JITSUVAX:

Jiu-Jitsu with Misinformation in the Age of Covid

Report on field test of empathetic refutational interview

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Reports on Task WP3.2 (field test of empathetic refutational interview)

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Summary

This document reports on the methods and results from two field studies in France and Romania, and a large-scale experiment to field test the effects of the Empathetic Refutational Interview (ERI) (Work Package 3.1 of the JITSUVAX project).

Scope and purpose of this document

This document reports on the methods and results from two field tests and one large-scale experiment to test the effects of the Empathetic Refutational Interview (ERI) (Work Package 3.1 of the JITSUVAX project).

The ERI is an empathy-based refutational tool developed in WP2 of JITSUVAX, which provides a framework for health care professionals (HCPs) to approach conversations about vaccination with hesitant patients and correct misconceptions patients hold about vaccination while simultaneously affirming and empathising with the patients' core beliefs. The objective of the field study was to establish whether the ERI is effective in overcoming vaccine hesitancy in the field and whether the ERI adds value to the existing motivational interviewing technique (MI) and conventional interviews.

The results will inform the development of a guidance document and multiplier guide, which will be covered in future JITSUVAX Deliverables as part of Work Package 4.

Project overview

Vaccine hesitancy—the delay or refusal of vaccination without medical indication—has been cited as a serious threat to global health by the World Health Organization (WHO), attributing it to misinformation on the internet. The WHO has also identified Health Care Professionals (HCPs) as the most trusted influencers of vaccination decisions.

JITSUVAX leverages those insights to turn toxic misinformation into a potential asset based on two premises:

1. The best way to acquire knowledge and to combat misperceptions is by employing misinformation itself, either in weakened doses as a cognitive "vaccine", or through thorough analysis of misinformation during "refutational learning".
2. HCPs form the critical link between vaccination policies and vaccine uptake.

The principal objective of JITSUVAX is to leverage misinformation about vaccinations into an opportunity by training HCPs through inoculation and refutational learning, thereby neutralizing misinformation among HCPs and enabling them to communicate more effectively with patients. We will disseminate and leverage our new knowledge for global impact through the team's contacts and previous collaborations with WHO and UNICEF.

Objectives and methods

Objectives and hypotheses

The aim of this task was to field test the new empathic refutational interview (ERI), developed and validated in WP2, with two specific research hypotheses:

- Is the ERI effective in overcoming vaccine hesitancy in the field?
- What does ERI add to motivational interviewing (MI) and conventional interviews?

Methods overview

To answer these questions, the JITSUVAX team trained HCPs to conduct the MI (Gagneur, Gosselin, and Dubé 2018) or the ERI (Holford et al., 2024), as refined by WP2. The teaching of interviewers was implemented by trainers who were themselves trained by the "train the trainers" workshop (February 2023, Coimbra, Portugal). Task WP3.1 was conducted in France by ORS-PACA and in Romania by UC and CPSS, thereby ensuring that the ERI was available —and tested— in different languages and socio-cultural contexts. The training procedure and setting conformed to precedent (Gagneur, Gosselin, and Dubé 2018; Opel et al. 2013; 2015) and benefitted from Gagneur's involvement in setting up training. Following training, HCPs applied their newly acquired interview techniques (MI or ERI) during consultations with patients.

The effectiveness of these dyadic conversations was assessed in comparison to a control group using quantitative and qualitative methods that were successfully used in previous research (Gagneur, Gosselin, and Dubé 2018; Opel et al. 2013; 2015). In addition to measuring the immediate impact on patients, as well as their intention to get vaccinated, we also conducted semi-structured interviews with the participating HCPs, which were qualitatively analysed.

Because the number of HCP-patient conversations that can be experimentally tested in a medical practice context was necessarily small, providing an additional evaluation by potentially very large samples of observers (e.g., recruited online) may help overcome potential statistical power issues. Therefore, in addition to the field studies, the effectiveness of the ERI was tested in a large-scale quantitative experiment led by Germany (UE). For this study, we collected data from a representative sample from the British general population. Participants were randomly assigned to one of six conditions and watched a 90-second-long video presenting a conversation about the measles, mumps and rubella (MMR) vaccination between a mother and a paediatrician using either ERI, the MI, or no specific communication technique (control). Thus, effectiveness of the new ERI, was tested in two mixed-method field studies conducted in France and Romania and a large-scale quantitative online experiment using a British online panel. The following sections present the methods and results obtained for each country successively. The results are then discussed globally.

Online Experiment in the UK

Overview

For the large-scale experiment, we produced animated videos presenting a conversation about the measles, mumps and rubella (MMR) vaccination between a mother and a paediatrician. The videos were produced in English to make this resource useable for all members of the project. Thus, we decided to collect data for this study in the UK instead of Germany to ensure that participants were able to understand the content of the video. In the UK, the MMR vaccine is recommended for all babies and young children. Parents of babies and young children will usually get contacted by their GP

surgery about the child's MMR vaccinations (NHS, 2024). If parents are worrying about the vaccine, they can speak to their GPs or their nurses.

Aims of the study

This large-scale experiment serves as an extension to the field studies and had three purposes. First, participants from the general public serve as an external evaluation of the effectiveness of the interviews without being biased in their judgements (e.g., by the general competence of a doctor). Second, participants in the field experiment may be prone to demand effects: Patients who are directly interacting with HCPs may feel uncomfortable to negatively evaluate a person's performance. Third, to test the hypotheses of Task WP3.1, high statistical power and thus large numbers of participants are required. This cannot be guaranteed in the initial field experiment for logistic reasons. Thus, members of the public instead of patients served as the sample for the quantitative online evaluation.

To test the effectiveness of the interviews (i.e., ERI and MI), we formulated and preregistered seven hypotheses (https://aspredicted.org/am3vp.pdf). We assumed that participants who watched the paediatrician using an empathetic communication technique (ERI or MI) will show higher trust in the paediatrician (H1), a higher vaccination intention (H2) and will more often recommend the paediatrician to friends (H3) compared to participants in the control condition. Further, we assumed that participants who watched the paediatrician using an empathetic communication technique (ERI or MI) will show lower agreement with misleading arguments and will indicate that they feel more confident to rebut the misleading arguments compared to participants in the control condition and participants in the ERI condition will show a lower agreement and will indicate that they feel more confident to rebut the arguments compared to participants in the MI condition (preregistered as H6 and H7).

Additionally, to better understand the effects of the communication techniques, we included one possible moderator variable (i.e., preference for participation in decision making, see H5 in preregistration). We also varied the gender of the paediatrician in the videos (male vs. female), to test whether the effects interact with the gender of the doctor (see H4 in preregistration).

Methods

Ethical approval

Ethical approval was provided by the University of Erfurt (#2023-32). The study was performed in accordance with "Guidelines to ensure good scientific practice" from the German Research Foundation. Informed consent was obtained from all participants.

Sample

Based on a power analysis, we preregistered a sample size of N = 1,700. We planned to collect data from a sample which is representative for age, gender and region.

We collected our data in February 2024 through an online sample provider (Bilendi). The sample provider invited participants to the survey.

Procedure

We implemented a 3 (ERI vs. MI vs. Control) x 2 (male vs. female) between-subjects design. Participants were randomly assigned to one of the six conditions.

At the beginning, participants had to give informed consent to the survey to continue in the study. Then, variables to collect social and demographical information (i.e., gender, age, region and children) followed. These variables were also used to check quotas (i.e., gender, age and region). Participants who fell into a quota that was already full were immediately redirected to the final page of the survey.

After the social and demographic items, participants received three items to measure their preference in participation in medical decision making. Then, participants watched one out of six videos with a duration of around 90 seconds. To ensure that participants watched the videos, a timer was included which allowed participants to continue to the next side after a minimum of 100 seconds. After the video, participants were asked to rate the empathy of the paediatrician. Next, participants received an attention check ("Which description best fits the paediatrician?") and had to choose one out of four options (e.g. "A man with dark hair, a beard, and glasses"). Then, participants indicated how much they would trust the paediatrician. Further, for the second attention check, participants specified the topic of the conversation in the video by choosing one out of three options (right answer: "Vaccination"). On the next slide, participants received two items to measure whether they would recommend the MMR vaccination and whether they would recommend a paediatrician who interacts with patients like the one from the video. Afterwards, participants were asked how much they agree with two misleading arguments. Participants who indicated a low agreement (i.e., lower than 4 on a 5-point scale) for both arguments were further asked how confident they are that they would have good arguments against the misleading arguments. Finally, participants were asked whether the quality of the video was good, so they were able to understand the conversation. The survey ended with a debriefing providing additional information about the MMR vaccination and debunks of the previously presented misleading arguments. The measures are described below.

