and phone text messages. Three weeks later, non-respondents were contacted by phone up to four times at varying times and days throughout one week to offer assistance in completing the questionnaire.

We received approval by the ethics committee of the University of Aix-Marseille (France) on 9 January 2021 for the study as a whole (T1 and T2) (ref. 2021–01-07–04). Written informed consent was obtained from all participants before study inclusion.

Data collection and outcomes

Initially, we collected data through two self-administered questionnaires during the postpartum stay at the maternity ward: one before the MI or leaflet distribution (T0) and a second afterward (T1). Then, at follow-up, we collected data through a self-administered or assisted phone questionnaire (T2) (see Appendix Material A1 for T2 questionnaire). All questionnaires collected data on: 1) VH with a modified version (13 items) of the Parents Attitudes about Childhood Vaccines (PACV)[15,16,21]; 2) intention to vaccinate their infant measured on a 1–10 scale (1 = 'not certain at all' to 10 = 'absolutely sure') in response to: *"How sure are you that you will vaccinate your baby at 2 months of age*?" (T0 and T1 questionnaires) or "at 12 *months of age?"* (T2 questionnaire). We collected sociodemographic data at T0 only. We did not include vaccine coverage as an outcome measure, as assessing the effect of MI on vaccination rates would have required a larger sample size, given the vaccination rates increase following mandates in France.

Statistical methods

A standardized VH score previously used in the Promovac/PromovaQ studies was constructed by summing up the item scores of the modified version of the PACV.[21] We then converted the score into a 0–100 VH scale by linear transformation with scores between 0 and less than 30 corresponding to low hesitation, scores between 30 and less than 50 corresponding to moderate hesitation and scores of 50 and higher corresponding to high hesitation.[15,20,22]

We used Chi^2 or Fisher tests (categorical variables) and Wilcoxon rank sum tests (continuous scores) for comparing participants characteristics and tested scores evolutions using Wilcoxon signed-rank tests.

To compare the impact of the MI-based intervention to the leaflet on participants' VH and vaccination intention (VI) seven months later, we calculated the scores differences between T2 and T0 and T2 and T1 for VH and VI, and tested for an association between these differences and the randomization group (MI/control) using linear regression models. We adjusted for potential confounders such as maternity, age, birth order of the child, educational degree, perceived financial situation, and flu vaccine status. We applied the Heckman's two-step selection model[23] to test and correct for a potential sample selection bias among T2 participants due to non-participation. This method has been used in epidemiological studies and population-based studies where selective participation is a concern.[24] The Heckman procedure involves two steps: 1) Selection equation: We first modeled the probability of participation at T2 to identify factors associated with non-participation. From this model, we derived the inverse Mills ratio (IMR), which captures the influence of unobserved variables related to the missingness process.[25] 2) Outcome equation: Next, we estimated the association between score changes (T2–T0 or T2–T1) and randomization group among those who participated at T2. The IMR was included in this regression model to adjust for potential selection bias. Further details on the outcome equation can be found in Appendix Material A2, and corresponding results are presented in Table A1.

We first estimated the overall impact of MI compared with the leaflet on outcomes, then conducted stratified analyses by education level (equivalent to high school or lower vs at least some post-secondary education) and perceived financial situation (feeling insecure vs not insecure) as proxies for social status. In order to measure if there was a maintaining effect of MI between just after the intervention and 7 months after, we tested with the same method the VH and VI scores differences between T2 and T1 and its association with randomization group.

We performed per protocol (PP) analyses since the outcomes were calculated as T2-T0 and T2-T1 score differences, and could thus be constructed only for participants with data at T0 and T2, and at T1 and T2, respectively. We used the statistical software SAS 9.4 (SAS Institute Inc., Cary, NC, USA) for data analysis, with statistical significance set at 0.05.

Results

Among the 733 participants who completed the T0 questionnaire, 562 (77%) agreed to be contacted for the follow-up study and 407/733 (64%) completed the T2 questionnaire (Appendix Material A3 - Flowchart). T2 participants were more likely to be in the MI group than non-T2 participants ($p = .01$), reported more often living with a partner ($p = .03$), being vaccinated against seasonal influenza during pregnancy ($p = .03$), and presented a lower initial VH score ($p < .0001$) (Table 1). However, T2 participant's sociodemographic characteristics, initial VH and vaccination intention scores did not significantly differ between MI and control groups (Appendix Materiel A4, Table 1 for T2 participants characteristics and Table 2 for their initial VH and VI scores).

Vaccine hesitancy score changes between T0 and T2: differences between randomization groups

Global difference

Among the T2 participants, in the control group, the average VH score was 29.9/100 at T0 and 25.8/100 at T2, representing a significant 14% decrease (−4.1 points, $p = .001$). In the MI group, the corresponding scores were 32.5/100 at T0 and 24.1/100 at T2, representing a significant 26% decrease (−8.4 points, $p < .0001$) (Figure 1). After adjusting on potential confounders and correcting for sample selection bias (IMR differed significantly from zero ($\beta = -41.4$, $p < .0001$)), the VH score decrease was 10.1 points higher in the MI group compared to the control group (Table 2).

Table 1. Characteristics of T0 participants according to their participation at T2 (n = 733).

		Participant at 7 months recall (T2)		
		No (n = 326)	Yes (n = 407)	*p*-value‡
		% †	% †	
Randomization group	Motivational interviewing	44.2	**53.8**	**
	Control (leaflet)	**55.8**	46.2	
Age of the mother	18–24	10.1	7.9	.12
	25–29	31.3	28.5	
	30–34	38.7	36.4	
	35 y and over	19.9	27.3	
Live with a partner[a]	Yes	89.0	**93.3**	*
	No	**6.8**	5.5	
	Don't know/refuse to answer	**4.3**	1.2	
Birth rank of new-born	1	50.0	51.6	.67
	2 or more	50.0	48.4	
Education level[b]	Low: Equivalent to high school or lower	38.7	33.1	.06
	High: At least some post-secondary education	57.1	64.7	
	Don't know/refuse to answer	4.3	2.2	
Perceived financial situation[a]	Insecure	28.5	30.9	.23
	Not insecure	63.5	64.1	
	Don't know/refuse to answer	8.0	5.0	
Vaccinated against seasonal influenza during pregnancy[b]	Yes	8.0	**14.3**	*
	No	**90.8**	84.4	
	Don't know/refuse to answer	1.2	1.2	
Initial vaccine hesitancy score	Low (<30)	35.6	**48.9**	***
	Moderate (30–50)	**33.7**	29.2	
	High (>50)	**30.7**	21.9	
Initial score of intention to vaccinate one's infant at 2 months of age[c]	Low (<5)	5.4	5.2	.48
	Moderate (5–8)	34.6	30.5	
	High (>8)	60.1	64.4	

†Due to rounding, the sum may not equal 100%.
‡Chi² or Fisher tests for categorical variables; Wilcoxon rank sum tests for continuous variables.
[a]3 missing values; [b]2 missing values; [c]11missing values.
**p* ≤ .05 ***p* ≤ .01 ****p* ≤ .001.

Table 2. Association between VH score evolution (T2-T0) and randomization group: results from linear regressions adjusted for confounding factors and Heckman correction when needed (n = 375†).

	β	Std. Err.	p
Globally	*n = 375*		
Intercept	**16.6**	**4.1**	***
MI-based intervention (ref. Leaflet)	**−10.1**	**1.8**	***
Inverse Mill's ratio	**−41.4**	**5.9**	***
Stratified on education level			
Equivalent to high school or lower	*n = 121*		
Intercept	15.6	10.2	.13
MI-based intervention (ref. Leaflet)	**−9.8**	**3.3**	**
Inverse Mill's ratio	**−25.2**	**10.5**	*
At least some post-secondary education	*n = 254*		
Intercept	**12.0**	**4.3**	**
MI-based intervention (ref. Leaflet)	**−8.4**	**2.1**	***
Inverse Mill's ratio	**−35.6**	**6.1**	***
Stratified on perceived financial situation			
Insecure	*n = 120*		
Intercept	9.4	6.0	.12
MI-based intervention (ref. Leaflet)	**−8.1**	**2.7**	**
Inverse Mill's ratio	**−26.6**	**7.5**	***
Not insecure	*n = 255*		
Intercept	**20.1**	**5.5**	***
MI-based intervention (ref. Leaflet)	**−11.7**	**2.5**	***
Inverse Mill's ratio	**−47.2**	**8.0**	***

The model on the sample (refered as globally) was adjusted for maternity ward, age, education level, perceived financial situation, birth rank of the newborn and influenza vaccination during pregnancy. The stratified models were adjusted on the same variables, apart the ones they were stratified on. Heckman correction was applied by including Inverse Mill's ratio (IMR) in the explanatory variables when it was significantly not null.

†32 participants excluded because of don't know answers/refusals regarding sociodemographic and economic characteristics .

Lecture. In the MI-based intervention group, after Heckman correction for sample selection bias introducing the inverse Mill's ratio (significantly not null), the VH score decreased by 10.1 points compared to the leaflet group between T0 and T2.

*$p \leq .05$ **$p \leq .01$ ***$p \leq .001$.

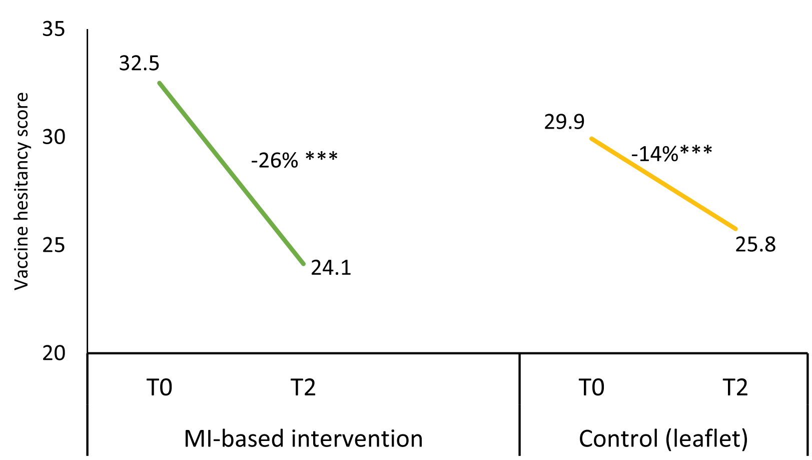

Figure 1. Changes in vaccine hesitancy scores by randomization group between the pre-intervention (T0) and 7 months after (T2), south-eastern France, November 2021- December 2022 (n = 407). ***$p \leq .001$.