Preferences in participation in medical decision making: We used the scale from Levinson et al., 2005 to measure preferences in participation in medical decision making. The scale includes three items (e.g. "I prefer to rely on my doctor's knowledge and not try to find out about my condition on my own."). Participants indicated their agreement to the items on a 5-point scale (ranging from *Strongly disagree* to *Strongly agree*). For analyses, we reverse coded two items

("I prefer to rely on my doctor's knowledge and not try to find out about my condition on my own" and "I prefer to leave decisions about my medical care up to my doctor") and planned to calculate the mean of all three items to indicate participant's preference for a patient-directed decision-making process. However, the calculated Cronbach's Alpha of all three items was $\alpha = 0.46$. By dropping one item ("I prefer that my doctor offers me choices and asks my opinion"), we increased the Cronbach's Alpha to $\alpha = 0.7$. Thus, we decided to use the mean of only two items of the scale for our analyses.

Empathy: We measured perceived empathy of the paediatrician in the video with the CARE Measure Questionnaire (Mercer, 2004). The scale includes ten items which we adapted so that they related to the situation in the video (e.g. "How was the doctor at making the patient feel at ease"). Participants could answer the items on a 5-point scale (ranging from *Poor* to *Excellent*). For analyses, we calculated the mean of the ten items. The Cronbach's Alpha for the whole scale was $\alpha = 0.97$.

Trust in Doctor: We used seven out of ten items from Hall et al. (2002) to measure trust in the paediatrician from the video. We decided to exclude three items that relate to a deeper relationship between doctor and patient (e.g., "The doctor will do whatever it takes to get you all the care you need"). The remaining scale consists of four items that indicate less trust (e.g. "The doctor's medical skills are not as good as they should be") and three that indicate more trust (e.g. "The doctor is extremely thorough and careful"). Participants could indicate how much they agree with the items on a 5-point scale (ranging from *Strongly disagree* to *Strongly agree*). We recoded the four items and calculated a mean of all seven items that shows how much the participants trust the doctor. The calculated Cronbach's Alpha including all seven items was $\alpha = 0.8$.

Vaccination intention: Participants were presented the following scenario: "Your friend is unsure whether she should have her baby vaccinated and asks you what you would do in her position?" Then,

they were asked whether they would have their baby vaccinated. Participants could answer on a 5-point scale (ranging from *Definitely no* to *Definitely yes*).

Recommendation of the paediatrician: Afterwards, participants read the following scenario: "Your friend is also looking for a new paediatrician and asks you for your recommendation." They were asked whether they would recommend a paediatrician who interacts with patients like the one from the video. Participants could answer on a 5-point scale (ranging from *Definitely no* to *Definitely yes*).

Agreement to misleading arguments: The next slide continued with "Your friend has heard the following claims and is not sure if they are true." Then, participants were asked to indicate their agreement to the following statements: "Vaccines given to children for diseases like measles and mumps cause autism" and "Attempts are made to cover up a link between vaccines and autism" on 5-point scale (ranging from *Totally disagree* to *Totally agree*). The mean of the two items was used as a measure of agreement to misleading arguments.

Confidence in ability to rebuttal misleading arguments: Next, participants saw the same two statements again and should indicate how confident they are that they would have good arguments to convince their friend that the claims are false on a 5-point scale (ranging from *I would find it very difficult* to *I would find it very easy*). The mean of the two items was used as a measure of confidence in ability to rebuttal misleading arguments.

Material

In cooperation with a video-production company from Erfurt (Bellmannmedia), we produced six animated videos in English. The videos show a reduced setting of a consultation room with a paediatrician and a mother who has her baby with her in the pram (Figure 1).

Figure 1

Screenshots from the produced videos

In the video, they are talking about the MMR vaccine and the mother is concerned since she heard about a link between the MMR vaccine and autism. In every video, the mother is the same, has the same script and the same emotions. Only the paediatrician varies between the video.

First, we manipulated the script of the paediatrician. Thus, the paediatrician is either talking in the way of MI, ERI or with no specific communication technique (Table 1). The scripts of MI and for the control condition were developed on the basis of Gagneur (2020). Apart from the paediatrician's script, the videos were produced to be as similar as possible (e.g., emotions and voice of paediatrician are nearly the same).

Additionally, we decided to produce each version of the video with a female and a male paediatrician. Thus, we have two versions of the video showing a male or a female paediatrician communicating in the sense of MI, two versions of the video showing a male or a female paediatrician communicating in the sense of ERI and two versions of the video showing a male or a female paediatrician communicating without following any communication technique.

Table 1

Scripts of videos separated for each communication technique.

MI	**ERI**	**Control**
HCP: What do you think about the advantages of vaccination?	*HCP*: What do you think about the advantages of vaccination?	*HCP:* It's important to immunize your child. If not, you're putting him in danger.
Mother: Well, I know that vaccines protect children against several diseases that we don't see anymore. My child received all his first vaccines but I'm worried that the MMR vaccine could cause autism. For other vaccines, I have fewer doubts but I'm still hesitating.	*Mother*: Well, I know that vaccines protect children against several diseases that we don't see anymore. My child received all his first vaccines but I'm still hesitating.	*Mother*: Well, I know that vaccines protect children against several diseases that we don't see anymore. My child received all his first vaccines but I'm worried that the MMR vaccine could cause autism. For other vaccines, I have fewer doubts but I'm still hesitating.
HCP: As you said, vaccines have reduced diseases in such an important way that they are now much less frequent. It's why you have vaccinated your child when he was a baby. If I understood you correctly, with the exception of MMR vaccine, other vaccines seem safe to you.	*HCP*: I see you are worried about this vaccine. Could you explain what worries you? *Mother*: I'm worried that the MMR vaccine could cause autism. For other vaccines, I have fewer doubts. *HCP*: It is normal to have questions and doubts about medical treatments and how they might affect us. The world can sometimes feel like a dangerous place, and we don't fully know why some medical conditions occur. It is understandable to want to know what caused a problem so we can try to avoid it or solve it.	*HCP:* Well, your doubts are unfounded. Studies have demonstrated that there is no link between autism and the MMR vaccine. The vaccine is safe, I assure you. You should be aware of the information that you could find on the Internet. We should update his vaccines now.
Mother: Yes, I know it's a good thing to prevent those infections. But about the MMR vaccine, I'm conflicted. You know, I've read a lot of books and articles. Lots of people are worried about the link between the MMR vaccine and autism. *HCP*: So, you find that it's important to protect your child against diseases when the vaccines are safe, but you're worried about what you've heard regarding autism and MMR vaccine. I see that you've done a lot of research about the subject. If you agree, I could give you some additional information for studies on autism and MMR vaccine.	*Mother*: Yes, I know it's a good thing to prevent those infections. But about the MMR vaccine, I'm conflicted. You know, I've read a lot of books and articles. Lots of people are worried about the link between the MMR vaccine and autism. *HCP*: If you agree, I could give you some additional information for studies on autism and MMR.	*Mother:* Yes, I know it's a good thing to prevent those infections. But about the MMR vaccine, I'm conflicted. You know, I've read a lot of books and articles. Lots of people are worried about the link between the MMR vaccine and autism. *HCP*: But you're putting him and other children who cannot receive vaccines in danger. The risks of diseases are much higher than the risks of vaccines. If I take this time to speak with you, it's because it's very important. We are talking about real dangers here.

Mother: Sure! I know it is important. I am just worried. *HCP*: In fact, you're right. One study had hypothesized a link between MMR vaccine and autism, but this study was fake, and the author lost his medical licence. More than 500 additional studies around the world have demonstrated that there is no link between the vaccine and autism. The frequency of autism is the same in vaccinated children as in nonvaccinated children. What do you think?	*Mother:* Sure! I know it is important. I am just worried. *HCP*: Fear and uncertainty can lead us to see connections that do not exist. In fact, people who have a reason to find fake links will often go to great lengths to publish false information. For example, in 1998, a doctor who was paid by personal injury lawyers published an article that falsely claimed a link between MMR and autism. After his dishonesty in science was exposed, the article was taken down. Since then, a lot of study has shown that vaccines do not cause autism. The article was retracted after his scientific misconduct was revealed, and extensive research has found that vaccines do not cause autism. What do you think?	*Mother:* Sure! I know it is important. I am just worried. *HCP:* I'm worried about the fact that your child could get diseases that could be prevented by vaccines. There really is no reason to be hesitant about this. Again, studies have demonstrated that there is no link between autism and the MMR vaccine. The vaccine is safe. In fact, I am doing this for so many years now and as a medical doctor I can tell you that your concerns are unfounded.

Results

Sample

We collected data of N = 1,714 participants. 24 participants who reported not having watched the video in a good quality were excluded from the sample. Thus, for our analyses, we had a final sample of N = 1,690. Table 2 provides an overview of the sample characteristics and compares them with our targeted quotas which were based on the distribution of the UK Population in 2023.

Table 2

Sample characteristics and comparisons to targeted quota.