Differences after stratifying on education level

Among participants with low education level, after adjusting on potential confounders and correcting for sample selection bias (IMR differed significantly from zero (β = −25.2, $p < .0001$)) the T2-T0 VH decrease was 9.8 points ($p \leq .01$) higher in the MI group than in the control group. Among those with high education level, after adjusting on potential confounders and correcting for sample selection bias (IMR differed significantly from zero (β = −35.6, $p < .0001$)) the T2-T0 VH score decrease was 8.4 points higher in the MI group than in the control group ($p < .0001$) (Table 2).

Difference after stratifying on perceived financial situation

After adjusting on potential confounders and correcting for sample selection bias for both participants who felt financially insecure (IMR differed significantly from zero ($\beta = -26.6$, $p < .0001$)) and those who did not (IMR differed significantly from zero ($\beta = -47.2$, $p < .0001$)): the decrease in VH scores was respectively 8.1 ($p \leq .001$) and 11.7 points ($p \leq .001$) higher in the MI group compared to the control group (Table 2).

Differences in vaccine intention scores changes between T0 and T2

Global difference

Among the T2 participants, in the control group, the average vaccine intention score, i.e. intention to vaccinate one's infant, was 8.9/10 at T0 (for vaccination at 2 months) and 9.2/10 at T2 (for vaccination at 12 months), representing a 4% increase (+0.4 point, $p = .002$). In the MI group, the corresponding scores were 8.4 at T0 and 9.3 at T2, representing an 11% increase (+0.9 point, $p < .0001$) (Figure 2). After adjusting on potential confounders and correcting for sample selection bias (IMR differed significantly from zero ($\beta = -2.2$, $p \leq .01$)), vaccine intention score increased by 0.8 point more in the MI group than in the control group between T0 and T2 ($p \leq .01$, Table 3).

Difference after stratifying on education level

Among participants with low education level, there was no evidence of sample selection bias (IMR not significantly different from zero: $p = .24$), the VI increase did not significantly differ between MI and control groups although it tended to be 0.8 points ($p = .09$) higher in the MI group among those with low education levels. On the other hand, among those with high education level, after adjusting on potential confounders and correcting for sample selection bias (IMR differed significantly from zero ($\beta = -1.8$, $p \leq .05$)), vaccine intention score increased by 0.6 point more in the MI group than in the control group between T0 and T2 (Table 3).

Difference after stratifying on perceived financial situation

Among participants not feeling financially insecure and after adjusting on potential confounders and correction for sample selection bias (IMR significantly not null ($\beta = -4.2$, $p < .0001$)); the VI score increase was 1.1 points ($p = .02$) higher in the MI group than in the control group. In participants feeling insecure, there was no evidence of sample selection bias (IMR not significantly different from zero, $p = .39$) and the VI score increase was 1.3 points ($p = .001$) higher in the MI group than in the control group (Table 3).

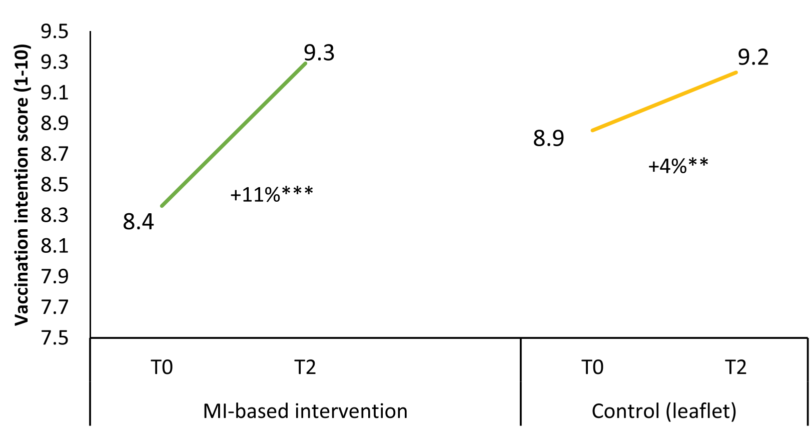

Figure 2. Changes in vaccine intention scores by randomization group between the pre-intervention (T0) and 7 months after (T2), south-eastern France, November 2021- December 2022 (n = 401[a]). $^{**}p \leq .01$ $^{***}p \leq .001$. [a]6 participants excluded because of don't know answers/refusals to intention question in T0 or T2.

Table 3. Association between VI score evolution (T2-T0) and randomization group: results from linear regressions adjusted for confounding factors and Heckman correction when needed (n = 373†).

	β	Std. Err.	*p*
Globally	*n = 373*		
Intercept	**−1.1**	**0.5**	*
MI-based intervention (ref. Leaflet)	**0.8**	**0.2**	***
Inverse Mill's ratio	**2.2**	**0.8**	**
Stratified on education level			
Equivalent to high school or lower	*n = 120*		
Intercept	0.9	2.6	.73
MI-based intervention (ref. Leaflet)	0.8	0.5	.09
Inverse Mill's ratio (NS, p = .24)	–	–	–
At least some post-secondary education	*n = 253*		
Intercept	−0.8	0.5	.11
MI-based intervention (ref. Leaflet)	**0.6**	**0.3**	*
Inverse Mill's ratio	**1.8**	**0.7**	*
Stratified on perceived financial situation			
Insecure	*n = 118*		
Intercept	−3.8	2.0	.052
MI-based intervention (ref. Leaflet)	**1.3**	**0.4**	***
Inverse Mill's ratio (NS, p = .39)	–	–	–
Not insecure	*n = 255*		
Intercept	−1.8	0.7	*
MI-based intervention (ref. Leaflet)	**1.1**	**0.3**	***
Inverse Mill's ratio	**4.2**	**1.0**	***

The model on the sample (refered as globally) was adjusted for maternity ward, age, education level, perceived financial situation, birth rank of the newborn and influenza vaccination during pregnancy. The stratified models were adjusted on the same variables, apart the ones they were stratified on. Heckman correction was applied by including Inverse Mill's ratio (IMR) in the explanatory variables when it was significantly not null.

† 6 participants excluded because of don't know answers/refusals to intention question in T0 or T2; among the 401 who did answered to this question in both questionnaires, 28 participants excluded because of don't know/refusals regarding sociodemographic and economic characteristics included in the selection equation Lecture. In the MI-based intervention group, after Heckman correction for sample selection bias introducing the inverse Mill's ratio (significantly not null), the VI score increased by 0.8 point compared to the leaflet group between T0 and T2.

*$p \le .05$ **$p \le .01$ ***$p \le .001$.

Differences in vaccine hesitancy and intention scores changes between T1 and T2

Among the T2 participants who also participated at T1 (n = 369), we found that T2-T1 evolution of VH and VI scores were not significantly different between MI-based intervention and leaflet, globally and after stratifying on education level or perceived financial situation except for participants feeling financially insecure where VI score increase was 0.7 points ($p \le .05$) higher in the MI group than in the control group (See Appendix Material A4 Tables A1–A4).

Discussion

Seven months on average after mothers received MI on immunization delivered after birth at maternity wards, we observed, in a context of mandatory childhood vaccination, a net decrease of 10.1/100 points in VH associated with MI intervention compared to the educational leaflet and a net increase in VI of 0.8/10 point. The improvements of VH and VI right after the intervention in maternity wards were maintained at follow-up.

These results are consistent with similar studies implemented in Quebec where childhood vaccination are not mandatory. These studies found in addition an improvement of vaccine coverage (VC) at 7 months of age (+7.3% increase in VC compared to control group) and at 24 months (+5.1% increase in VC).[16,17,19] In the era of misinformation on vaccination, the long-lasting effects of MI over time is an essential result suggesting that MI could be an efficient strategy to maintain and consolidate childhood vaccine confidence. While different vaccines are recommended in most childhood vaccination schedules at 2 months and 12 months of ages, our results also suggest that MI could address various roots of vaccine concerns related or not to vaccine controversies. Indeed, the MI approach allowed midwives to answer specific and personal questions of each participating mothers: 90% of women reported not having any more questions about vaccination after receiving the MI intervention, with 96% reporting it had respected their views on vaccination (data previously published[20]). This personal approach, its benevolence, empathy, non-judgment, affirmation and, above all, the respect of women's autonomy in resolving their own ambivalence toward vaccination, are key aspects explaining that the impact of MI can be maintained over time, no matter the vaccines involved. Respect for autonomy means that parents are not forced to make a change, but adopt it themselves, which may explain why the change is stable, while non-judgment and empathy promote a climate of trust and greater receptiveness to the information conveyed by the healthcare professional.

Several studies identified economic and educational levels as determinants of vaccination uptake and hesitancy, but directions of these associations differ by vaccine, across time and country.[26-29] In the specific context of French parents, a nationwide cross-sectional study performed in 2016 found that vaccine refusal and delay were more frequent in more educated parents.[29,30] In our study, we observed a long-lasting impact of MI-based intervention compared to the leaflet, with a net decrease in VH in participants with low education levels (9.8/100 points higher than the leaflet), with high education levels (8.4/100 points higher) and in participants both feeling financially insecure (8.1/100 points higher) and secure (11.7/100 points higher). This long-lasting impact was also observed on VI in participants with high education levels (0.6/10 points higher) and both feeling financially insecure (1.1/10 points higher) or secure (1.3/10 points higher). However, we do not observe a significant impact of MI on VI among participants with low education levels (0.8/10 points higher with $p = .08$) while we observe an effect on VH. This is potentially due to a lack of power among this group. These results suggest that MI may be efficient in addressing VH and VI across different socioeconomic categories which offers an interesting opportunity to address the socio-economic disparities in vaccine hesitancy in a variety of settings (in maternity wards, but also as part of community-based approaches).[31]

Our study presents several limitations, some of them were already discussed in a previous article.[20] We did not measure MI's effect on vaccine coverage because this would have required a larger sample size, in the context of increasing vaccination rates due to vaccination mandates in France.[1] As an alternative, we measured amongst parents their intention to vaccinate their infant at two (T0 and T1 questionnaires) and twelve months (T2 questionnaire), and estimated the evolution of VI at 7 months after the intervention. Although recommended vaccines are different at 2 and 12 months of age, there was no mention of specific vaccines in both VI questions. In addition, MI-interventions were not targeted to a specific vaccine: therefore participating parents were free to talk and ask question related to any childhood vaccine at any age of life.