	Participants	**Percentage in Sample**	**Targeted quota based on distribution of UK Population**
Gender			
Female	829	49,35%*	49,4%
Male	851	50,65%*	50,6%
Non binary	8	-	-
Preferred not to answer	2	-	-
Age			
18 – 29	374	22,13%	22,3%
30 – 39	348	20,59%	20,56%
40 – 49	338	20%	19,96%
50 – 59	352	20,83%	20,74%
60 – 69	278	16,45%	16,44%

Region			
South East	235	13,9%	13,86%
London	223	13,2%	13,12%
North West	185	10,95%	11,07%
East England	161	9,53%	9,47%
West Midlands	151	8,93%	8,88%
South West	144	8,52%	8,52%
Yorkshire and the Humber	135	7,99%	8,18%
Scotland	139	8,22%	8,17%
East Midlands	125	7,4%	7,29%
Wales	76	4,5%	4,63%
North East	68	4,02%	3,95%
Northern Ireland	48	2,84%	2,84%

Note: *Calculated percentage only displaying the distribution of female and male to compare them with the targeted quota.

In our final sample, 552 participants were assigned to the MI-condition where 280 watched the video with the female paediatrician and 272 the video with the male one (Table 3). 571 participants received a video demonstrating ERI, with 287 of them viewing the female paediatrician and 284 the male one. Finally, 567 participants were assigned to the control condition and 275 of them in the female paediatrician condition and 292 in the male paediatrician condition.

Table 3

Assignment of number of participants to each condition group.

	Female paediatrician	**Male paediatrician**	**Sum**
MI	280	272	552
ERI	287	284	571
Control	275	292	567
Sum	842	848	1690

Manipulation check

To test whether paediatricians using ERI and MI were perceived as more empathetic than paediatricians communicating without following any technique, we calculated an ANOVA with empathy as outcome variable and communication technique and paediatricians' gender as predictors. Based on a previous study showing that men were better evaluated for the same altruistic behaviour than women (Heilman & Chen, 2005), we assumed that this effect also exists for empathetic communication.

The results of descriptive analyses are presented in Table 4. The ANOVA showed a significant effect of communication technique, $F(2) = 78.19$, $p < 0.001$. Follow-up contrast analysis indicated higher perceived empathy for MI and ERI compared to the control group, $p < 0.001$. Additionally, paediatricians' gender also significantly predicted perceived empathy, $F(1) = 4.45$, $p = 0.02$. Here, male paediatricians are perceived as more empathetic than female ones.

Table 4

Descriptive statistic for empathy scale (CARE) separated for each condition group.

	Mean	SD
Communication technique		
MI	3.83	0.86
ERI	3.8	0.82
Control	3.17	1.09
Paediatricians' gender		
Female	3.55	0.97
Male	3.65	0.99

Effects on trust

To test our first hypothesis, we calculated an ANOVA with trust as outcome variable and communication technique, paediatricians' gender, and their interaction as predictors. The results of descriptive analyses are presented in Table 5. The ANOVA showed a significant effect of communication technique, $F(2) = 42.61$, $p < 0.001$, and no significant effect of paediatricians' gender, $F(1) = 0.72$, $p = 0.4$. Further, follow-up contrast analysis indicated higher trust for MI and ERI compared to the control group, $p < 0.001$.

To partly test Hypothesis 4, we included the interaction term of both predictors in the ANOVA and found no significant interaction effect, $F(2) = 0.63$, $p = 0.54$.

Additionally, we calculated a moderator analysis to test whether the effect of communication technique on trust is moderated by preferences in participation in medical decision making (Hypothesis 5). The overall model was significant, $F(3, 1686) = 51.21$, $p < 0.001$, predicting 8.35% of the variance. Additionally, results showed that preferences in participation in medical decision making moderated the effect between communication technique and trust significantly, $F(1, 1686) = 29.27$, $p < 0.001$. Figure 2 displays the mean of trust as a function of both predictors and illustrates that participants with medium or high preference in participation in medical decision making in the control condition showed lower trust icompared to the participants with medium or high preference in participation in decision making in the empathetic communication conditions. When participants had a low preference in participant in decision making, they showed comparable rating of trust in both communication conditions.

Table 5

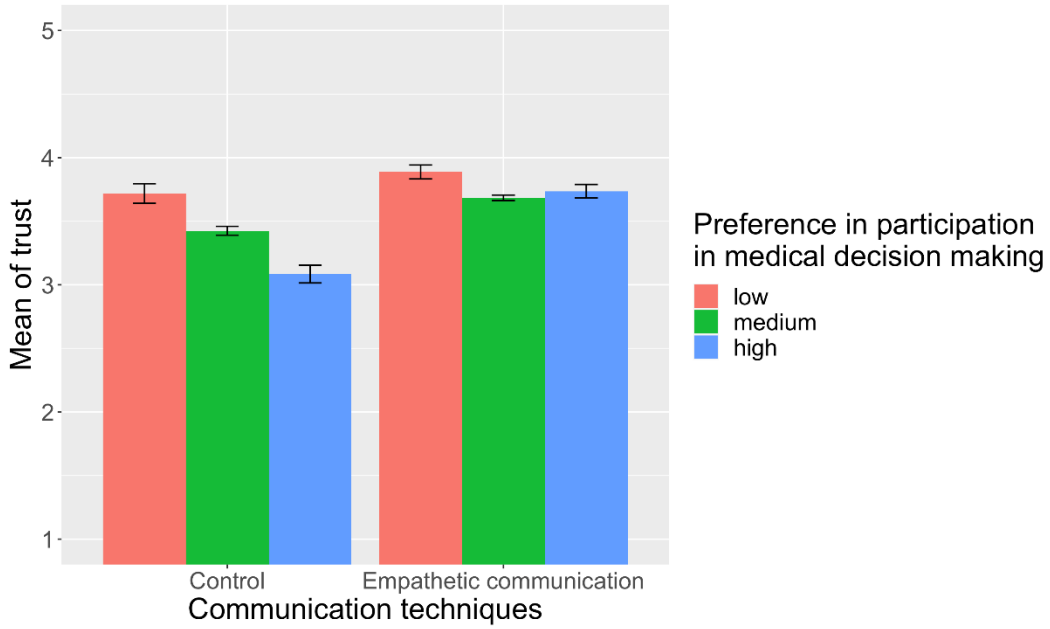
Descriptive statistic for trust scale separated for each condition group.

	Mean	SD
Communication technique		
MI	3.72	0.66
ERI	3.72	0.62
Control	3.41	0.71
Paediatricians' gender		
Female	3.6	0.67
Male	3.63	0.69

Figure 2

Mean of trust depending on communication technique and preference in participants in medical decision making.

Note: Preference in participation in medical decision making was subdivided into low (lower than mean – 1 sd), medium and high (higher than mean + 1 sd). Bars indicating standard errors.



Effects on vaccination intention

For Hypothesis 2, we calculated an ANOVA with vaccination intention as outcome variable and communication technique, paediatricians' gender and their interaction as predictors. Descriptive analyses are presented in Table 6. The ANOVA indicated a significant effect of communication technique, $F(2) = 3.33$, $p = 0.036$, no significant effect of paediatricians' gender, $F(1) = 0.28$, $p = 0.6$, and no significant interaction effect, $F(2) = 0.25$, $p = 0.77$ (referring to Hypothesis 4). We continued with contrast analysis which showed that participants in the MI and ERI condition would more often vaccinate their fictious child than participants in the control group, $p = 0.036$. Additionally, the contrast analysis presented a higher intention for participants in the ERI group compared with participants in the MI group, $p = 0.01$.

Again, to test Hypothesis 5, we calculated a moderator analysis to test whether the effect of communication technique on vaccination intention is moderated by preferences in participation in medical decision making. The overall model was significant, $F(3, 1686) = 13.07$, $p < 0.001$, predicting 2.27% of the variance. Moreover, the results indicated preferences in participation in medical decision making as a significant moderator of the effect between communication technique and vaccination intention, $F(1, 1686) = 9.06$, $p = 0.003$. Figure 3 displays the mean of vaccination intention as a function of both predictors and shows that participants in the control condition showed a greater difference in vaccination intention independent of preferences in participant compared to the participants in the empathetic communication conditions.

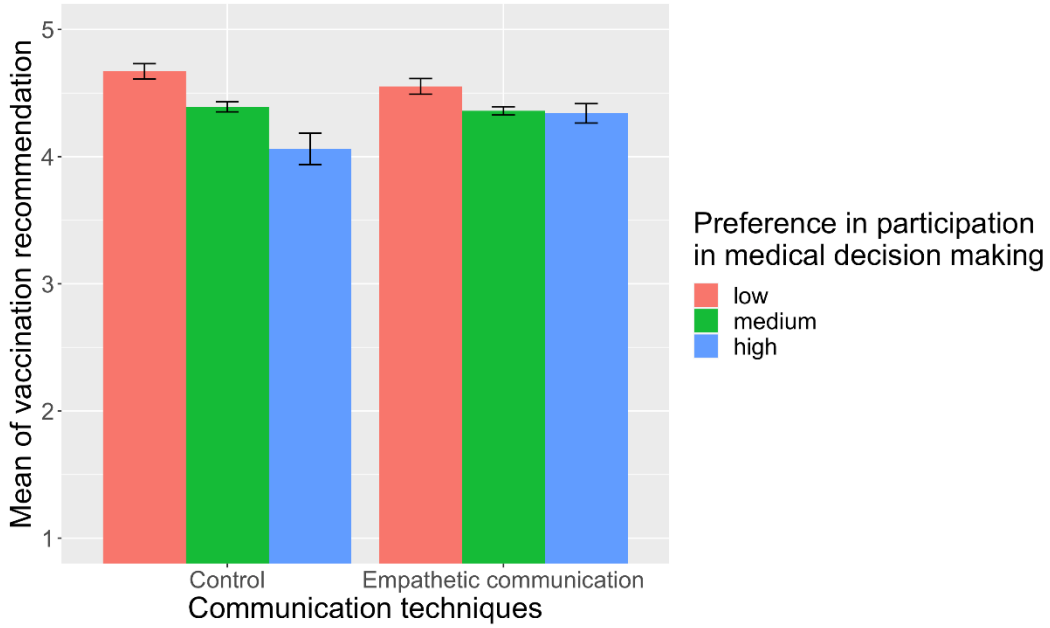
Table 6

Descriptive statistic for vaccination intention separated for each condition group.