We performed PP rather than intention-to-treat (ITT) analyses, when ITT is usually recommended. However, in our study, ITT did not seem to be the most appropriate, as attrition was not random: agreeing to participate again to the study 7 months after intervention (at T2) was associated with being vaccinated against seasonal influenza during pregnancy, lower initial VH and being in MI group. Therefore, the evolution of the VH score in participants at T2 might have been underestimated compared to those who refused to participate at follow-up. Thus, the estimated associations with the randomization group – i.e. the impact of MI compared to the leaflet – would have also been underestimated when not taking into account refusers characteristics, due to sample selection bias. Instead, the Heckman's two-step selection method[23] applied to T2-T0 scores evolution (by definition in PP) allowed to test for sample selection bias and correct the estimations when necessary, by introducing the IMR (effect of all unobserved variables that can influence the missingness process) in the models. In addition, potential biases were also limited as T2 participants sociodemographic characteristics, initial VH and vaccination intention scores did not significantly differ between MI and control groups and as results were adjusted on potential confounders. Finally, the sustained impact of MI on VH and VI suggests that the Hawthorne effect (where individuals change their behavior because they know they are being observed) was likely minimal or absent.[20,32]

Conclusion

This study is the first to demonstrate, within the French context of childhood vaccination mandates and high parental vaccine hesitancy, that a MI-based intervention presents a maintaining effect over an educational leaflet in reducing VH and increasing intention to vaccinate seven months post-intervention. MI should be considered as a key strategy among educational interventions to strengthen and sustain vaccine confidence. Our findings, alongside those from the EMMIE programme in Quebec, where MI is systematically offered to every mother at post-partum, underscore the importance of studying the conditions for a larger-scale implementation of MI in maternity settings. This includes adapting the approach to other under-vaccinated populations, such as pregnant women in France.[33,34] Ultimately, once acquired, MI serves as a versatile communication tool that healthcare professionals can apply across a wide range of clinical topics and settings.

Note

[a]. Items 1 to 23 have been adapted from the Parents' Attitudes about Childhood Vaccines (PACV) questionnaire. Opel DJ, Taylor JA, Mangione-Smith R, Solomon C, Zhao C, Catz S, et al. Validity and reliability of a survey to identify vaccine-hesitant parents. Vaccine. 2011;29(38):6598–605.

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Author contributions

CRediT: **Lauriane Ramalli:** Conceptualization, Data curation, Formal analysis, Funding acquisition, Investigation, Methodology, Resources, Validation, Writing – original draft, Writing – review & editing; **Chloé Cogordan:** Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Project administration, Resources, Supervision, Validation, Writing – original draft, Writing – review & editing; **Lisa Fressard:** Data curation, Formal analysis, Methodology, Validation, Visualization, Writing – review & editing; **Xavier Donato:** Project administration, Resources, Supervision, Writing – review & editing; **Magalie Biferi:** Project administration, Resources, Supervision, Writing – review & editing; **Valérie Verlomme:** Project administration, Resources, Supervision, Writing – review & editing; **Pierre Sonnier:** Conceptualization, Writing – review & editing; **Hervé Meur:** Conceptualization, Writing – review & editing; **Gwenaelle Maradan:** Conceptualization, Investigation, Methodology, Project administration, Software, Supervision, Writing – review & editing; **Cyril Bérenger:** Methodology, Project administration, Software, Writing – review & editing; **Patrick Berthiaume:** Methodology, Resources, Supervision, Writing – review & editing; **Arnaud Gagneur:** Conceptualization, Methodology, Resources, Supervision, Validation, Writing – review & editing; **Pierre Verger:** Conceptualization, Methodology, Project administration, Resources, Supervision, Validation, Writing – review & editing.

Disclosure statement

No potential conflict of interest was reported by the author(s).

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Lauriane Ramalli is an epidemiologist with 11 y of experience at the Provence-Alpes-Côte d'Azur and Corsica regional unit of Santé publique France. Her work centers on designing, coordinating, and evaluating public health surveillance systems and epidemic investigations. She evaluates prevention and health promotion interventions (e.g., motivational interviewing for vaccination, health mediation) and supports public health authorities in designing and adapt public health strategies. Her expertise focuses on vaccination, perinatal health, and evidence-based public health interventions. As a supervisor for the European Programme for Intervention Epidemiology Training (EPIET) (European Centre for Disease Prevention and Control - ECDC), she also mentors trainees in applied epidemiology.

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Ethical statement

The project was approved by the ethics committee of the University of Aix-Marseille (France) on 9 January 2021 (ref. 2021–01-07–04).

Use of artificial intelligence tools

No artificial intelligence tool was used for this project and this article.

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Appendices

Appendix material A1 T2 questionnaire

Post-questionnaire T2 7 months after intervention/leaflet (English version)

1. Do you want your baby to have all the recommended shots?[a]

- ☐ Yes
- ☐ No
- ☐ *Don't know*
- ☐ *Do not wish to answer*

2. Overall, how hesitant do you feel about childhood vaccines?

- ☐ Not at all hesitant
- ☐ Not very hesitant
- ☐ Neither hesitant nor not hesitant
- ☐ Somewhat hesitant
- ☐ Very hesitant
- ☐ *Do not wish to answer*

For the following statements, please indicate whether you strongly disagree, disagree, agree or strongly agree

3. Children get more shots than are good for them.

- ☐ Strongly disagree
- ☐ Disagree
- ☐ Neither agree nor disagree
- ☐ Agree
- ☐ Strongly agree
- ☐ *Do not wish to answer*

4. I believe that many of the illnesses shots prevent are severe.

- ☐ Strongly disagree
- ☐ Disagree
- ☐ Neither agree nor disagree
- ☐ Agree
- ☐ Strongly agree
- ☐ *Do not wish to answer*

5. It is better for my child to develop immunity by getting sick than to get a shot.

- ☐ Strongly disagree
- ☐ Disagree
- ☐ Neither agree nor disagree
- ☐ Agree
- ☐ Strongly agree
- ☐ *Do not wish to answer*

6. It is better for children to get one vaccine at a time.

- ☐ Strongly disagree
- ☐ Disagree
- ☐ Neither agree nor disagree
- ☐ Agree
- ☐ Strongly agree
- ☐ *Do not wish to answer*

7. I trust the information I receive about shots.

- ☐ Strongly disagree
- ☐ Disagree
- ☐ Neither agree nor disagree
- ☐ Agree
- ☐ Strongly agree

☐ *Do not wish to answer*

8. I am able to openly discuss my concerns about shots with my child's doctor.

☐ Strongly disagree
☐ Disagree
☐ Neither agree nor disagree
☐ Agree
☐ Strongly agree
☐ *Do not wish to answer*

9. How concerned are you that your child might have a serious side effect from a shot?

☐ Not at all concerned
☐ Not too concerned
☐ Neither concerned nor unconcerned
☐ Somewhat concerned
☐ Very concerned
☐ *Do not wish to answer*

10. How concerned are you that any one of the childhood shots might not be safe?

☐ Not at all concerned
☐ Not too concerned
☐ Neither concerned nor unconcerned
☐ Somewhat concerned
☐ Very concerned
☐ *Do not wish to answer*

11. How concerned are you that a shot might not prevent the disease?

☐ Not at all concerned
☐ Not too concerned
☐ Neither concerned nor unconcerned
☐ Somewhat concerned
☐ Very concerned
☐ *Do not wish to answer*

12. How sure are you that following the recommended shot schedule is a good idea for your child?

Circle a number between 1 and 10, where 1 is not at all sure and 10 is completely sure that the recommended shot schedule is a good idea for your child.

Not at all sure 1	2	3	4	5	6	7	8	9	Completely trust 10

☐ *Do not wish to answer*

13. All things considered, how much do you trust your child's doctor? *Circle a number between 1 and 10, where 1 is not to trust at all and 10 is to trust your child's doctor completely*

Do not trust at all 1	2	3	4	5	6	7	8	9	Completely trust 10

☐ *Do not wish to answer*

14. How sure are you that your baby will have the following booster shots at 11 months?

a) The hexavalent vaccine: this includes vaccines against diphtheria, tetanus, poliomyelitis, whooping cough, haemophilus influenzae b and hepatitis B

For each item, circle a number between 1 and 10, where 1 means you are not at all sure and 10 means you are completely sure that your baby will be vaccinated with the hexavalent vaccine booster.

Not at all sure 1	2	3	4	5	6	7	8	9	Completely trust 10

☐ *My baby has not received the first two doses of the hexavalent vaccine*
☐ *Do not wish to reply*

b) Pneumococcal vaccine:

Circle a number between 1 and 10, where 1 you are not at all sure and 10 means you are completely sure about having your baby vaccinated with this booster.

Not at all sure 1	2	3	4	5	6	7	8	9	Completely trust 10

☐ *My baby has not had the first two doses of pneumococcal vaccine*
☐ *Do not wish to answer*

15. How sure are you that your baby will be vaccinated at the age of 12 months?

a) Against MMR (measles, mumps, rubella)

Circle a number between 1 and 10, where 1 means you are not at all sure and 10 means you are completely sure that your baby will be vaccinated against MMR at the age of 12 months.

Not at all sure 1	2	3	4	5	6	7	8	9	Completely trust 10

☐ *Do not wish to answer*

b) Against meningococcus B

Circle a number between 1 and 10, where 1 means that you are not at all sure and 10 means that you are completely sure that your baby will be vaccinated against meningococcal B at the age of 12 months.

Not at all sure 1	2	3	4	5	6	7	8	9	Completely trust 10

☐ *Do not wish to answer*

c) Against meningococcus C

Circle a number between 1 and 10, where 1 means that you are not at all sure and 10 means that you are completely sure that your baby will be vaccinated against meningococcal C at the age of 12 months.

Not at all sure 1	2	3	4	5	6	7	8	9	Completely trust 10

☐ *Do not wish to answer*

16. Do you feel stressed about the forthcoming vaccinations for your baby?

Circle a number between 0 and 10, where 0 is no stress and 10 is a lot of stress about your baby's vaccination

No stress 0	1	2	3	4	5	6	7	8	9	A lot of stress 10

☐ *Do not wish to answer*

Appendix material A2. Heckman's two-step selection method

The selection equation (factors associated to participation at T2) included sociodemographic characteristics, vaccination against seasonal influenza during pregnancy, as well as the two interaction terms between randomization group and each of the baseline outcomes. The outcome equation (association between score evolution and randomization group) included a variable calculated from the selection equation estimates: the inverse Mills ratio (IMR), allowing to test for sample selection bias and to correct it.[23] The variable identifying the midwife who gave the leaflet/conducted the MI was associated with T2 participation but not with the outcomes, and was thus used as an instrumental variable for Heckman model identification; an instrument is indeed necessary in the selection equation to estimate reliable estimates in the outcome equation.[35]

Table A1. Selection equation for VH score evolution. Factors associated with participation at T2: results from probit regression, n = 654.