	Mean	SD
Communication technique		
MI	4.32	0.99
ERI	4.45	0.81
Control	4.37	0.87
Paediatricians' gender		
Female	4.39	0.9
Male	4.37	0.89

Figure 3

Mean of vaccination intention depending on communication technique and preference in participants in medical decision making.
Note: Preference in participation in medical decision making was subdivided into low (lower than mean – 1 sd), medium and high (higher than mean + 1 sd). Bars indicating standard errors.



Effects on recommendation of the paediatrician

Further, we tested Hypothesis 3 with an ANOVA with recommendation of the paediatrician as outcome variable and communication technique, paediatricians' gender and their interaction as predictors. Table 7 displays the descriptive statistic. The results of the ANOVA indicated a significant effect of communication technique, $F(2) = 88.65$, $p < 0.010$, and a significant effect of paediatricians' gender, $F(1) = 3.9$, $p = 0.048$. More specifically, the analysis presented a higher recommendation for the male paediatricians compared to female ones. Additionally, follow-up contrasts showed a significant difference between the control group and both empathetic communication techniques, $p < 0.001$.

We again included the interaction term of both predictors in the ANOVA to partly test Hypothesis 4. Here, the interaction term was not a significant predictor of the recommendation, $F(2) = 0.55$, $p = 0.58$.

Furthermore, a moderation analysis was conducted to determine whether the interaction between communication technique and preferences in participation in medical decision making significantly predicted the recommendation of the paediatrician (Hypothesis 5). The overall model was significant, $F(3, 1686) = 88.94$, $p < 0.001$, predicting 13.66% of the variance. Results show that preferences in participation in medical decision-making moderated the effect between communication technique and recommendation of the paediatrician, $F(1, 1686) = 43.63$, $p < 0.001$. Figure 4 displays the mean recommendation of the paediatrician as a function of both predictors and illustrates that participants in the control condition with low preferences in participation would more often recommend the paediatrician while the recommendations of participants in the empathetic communication conditions are less dependent on preferences in participation.

Table 7

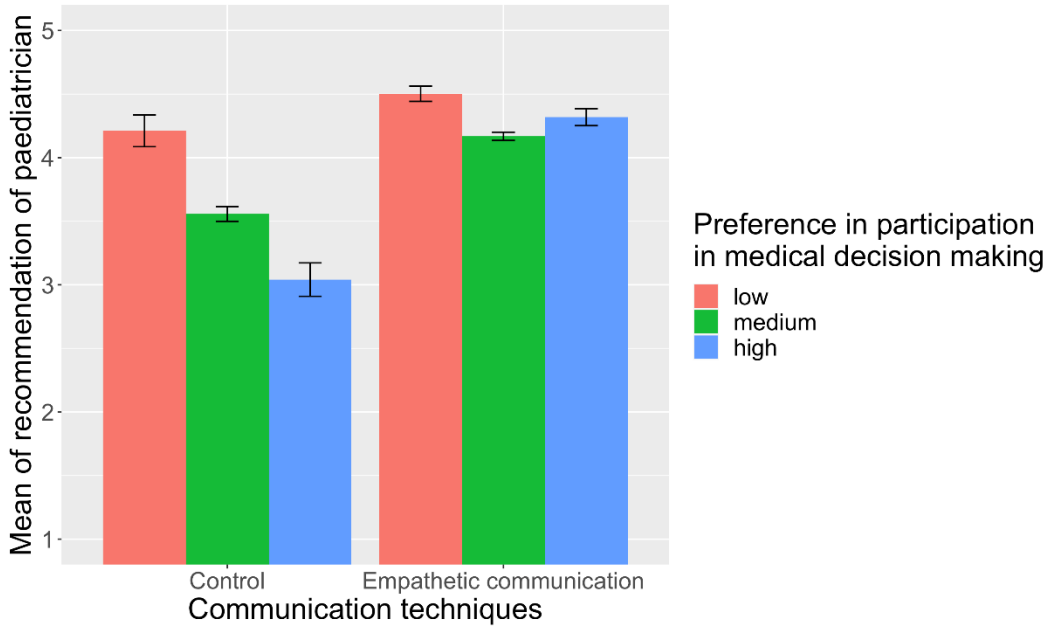
Descriptive statistic for recommendation of the paediatrician separated for each condition group.

	Mean	SD
Communication technique		
MI	4.22	0.92
ERI	4.26	0.87
Control	3.56	1.21
Paediatricians' gender		
Female	3.97	1.07
Male	4.05	1.05

Figure 4

Mean of recommendation of the paediatrician depending on communication technique and preference in participants in medical decision making.

Note: Preference in participation in medical decision making was subdivided into low (lower than mean – 1 sd), medium and high (higher than mean + 1 sd). Bars indicating standard errors.



Effects on agreement to misleading arguments

To test Hypothesis 6, we calculated an ANOVA with agreement to misleading arguments as outcome variable and communication technique as predictor. The results of descriptive analyses are presented in Table 8. The ANOVA indicated no significant effect of communication technique on the agreement, $F(2) = 1.42$, $p = 0.24$.

Table 8

Descriptive statistic for agreement to misleading arguments separated for each communication technique.

	Mean	SD
Communication technique		
MI	2.24	1.12
ERI	2.14	1.08
Control	2.22	1.07

Effects on confidence in ability to rebut misleading arguments

Finally, for Hypothesis 7, we calculated an ANOVA with confidence in ability to rebut misleading arguments as outcome variable and communication technique as predictor. Table 9 presents the descriptive analyses. Moreover, the ANOVA indicated no significant effect of communication technique on the confidence, $F(2) = 0.43$, $p = 0.65$.

Table 9

Descriptive statistic for confidence in ability to rebuttal misleading arguments separated for each communication technique

	Mean	SD
Communication technique		
MI (n = 434)	3.25	1.15
ERI (n = 454)	3.31	1.11
Control (n = 445)	3.26	1.13

Note. For this measurement, the sample size in each group varied from the other measurements as participants indicating a high agreement to the misleading arguments did not receive the measurement of confidence in ability to rebuttal.

Discussion

To test the effectiveness of ERI compared to MI and a control group, we ran a large-scale online experiment to ensure adequate statistical power. Based on our data, we were able to confirm the majority of our preregistered hypotheses. The results show that empathetic communication techniques (i.e. ERI or MI) increase trust in the physician, increase vaccination intention, and make patients more likely to recommend the physician to friends. Thus, we can confirm our first three hypotheses. Further analysis indicated the highest vaccination intention in the ERI condition. In sum, our results show that the ERI is at least comparable to the MI in improving the relationship between physician and patients. Moreover, the ERI indeed raises vaccination intention even more.

With regard to Hypothesis 4, we did not see any differences of the effects of the empathetic communication techniques in dependence of the physician's gender. Thus, we can assume that male and female physicians benefit in the same way from an empathetic communication technique.

Additionally, we tested in Hypothesis 5 whether the effects of empathetic communication techniques are moderated by patients' preferences in medical decision making. Here, we assumed that participants with a greater preference in participation in decision-making process will show the highest effects of an empathetic communication technique. For all three outcome variables (trust, vaccination intention and recommendation of the physician), we identified preferences in decision making as a significant moderator. However, the specific form of the interaction differed from what we expected. In our results, participants with a low preference in participation show higher values in all outcomes when physicians did not follow an empathetic communication technique. In contrasts, when physicians used an empathetic communication technique, differences between the levels of preference in participation decreased.

Finally, we also investigated whether communication using the ERI reduces the agreement with misleading arguments and provides patients good arguments to rebut these arguments. Contrary to our assumptions from Hypotheses 6 and 7, we did not find any effects of the communication techniques on theses outcome variables. In conclusion, our results strengthen previous results indicating ERI as a promising approach to talk to vaccine hesitant patients. Moreover, in our study we reduced the conversations to around 90 seconds. It can be assumed that conversations in a realistic setting have a longer duration. Thus, it is possible that we underestimated the effects of the empathetic communication technique as effects could be stronger when the conversations are longer.

Field test in France

Organization of primary health care in France and role of health-care professionals in vaccination

In France, GPs have traditionally been responsible for vaccinating the population, but more and more professionals have become involved in this role over the last decade: nurses, midwives and pharmacists can now prescribe and deliver vaccinations (Ministère des Solidarités et de la Santé 2022; Verger et al. 2015). In addition, patients are free to choose their healthcare professionals (GP, paediatrician, nurse, etc.) for treatment and vaccination, and can also be vaccinated at a vaccination centre of their choice.

Train the trainers (February 2023)

Four general practitioners (GPs) teaching in the General Medicine Department of the Faculty of Medical and Paramedical Sciences at La Timone (Marseille) took part in the training of trainers course in Coimbra to learn about the ERI. They did not, however, attend the MI training provided by Gagneur & Berthiaume during the Coimbra workshops, as the latter two trained the residents in family medicine in the MI group in France.

Training of residents (April 2023)

The experiment was carried out among the class of residents starting their practical training in a general practice from May to October 2023. Residents' training in ERI or MI was compulsory, and allowed them to get credit for participation. The allocation of residents between the two groups was randomized. The training took place in Marseille in April 2023, face-to-face, at the Marseille's Faculty of Medicine (MI) or at the Marseille's North Hospital (ERI).

- In the MI group, 36 residents out of 46 selected (78%) received full training by Gagneur and Berthiaume (3 successive groups of about 12 residents).
- Training for the ERI group was carried out at the same time by the four doctors trained in Coimbra (RL, EM, CG, AB), divided into two pairs and three sub-groups of approximately 10 residents: 31 residents out of 39 selected (79%) were trained.
- A group of 29 untrained residents was also formed and offered training in ERI and/or EM, planned after the patient experimentation.

Deviations from expected numbers

The number of residents initially expected in each group was around 50. The discrepancies with the actual numbers were due to geographical constraints, and in particular to the fact that residents living in a municipality far from the city of Marseille were not always able to travel to Marseille where the courses were held.

Training content

ERI training

One week before the training, the residents received a guide summarising the principles of ERI (translated into French) and providing a link to the taxonomy of attitudinal roots of vaccination counter-arguments on the JITSUVAX site (information available in French).

The four teacher-trainers developed a teaching presentation (powerpoint) for the residents based on the guidelines provided by the WP2 research team and their own participatory teaching methods. The duration of the course was similar to that of the MI group, and the residents were offered a 3-hour debriefing after one month's use of the ERI technique during their internship in a GP practice.

MI training

One week before the training, the residents received a guide summarising vaccination information useful for answering patients' questions about vaccines in adulthood and adolescence. The two MI specialists trained the residents during a 2-day face-to-face workshop about MI's theoretical foundations, its adaptation to vaccination and role-playing exercises. The trained residents then put this approach into practice with their patients during a pilot phase during the following months (May and June 2023). During this time, residents benefitted from a 3-h group debriefing by Gagneur et Berthiaume in order to address their potential difficulties in practicing MI.

Evaluation of the acquisition of ERI/MI specific skills by residents

The residents among the MI group completed the same MISI (Motivational Interviewing Skills in Immunization) questionnaire (Gagneur, Gosselin, et al. 2019) just before the 2-day practice training and again at its end. The MISI is a validated instrument previously used in a similar training program for general medicine residents in France (Mitilian et al. 2022) and among nurses in Quebec (Gagneur, Bergeron, et al. 2019). It assesses three key dimensions of MI (Table A1): 1/knowledge of MI theory and principles (in 6 multiple-choices questions), 2/MI-related self-perceived skills (in 12 6-point Likert scales questions concerning the frequency of some of their discussion behaviors), and 3/self-confidence in using MI (in 7 10-point confidence scales on its general use, application of MI techniques, and perceived self-efficacy)

The residents among the ERI group completed the same ERISI (Emphatic Refutational Interviewing Skills in Immunization) questionnaire in the same conditions as in the MI group. This questionnaire was developed in the WP2 following the same principles as those of the MISI. The ERISI assesses three key dimensions of ERI (Table A2): 1/knowledge of ERI theory and principles (in 5 multiple-choice questions and 1 open-ended question), 2/self-confidence in using ERI (in 7 confidence 10-point scales on its general use, application of MI techniques, and perceived self-efficacy), and 3/perceived difficulties in addressing vaccination counterarguments with patients (in 11 5-point scales).

Impact of ERI/MI training on residents' psychosocial resources regarding vaccination

To measure the impact of the two ERI and MI training courses on the psychosocial skills/resources that encourage vaccination behaviour among healthcare professionals, we used the short international version of the Pro-VC-Be (Professionals-Vaccine Confidence-Behaviors). Residents were asked to complete it just before their training session and about a month afterwards (so as not to overload the work of completing the questionnaires just at the end of each training session). The Pro-VC-Be, initially developed in French and validated in France, Belgium and Quebec with GPs and nurses (Verger et al. 2022), was adapted as part of the Jitsuvax project (WP1) for use in various European countries (Garrison et al. 2023). Its short version uses 10 items to measure the following dimensions of confidence and vaccination behaviour: perception of vaccine safety, perception of their usefulness, perception of the benefit-risk balance of vaccines, collective responsibility, confidence in the health authorities, perception of the constraints of vaccination (cost, access, etc.), commitment to patient vaccination, feeling of self-efficacy in vaccine communication, openness to patients, and default confidence in vaccination. Answers were collected on a 5-point Likert scale, from 1="Strongly disagree" to 5="Strongly agree" with an "Unsure/Neither agree nor disagree" option at the middle of the scale.

Field test among patients

The residents were required to work in a private practice during a 6-month internship: for the residents taking part in the study, this training period began in May 2023. In order to assess the impact of the ERI (or MI) technique on the degree of vaccine readiness and intention to vaccinate among patients, a before-and-after design was implemented with the help of residents who volunteered to take part in the study, divided into three groups: ERI, MI and no training (control group). In the practices that

agreed to take part, the secretaries invited patients in the waiting room to take part in the study, gave them an information document about the study, a consent form and a short questionnaire to complete before the consultation, and collected in a separate file their name and telephone numbers and/or email address. If they consented, participants were contacted by a researcher within the following weeks to complete the same questionnaire. Signed consent forms, anonymous questionnaires completed before consultation, and the separate file with contact information, were collected and centralized by the Department of Family Medicine. The questionnaires were then transmitted to the ORS Paca research department for data entry and analysis.

Questionnaires (pre-post)

They consisted of three parts: 1) measurement of vaccine readiness using the 7C, an instrument validated in French (Geiger et al. 2021); 2) measurement of intention to vaccinate themselves (with a single item using a Likert scale) or their children (same scale); 3) year and month of birth and sex of the patient. In addition, the post questionnaire also included 7 items on the patient's satisfaction with the consultation (6 items) and the name of the vaccine(s) discussed during the consultation (1 item). In order not to limit the number of patients who could be included, any vaccine could be the subject of the consultation.

Similar questionnaires were used at T0 (baseline) and T1 (after training) which both included items to measure:

1) patients' intention to get themselves vaccinated, or have their child vaccinated, against any disease (excluding the COVID-19), when recommended by their doctor; answers were collected with 5-point Likert-scales (Not at all to Absolutely, including a "don't know" answer in the middle of the scale);
2) Patients' general Vaccine Readiness (VR): we used the 7C scale short form (Geiger et al. 2022), validated in French (Geiger et al. 2021) including 7 items measuring 7 dimensions: 1) "confidence" in health authorities to ensure vaccines safety and efficacy; 2) "complacency", i.e. low perception of infectious diseases risks; 3) structural or psychological "constraints" making vaccination difficult or costly; 4) "calculation", i.e. vaccine personal benefits/risks balance perception; 5) "collective responsibility", i.e. willingness to protect others acting collectively; 6) "compliance", i.e. support for sanctioning of unvaccinated people; 7) "conspiracy", i.e. belief in fake news related to vaccination); the 7C uses a five-level agreement Likert scale (1="Strongly disagree" to 5="Strongly agree", with a "don't know" option placed in the middle of the scale). The wording of these items was slightly adapted to enable patients to understand them better.

Finally, the T0 questionnaire included questions on sociodemographic characteristics (gender, age), while the T1 questionnaire included satisfaction questions about the interview course.

Numbers of patients

With a target of around 50 residents in family medicine to be recruited for each condition, we had planned initially that each resident should conduct 3 interviews with patients during the field test ($N_{interviews}$ = 450). A size of 150 patients per group was required to allow us to detect a 15% difference between control and intervention groups, with a statistical power of 80% and alpha of 5%. Because the number of residents who participated in the field test was smaller during the study than expected, we asked them to include at least 10 patients in the study and proposed them an indemnification of 10 Euros for each included patient. Ethical approval

This study was approved by the Aix-Marseille University Ethics Committee (N° 2023-04-13-09).