	β	Std. Err.	*p*-value
Intercept	**1.31**	0.39	.001
Name of the midwife (ref. Magali)			
Florence	**−0.34**	0.12	.01
Isabelle	**−0.38**	0.13	.004
Age of the mother (ref 35 y and older)			
18–24	−0.35	0.22	.11
25–29	**−0.30**	0.15	.04
30–34	**−0.33**	0.14	.01
Live with a partner (ref Yes)			
No	−0.07	0.22	.75
Number of children (ref. 2 or more)			
1	0.08	0.11	.44
Educational level (ref. At least some post-secondary education)			
Equivalent to high school or lower	−0.06	0.12	.62
Perceived financial situation (ref. Comfortable)			
Precarious	0.12	0.12	.31
Vaccinated against seasonal influenza during pregnancy (ref. Yes)			
No	−0.25	0.16	.13
Initial vaccine hesitancy score [0;100]*Randomization group			
MI-based intervention	**−0.01**	0.00	.03
Leaflet	**−0.01**	0.00	.002
Initial score of intention to vaccinate one's infant at 2 months of age[1;10] *Randomization group			
MI-based intervention	0.00	0.03	.93
Leaflet	−0.02	0.03	.45

Appendix material A3. Flowchart

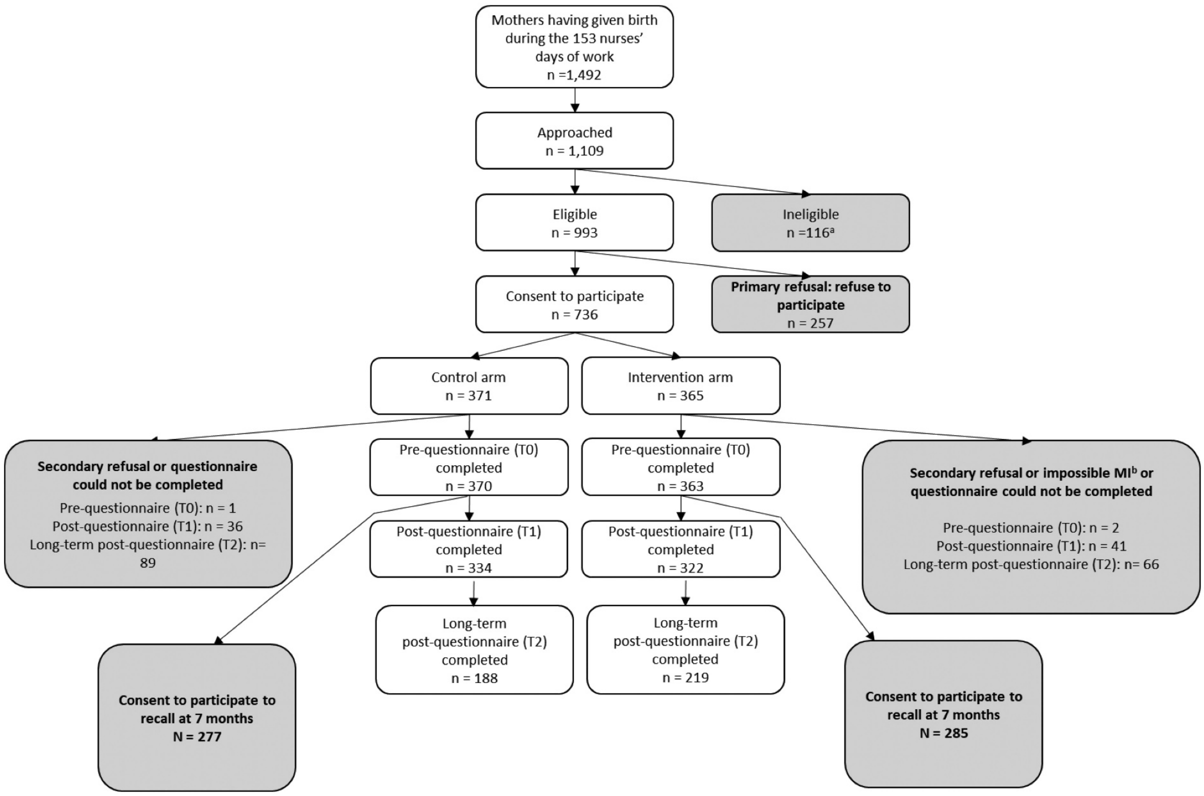

Figure A1. Flowchart of inclusion criteria, Southeastern France, November 2021–April 2022a. [a]Ineligible: age under 18 y, residence outside the two districts of the study area at the time of delivery, inability to read and speak French, COVID-19-positive at the time of delivery, severe medical condition of the newborn and/or mother preventing participation and/or requiring transfer to a neonatal unit/another maternity hospital or discharged within 24 h of delivery for any other reason. [b]Impossible MI: the MI could not be carried out because the mother was not present in her room or was not available when the midwife visited her.

Appendix material A4. Additional tables for results

TableA2. Characteristics of T2 participants according to their randomisation group (n=407).

	All (n=407)		Randomisation group		
			MI-based intervention (n=219, 54%)	Leaflet (n=188, 46%)	
	N	% †	col. % †		p-value‡
Age of the mother					
18-24	32	7.9	8.7	6.9	0.36
25-29	116	28.5	27.9	29.3	
30-34	148	36.4	39.3	33.0	
35 years and over	111	27.3	24.2	30.9	
Live with a partner[a]					
Yes	377	93.3	91.3	95.7	0.20
No	22	5.5	6.9	3.8	
Don't know/refuse to answer	5	1.2	1.8	0.5	
Number of children					
1	210	51.6	53.9	48.9	0.32
2 or more	197	48.4	46.1	51.1	
Education level[b]					
Equivalent to high school or lower	134	33.1	34.9	31.0	0.61
At least some post-secondary education	262	64.7	63.3	66.3	
Don't know/refuse to answer	9	2.2	1.8	2.7	
Perceived financial situation[a]					
Precarious	125	30.9	31.7	30.1	0.78
Comfortable	259	64.1	62.8	65.6	
Don't know/refuse to answer	20	5.0	5.5	4.3	
Vaccinated against seasonal influenza during pregnancy[b]					
Yes	58	14.3	13.8	15.0	0.92
No	342	84.4	84.9	84.0	
Don't know/refuse to answer	5	1.2	1.4	1.1	