Statistical analyses

Regarding the evaluation of residents' acquisition of skills

MISI scoring

The MISI scoring is presented in detail in Appendix (Table A1). The total scores obtained for each dimension of the MISI were calculated by summing the responses of the items in that dimension: thus, theoretical totals ranged from 0 to 6 for MI knowledge, from 0 to 12 for MI skills application, and from 7 to 70 for self-confidence in using MI in clinical practice. Each raw total was then linearly transformed to a 0-100 scale, by subtracting from it the observed minimum, dividing the result by the number of items with no missing values, and then multiplying by 100.

The individual score was not calculated for any dimension of the MISI for which 20% or more of the data for its component items were missing.

ERISI scoring

The ERISI scoring is presented in detail in Appendix (Table A2). The total scores obtained for each dimension of the ERISI were calculated by summing the responses of the items in that dimension: thus, theoretical totals ranged from 0 to 7 for ERI knowledge, from 7 to 70 for self-confidence in using ERI in clinical practice, and from 11 to 55 for perceived difficulty to rebut anti-vaccination arguments. Each raw total was then linearly transformed to a 0-100 scale, by subtracting from it the observed minimum, dividing the result by the number of items with no missing values, and then multiplying by 100.

The individual score was not calculated for any dimension of the ERISI for which 20% or more of the data for its component items were missing.

Data analysis

Each key dimension of participant MI/ERI training was analysed separately from the others. Scores before and after the training session were compared in pairs by running exact Wilcoxon-Pratt signed-rank tests. Effect size, reflecting the magnitude of the training session's effect, was calculated for each dimension, by using the Z-score of the signed-rank test as follows: with n the number of paired observations (Tomczak and Tomczak 2014). Calculating effect size makes it possible to neutralize the effects of sample size and score dispersion in considering the strength of the changes: *r* values between 0 and 0.3 reflect small effect sizes, between 0.3 and 0.5 moderate effect sizes, and between 0.5 and 1 large effect sizes.

Regarding the Pro-VC-Be factors, scores were compared between MI and ERI groups separately at T0 then at T2, using Wilcoxon rank-sum tests. Scores before (T0) and after (T2) the training sessions were compared in pairs in each group separately, using Wilcoxon-Pratt signed-rank tests.

Analyses were performed with SAS 9.4 and R 4.1.2, and $P<.05$ indicates statistical significance.

Patients experiment

Outcomes construction

Answers to the vaccination intention (VI) items were dichotomized as follows: "Yes, definitely or probably" vs "don't know, probably not or definitely not". Internal consistency of the 7C was checked with Cronbach's alpha, calculated on the 7 items before intervention. The Cronbach's alpha at T0 was 0.73 when inverting items 4 (calculation) and 7 (conspiracy), as recommended by the authors, because relating negatively to vaccination readiness in their results (Geiger et al. 2022); but in our study, it increased at 0.85 when inverting only item 7 (conspiracy). We thus calculated a cumulative VR score in pre- and post-intervention by summing the 7 items, after reversing only the coding of item 7, and then linearized it from 0 to 100: the higher the score, the higher the VR.

Data analyses

For the descriptive analyses at T0 and T1, we used frequencies and percentages for categorical variables, and means with standard deviations for continuous scores. To implement paired analyses between pre- and post-questionnaires, we used the Bowker symmetry test for categorical variables.

The analyses exploring whether the consultation impact on VI or VR varied according to residents' formation group used difference-in-difference (D-I-D) models. These models allow changes over time (pre/post-intervention) of an outcome to be compared across several groups while taking into account the repeated (T0, T1) and hierarchical (patients level nested into residents level) nature of the data (Gertler et al. 2016; Warton, Parker, and Karter 2016). We applied GEE binomial models for VI (categorical outcomes) and mixed models with random intercepts for the VR score (continuous outcome). The models were adjusted for gender and age and implemented by intention-to-treat (ITT): all patients who agreed to participate and completed the baseline questionnaire were included, with missing post-questionnaire data handled by the D-I-D models without imputation (Twisk et al. 2020). We also run per-protocol (PP) analyses as sensitivity analyses, including only patients who answered both T0 and T1 questionnaires. Analyses used SAS 9.4 (SAS Institute Inc., Cary, NC, USA), with statistical significance set at 0.05.

Findings summary

Residents' acquisition of skills and improvement of general psychosocial resources after ERI/MI training

MI group

Among the MI group, 36 residents completed the MISI before the training (T0): 72% were women and the median [IQR] age was 28 [27;29] years. After the training (T1) 33 (92%) completed this questionnaire again. In addition, 36 and 17 residents completed the I-Pro-VC-Be short form before and after their training respectively. Mean MISI scores significantly increased between T0 and T1 in the 3 key dimensions of the MISI (knowledge acquisition, MI skills application, and self-confidence in using MI) with important effect sizes (0.84, 0.67, 0.82 respectively, Table 10).

Regarding the dimensions of the I-Pro-VC-Be, the perception of vaccines benefits/risks balance, commitment to vaccination and self-efficacy in vaccination communication also significantly improved (Table 11).

Table 10

Comparison of mean scores of each core aspect of MI training between questionnaires completed before and after the training sessions (exact Wilcoxon-Pratt signed-rank tests)

	Score pre-session 1	Score difference between post-session 1 and pre-session 1		
	mean ± SD	mean ± SD	Pr ≥ |Z|	Effect size *r*
Knowledge acquisition (/100) *(n=36,33, respectively)*	52.3 ± 25.3	**36.4 ± 26.0**	**<.0001**	0.84 [0.75;0.88]
Perception of application of MI skills *(/100) (n=35,33, resp.)*	20.8 ± 17.0	**34.0 ± 37.3**	**<.0001**	0.67 [0.44;0.81]
Self-confidence in applying MI *(/100) (n=35, 33, resp.)*	43.7 ± 12.4	**20.0 ± 13.9**	**<.0001**	0.82 [0.69;0.87]

Note. The effect size (r) value varies from 0 to close to 1. Values of *r*: 0.10 - < 0.3 (small effect); 0.30 - < 0.5 (moderate effect); >= 0.5 (large effect). Interpretation: knowledge acquisition score increased by 36 points between post- and pre-session 1; session 1 had a large effect on the change in the score (r=0.84)

Table 11

Mean Pro-VC-Be factors at T0 and T2 in MI and ERI training groups.

Scores from 1=Strongly disagree to 5=Strongly agree with 3=Unsure/Neither agree or disagree – mean (SD)	MI training		ERI training	
	T0 (n=36)	T2 (n=17)	T0 (n=30)	T2 (n=9)
Vaccines are safe.	3.4 (1.0)	3.6 (1.1)	2.9 (1.1)	3.3 (0.7)
Today, some vaccines recommended by [insert relevant authority] are not useful, because the diseases they prevent are not serious.	1.6 (0.6)	1.3 (0.5)	1.4 (0.6)	1.6 (0.7)
The benefits of vaccines outweigh their potential risks.	4.5 (0.5)	4.9 (0.3)*	4.8 (0.4)	4.9 (0.3)
I recommend the vaccines on the vaccination schedule to my patients because it's essential to contribute to protection of the population (community immunity).	4.8 (0.4)	4.9 (0.3)	4.7 (0.5)	4.9 (0.3)
I trust the health ministry to ensure that vaccines are safe.	3.9 (0.8)	4.3 (0.6)	3.9 (1.1)	4.6 (0.5)*
I am committed to ensuring that my patients are vaccinated.	4.1 (0.7)	4.8 (0.4)*	4.5 (0.6)¤	4.8 (0.4)
I feel sufficiently trained on how to bring up the question of vaccines with hesitant patients.	2.6 (0.8)	3.9 (0.7)**	2.4 (0.8)	3.9 (0.9)**
I inform my patients about the benefits and risks of vaccines without trying to influence them.	3.0 (1.0)	3.7 (0.9)	3.1 (1.1)	3.3 (1.1)
The cost of some vaccines is a problem for some patients and can keep me from prescribing them.	2.5 (1.1)	2.2 (1.0)	2.4 (1.2)	1.9 (1.1)
I may sometimes recommend vaccines from the official schedule even if I feel the vaccination policy is not sufficiently clear.	2.9 (1.3)	2.1 (1.5)	3.2 (1.3)	3.2 (1.4)¤

Note. Differences between groups MI and ERI at T0 or at T2: exact Wilcoxon rank-sum tests: ¤p<0.05 ¤¤p<0.01 ¤¤¤ p<0.001. Paired comparisons (evolution between T0 and T2) in each group separately: exact Wilcoxon-Pratt signed-rank tests. p-values are computed among the residents who completed both T0 and T2 questionnaires. * p<0.05 **p<0.01 ***p<0.001

ERI group

Among the ERI group, 30 completed the ERISI before and after the training: 63% were women and the median [IQR] age was 28 [27;28] years. In addition, 30 and only 9 residents completed the I-Pro-VC-Be short form before and after the training respectively. Mean ERISI scores significantly increased significantly improved from before to after training in the 3 key dimensions of this questionnaire (significant increase in the scores of knowledge acquisition, and self-confidence in applying ERI techniques in clinical practice, and significant decrease in perceived difficulties to rebut anti-vaccination arguments, Table 13). Effect sizes were also large especially for the first two 2 dimensions (0.80, 0.85, 0.45 respectively, Table 12).

Regarding the dimensions of the I-Pro-VC-Be, at T0, residents from the ERI training group (n=30) had a slightly higher score of commitment to vaccination than those from the MI group (n=36; 4.5 ± 0.6 *vs* 4.1 ± 0.7, p=0.02); there was no other difference in Pro-VC-Be factors between the two training groups at baseline (Table 14). In the ERI group, trust in authorities and self-efficacy significantly improved after the training (Table 12).

Table 12

Comparison of mean scores of each core aspect of ERI training between questionnaires completed before and after the training sessions (exact Wilcoxon-Pratt signed-rank tests, n=30)

	Score pre-session 1	Score difference between post-session 1 and pre-session 1		
	mean ± SD	mean ± SD	Pr ≥ |Z|	Effect size *r*
Knowledge acquisition (/100)	50.6 ± 20.8	**24.4 ± 19.5**	**<.0001**	0.80 [0.64;0.86]
Self-confidence in applying ERI *(/100)*	51.7 ± 9.0	**17.0 ± 10.2**	**<.0001**	0.85 [0.80;0.87]
Perceived difficulties to rebut anti-vaccination arguments *(/100)*	37.8 ± 16.0	**-8.1 ±14.8**	**0.0052**	0.48 [0.16;0.74]

Note. The effect size (r) value varies from 0 to close to 1. Values of *r*: 0.10 - < 0.3 (small effect); 0.30 - < 0.5 (moderate effect); >= 0.5 (large effect). Interpretation: knowledge acquisition score increased by 24 points between post- and pre-session 1; session 1 had a large effect on the change in the score (r=0.80)

Vaccine readiness and intention to get vaccinated among patients

Among the included patients (n=150), 120 (80%) completed a questionnaire before and after the encounter with a resident. The characteristics of these patients are presented in Appendix (Table A3): their demographic characteristics did not differ between the three groups (MI, ERISI, control) nor did their vaccine readiness and intentions at baseline (T0=before encounter).

Patients' vaccine readiness

Among the whole sample of patients who completed both the pre- and post-questionnaires, the results (Figure 5) indicate a significant change post-encounter only for the disagreement with compliance (punishing unvaccinated people) which increased from 54% to 71% (p=0.004). For the other items, none of the observed changes were significant.

Considering each group separately, the vaccine readiness score increased by +4% in the control group (T0 score: 64/100), +5% in the MI group (T0 score: 67) and +6% in the ERI group (T0 score: 59) without any significant difference of pre-post VR score evolution between the groups according to the D-I-D modelling, both in ITT and PP analyses (Table 13 and, in Appendix, Table A4).

Figure 5

Evolution of the vaccine readiness items (7C scale) among patients (n=150).

Note: P-values for Bowker test of symmetry of proportions (i.e. equivalence of proportions) for paired samples (equivalent of McNemar's test for binary variables). Test run on the sample of participants who answered both questionnaires, refusals excluded. Confidence: I am convinced that the state only authorizes vaccines that are safe and effective. (Lack of) complacency: I get vaccinated because it is too dangerous to get sick from diseases. (Lack of) perceived constraints: Vaccinations are so important to me that I prioritize getting vaccinated over other things. Calculation: I only get vaccinated when I am sure that the benefits are greater than the risks. Collective responsibility: I see vaccination as a responsibility in order to protect others. Compliance: It should be possible to punish people by law if they are not vaccinated. Conspiracy: Vaccines are more dangerous than diseases.

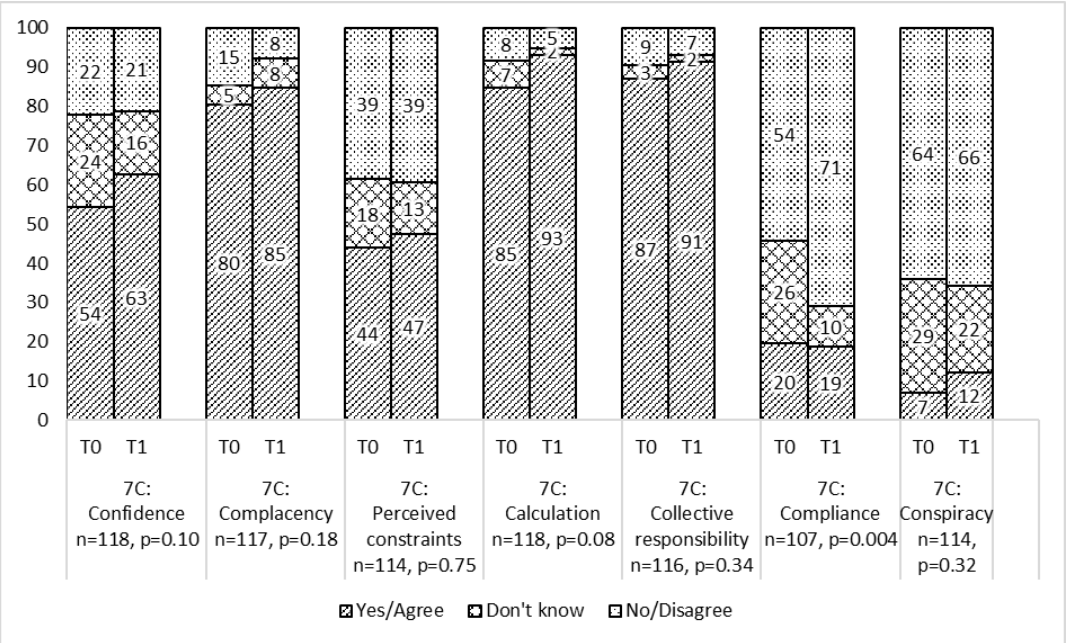


Table 13

Evolution of patients' vaccine readiness and vaccine intention according to the group of residents.

	T0 (BEFORE) % or mean (SD)	T1 (AFTER) % or mean (SD)	Evolution	*p* for ITT D-I-D effect‡
Score of vaccination readiness [0;100] (n=150)				
Group of residents				0.79[a]
Motivational interviewing (n=39;42)	66.8 (20.7)	69.8 (15.7)	+5%	0.89[b]
Refutational interviewing (n=30;30)	58.9 (19.6)	62.6 (17.7)	+6%	0.51[b]
Control (n=51;48)	63.9 (23.7)	66.4 (18.6)	+4%	-
Intention to get themselves vaccinated (n=148, ref. No/Don't know)				
Group of residents				0.10[a]
Motivational interviewing (n=45;44)	60.0	59.1	-2%	0.65[b]
Refutational interviewing (n=34;30)	55.9	40.0	-28%	<.0001[b]
Control (n=63;49)	58.7	61.2	+4%	-
Intention to have their children vaccinated (n=84, ref. No/Don't know)				
Group of residents				0.25[a]
Motivational interviewing (n=27;18)	51.9	66.7	+29%	0.86[b]
Refutational interviewing (n=9;14)	44.4	28.6	-36%	0.07[b]
Control (n=34;17)	61.8	76.5	+24%	-

Note. Abbreviations. D-I-D = difference-in-difference; DTP = diphtheria, tetanus, poliomyelitis

‡ Mixed models with random intercept or GEE binomial regressions testing for magnitudes of the pre-to-post evolution of respectively vaccine readiness or intentions. Models adjusted for age (continuous) and gender. Test for differences in evolution between categories (D-I-D effect)

Lecture: Before the intervention, the score of vaccination readiness was 66.8/100 among the MI group. After the intervention, it was 69.8, an increase of 5%. This evolution was not significantly different from the evolutions estimated in the other groups of residents (p=0.79)

[a] Global p-value for the interaction group (MI, ERI, control) * post-intervention (yes, no)

[b] Specific p-value for the interaction group*post-intervention (ref. control, yes)

Before the intervention, 60% of the MI group patients reported they would get vaccinated if a health care professional recommended a vaccine (covid-19 excluded) to them. After the intervention, they were 59.1% a decrease of -2%. This evolution was not significantly different from the evolutions estimated in the control group (p=0.65), while the decrease in the ERI group (-28%) was significantly higher (p<.0001).

Patients' vaccine intentions

Patients' vaccine intentions for themselves (n = 148) decreased by -2% at T1 (after encounter; T0 score: 60) in the MI group and by -28% in the ERI group (T0 score: 56), a significant difference ($p<10^{-3}$) in pre-post VI score change compared to the control group (T0 score: 59; +4% increase at T1) according to both ITT and PP D.I.D modelling. Patients' vaccine intentions for their children (n=84) increased at T1 by +24% in the control group (T0: 62), and by +29% in the MI group (T0 score: 52), while it decreased by -36% in the ERI group (T0 score: 44): none of these changes were significant (Table 13, and, in Appendix, Table A4-A5).

Of notice, we did not find clear coherence between changes in VI and VR among the 27 ERI patients who completed both T0 and T1 questionnaires: among the 6 patients whose VI for themselves decreased (from "yes" to "don't know"/"no" or from "don't know" to "no"), the VR score decreased for 3 and increased for 3 of them; among the 15 ERI patients whose VI for themselves remained stable, 5 had a decreased VR, 3 had a stable VR and 7 had an increased VR; finally, among the 6 ERI patients

whose VI for themselves increased, the VR score decreased for 2, remained stable for 2 and increased for 2 of them.