Abbreviations: col. = column; MI = motivational interviewing; SD = standard deviation.
† Except when otherwise stated. Due to rounding, the sum may not equal 100%.
‡ Chi^2 or Fisher tests for categorical variables; Wilcoxon rank sum tests for continuous variables.
[a]3 missing values; [b] 2 missing values

Table A3. Initial vaccine hesitancy score and score of intention to vaccinate their infant at 2 months of age of T2 participants according to their randomisation group (n=733).

	Randomisation group		
	MI-based intervention Mean (SD)	Leaflet Mean (SD)	p-valueǂ
Initial vaccine hesitancy score [0;100]	**32.5 (21.4)**	20.9 (20.5)	0.32
Initial score of intention to vaccinate one's infant at 2 months of age[c] [1;10]	8.4 (2.2)	8.8 (1.8)	0.07
Abbreviations: SD = standard deviation			

ǂ Chi^2 or Fisher tests for categorical variables; Wilcoxon rank sum tests for continuous variables.

Table A4. Association between VH score evolution (T2-T1) and randomisation group: results from linear regressions adjusted for confounding factors (n=342 †).

T2-T1 VH score evolution	β	Std. Err.	p
Globally	n=342		
Intercept	11.6	8.4	0.17
MI-based intervention (ref. Leaflet)	1.7	1.7	0.33
Inverse Mill's ratio (NS, p=0.47)	-	-	-
Stratified on education level			
Equivalent to high school or lower	*n=106*		
Intercept	29.4	18.1	0.10
MI-based intervention (ref. Leaflet)	2.4	3.3	0.45
Inverse Mill's ratio (NS, p=0.80)	-	-	-
At least some post-secondary education	*n=236*		
Intercept	-6.9	12.5	0.58
MI-based intervention (ref. Leaflet)	0.8	2.0	0.68
Inverse Mill's ratio (NS, p=0.16)	-	-	-
Stratified on perceived financial situation			
Insecure	*n=114*		
Intercept	29.2	15.5	0.06
MI-based intervention (ref. Leaflet)	-1.0	3.0	0.75
Inverse Mill's ratio (NS, p=0.61)	-	-	-
Not insecure	*n=228*		
Intercept	7.3	14.6	0.62
MI-based intervention (ref. Leaflet)	3.4	2.0	0.08
Inverse Mill's ratio (NS, p=0.47)	-	-	-

The model on the sample (referred as globally) was adjusted for maternity ward, age, education level, perceived financial situation, birth rank of the newborn and influenza vaccination during pregnancy. The stratified models were adjusted on the same variables, apart the ones they were stratified on. Heckman correction was applied by including Inverse Mill's ratio (IMR) in the explanatory variables when it was significantly not null.

† On the 369 participants to T1 and T2, 27 participants excluded because of don't know answers/refusals regarding sociodemographic and economic characteristics included in the selection equation.

* p≤0.05 ** p≤0.01 *** p≤0.001.

Table A5. Association between VI score evolution (T2-T1) and randomisation group: results from linear regressions adjusted for confounding factors and Heckman correction when needed (n=340†).

T2-T1 VH score evolution	β	Std. Err.	p
Globally	*n=340*		
Intercept	0.0	1.0	1.0
MI-based intervention (ref. Leaflet)	0.0	0.2	1.0
Inverse Mill's ratio (NS, p=1.00)	-	-	-
Stratified on education level			
Equivalent to high school or lower	*n=105*		
Intercept	3.8	2.2	0.09
MI-based intervention (ref. Leaflet)	0.1	0.4	0.88
Inverse Mill's ratio (NS, p=0.20)	-	-	-
At least some post-secondary education	*235*		
Intercept	-1.6	1.3	0.23
MI-based intervention (ref. Leaflet)	-0.1	0.2	0.6
Inverse Mill's ratio (NS, p=0.31)	-	-	-
Stratified on perceived financial situation			
Insecure	*n=112*		
Intercept	-2.3	1.7	0.19
MI-based intervention (ref. Leaflet)	**0.7**	**0.3**	*
Inverse Mill's ratio (NS, p=0.94)	-	-	-
Not insecure	*n=228*		
Intercept	-2.0	1.7	0.23
MI-based intervention (ref. Leaflet)	-0.3	0.23	0.16
Inverse Mill's ratio (NS, p=0.43)	-	-	-

The model on the sample (referred as globally) was adjusted for maternity ward, age, education level, perceived financial situation, birth rank of the newborn and influenza vaccination during pregnancy. The stratified models were adjusted on the same variables, apart the ones they were stratified on. Heckman correction was applied by including Inverse Mill's ratio (IMR) in the explanatory variables when it was significantly not null.

† On the 369 participants to T1 and T2, 4 participants excluded because of don't know answers/refusals to intention question in T1 or T2 and 25 participants excluded because of don't know answers/refusals regarding sociodemographic and economic characteristics included in the selection equation.

* $p \leq 0.05$ ** $p \leq 0.01$ *** $p \leq 0.001$.