Patients' satisfaction

Among the 107 participants who answered the satisfaction items of the T1 questionnaire, 83% reported satisfaction about the encounter with the residents ("somewhat yes": 15%; "yes": 68%); 75% found it useful ("somewhat yes": 23%; "yes": 51%); 75% had no more questions about vaccination afterwards; 86% reported that it had respected their views on vaccination ("somewhat yes": 19%; "yes": 67%) and 87% that its duration was appropriate. They would recommend it in 82% ("somewhat yes": 22%, "yes": 61%) to other patients. These proportions were highest in the MI group with a significant difference between groups found only for the item "respect of patients' view on vaccination" (p = 0.047): 75% felt that residents respected it in the MI group, versus 67% on average in the two others.

Table 14

Patients' satisfaction according to resident group (n = 107).

	Total sample		**MI**		**ERI**		**Control**	
	N=107	**%**	**N=40**	**col. %**	**N=16**	**col. %**	**N=51**	**col. %**
Satisfaction with the discussion with the resident								
Refuse to answer	3	2.8	0	0.0	0	0.0	3	5.9
No	3	2.8	1	2.5	1	6.3	1	2.0
Rather no	1	0.9	0	0.0	1	6.3	0	0.0
Neither no or yes	11	10.3	3	7.5	2	12.5	6	11.8
Rather yes	16	15.0	6	15.0	5	31.3	5	9.8
Yes	73	68.2	30	75.0	7	43.8	36	70.6
p-value[a] : 0.12								
Would you recommend this type of discussion to other patients in consultation?								
Refuse to answer	3	2.8	0	0.0	0	0.0	3	5.9
No	2	1.9	0	0.0	1	6.3	1	2.0
Rather no	2	1.9	0	0.0	1	6.3	1	2.0
Neither no or yes	12	11.2	6	15.0	4	25.0	2	3.9
Rather yes	23	21.5	9	22.5	3	18.8	11	21.6
Yes	65	60.8	25	62.5	7	43.8	33	64.7
p-value[a] : 0.09								
Do you think that the discussion did respect your viewpoint about vaccination?								
Refuse to answer	4	3.7	0	0.0	0	0.0	4	**7.8**
Rather no	3	2.8	1	2.5	2	**12.5**	0	0.0
Neither no or yes	8	7.5	3	7.5	0	0.0	5	9.8
Rather yes	20	18.7	6	15.0	6	**37.5**	8	15.7
Yes	72	67.3	30	**75.0**	8	50.0	34	66.7
p-value[a] : 0.0465								
Did you find the discussion about vaccination with the resident useful?								
Refuse to answer	3	2.8	0	0.0	0	0.0	3	5.9
No	8	7.5	4	10.0	3	18.8	1	2.0
Rather no	3	2.8	1	2.5	0	0.0	2	3.9
Neither no or yes	13	12.2	3	7.5	1	6.3	9	17.7
Rather yes	25	23.4	8	20.0	6	37.5	11	21.6
Yes	55	51.4	24	60.0	6	37.5	25	49.0
p-value[a] : 0.16								

The discussion duration was…								
Refuse to answer	7	6.5	1	2.5	1	6.3	5	9.8
Slightly too long	1	0.9	1	2.5	0	0.0	0	0.0
Neither too long or too short	93	86.9	36	90.0	14	87.5	43	84.3
Slightly too short	2	1.9	1	2.5	1	6.3	0	0.0
Too short	4	3.7	1	2.5	0	0.0	3	5.9
p-value[a] : 0.41								
Following the discussion, do you still have any questions about vaccination?								
Refuse to answer	3	2.8	0	0.0	0	0.0	3	5.9
No	80	74.8	30	75.0	12	75.0	38	74.5
Don't know	1	0.9	0	0.0	0	0.0	1	2.0
Yes	23	21.5	10	25.0	4	25.0	9	17.7
p-value[a] : 0.65								

[a] Fisher tests

Field test in Romania

Organization of primary health care in Romania and role of health-care professionals in vaccination

Romania has a mandatory social health insurance system, where the primary health care services are delivered by the family doctors, who serve as the system's gatekeepers. They are independent/ private providers delivering preventive and curative health services under a contract with the county health insurance houses, based on a mix of capitation and fee for service (around 50% each). Family doctors provide vaccination free of charge, according to the National Immunization Program. Family doctors play a pivotal role in the vaccination process by offering guidance, administering vaccines, monitoring adverse reactions, and assessing vaccine eligibility. Their vaccination efforts are complemented by support from other primary healthcare professionals, including nurses from their practice and community nurses, who provide health education and promote vaccination, mainly in rural areas.

The field test conducted in Romania was a collaboration with the Center for Health Policies and Services (CHPS). For comparison purposes, the design of this field test was very similar to the French study, described in the previous section, although in this case general practitioners instead of residents were recruited. Some of the measures were also adapted due to the time restrictions of the training delivered in Romania. This field test also included semi-structured interviews with participating physicians.

Preregistration

The experimental design, variables, recruitment strategy, inclusion criteria, and sample size calculations of this field test were pre-registered at https://osf.io/p87m3.

Train the trainers

One of our team members, Angelo Fasce, travelled to Bucharest to train Mirela Mustață and Iulia Vișinescu as they could not attend the Coimbra course (the agreement between JITSUVAX and the CHPS was not yet in force at that time). The training session took place at the CHPS headquarters on January 19, 2024, and focused on the conceptual and technical principles of ERI, since both already had extensive previous experience in delivering MI training. The three reviewed all the materials prepared by the CHPS for the training of doctors.

Training of physicians

The inclusion criteria of the physicians for the experimental groups were the following:

1) The respective physician expresses willingness to participate in the training provided as part of the project, to discuss vaccination with his/her patients, and to complete all the outcome measures.
2) The respective physician includes in the intervention nurse employed at his/hers GP practice, with whom to collaborate in the data collection process.
3) That nurse is willing to collect and provide data for the study on patients with whom the respective physician discussed vaccination after the training, during the study period.
4) The respective physicians participate in the 6-hour training.

The inclusion criteria of the physicians for the control group were the following:

1) The respective physician is willing to discuss vaccination with his/her patients.
2) The respective physician includes in the intervention the nurse employed at his/hers GP practice, with whom to collaborate in the data collection process.
3) That nurse is willing to collect and provide data for the study on patients with whom the respective physician discussed vaccination after the training, during the study period.

Thirty pairs of physicians and nurses (with a role in data collection) were recruited through direct messages sent to family medicine practices within the selected county as well as through professional organizations' channels. We excluded physicians who do not have sufficient current vaccination responsibilities. Physicians were recruited through direct messages sent to family medicine practices within the selected county as well as through professional organizations channels. Physicians in the experimental group were offered €250 in exchange for their participation; physicians in the control group were offered €200; and participating nurses were offered €100 in thanks for their contribution.

The training sessions for the physicians assigned to the experimental groups were facilitated by Mirela Mustață with the support of a local GP who also serves as a lecturer at the University of Medicine and Pharmacy of Craiova, who received training in ERI and already possesses a strong background in MI. The two 6-hour courses in ERI and MI took place within the facilities of the University of Medicine and Pharmacy of Craiova, in Dolj county, on January 27th and 28th, 2024, respectively. The initial expectations of having 10 physicians per group were met (i.e., 10 trained in ERI, 10 trained in MI, and 10 who did not receive training for the control group), with a total of 30 nurses collaborating in data collection.

Training content

ERI training

The ERI training delivered to the physicians followed the general guidelines established by the Coimbra course, also reflected in the French field test training and in the materials developed by the Bristol node and implemented in collaboration with the UK NHS. The training included a theoretical module and several role-playing exercises that helped physicians understand the conceptual foundations of ERI and acquire the necessary skills to deploy the intervention. Prior to the training, the project's web-tool was translated into Romanian by the CHPS team, with the technical support of Angelo Fasce. Physicians used this tool during training and its subsequent use was encouraged. The Romanian version of the website can be found at: https://jitsuvax.info/ro/

MI Training

The MI training was built upon training materials previously produced by CHPS in collaboration with Arnaud Gagneur, which was previously used in a similar training program for GPs. The training

materials were updated and were adapted to also reflect the French field test training. The training comprised both theoretical modules and practical role-playing exercises, designed to provide physicians with a deep understanding of the conceptual foundations of MI and equip them with the requisite skills to effectively implement the intervention.

Evaluation of the acquisition of ERI/MI specific skills by physicians

To evaluate the acquisition of ERI and MI specific skills, the GPs completed shortened versions of the ERISI and MISI questionnaires at the beginning of the training and again at its end. Both groups completed the scale on perceived difficulties in addressing vaccination counterarguments with patients, as described in the French field test. To measure the impact of the training courses on the determinants of vaccination behaviour among healthcare professionals, both groups also completed the short international version of the Pro-VC-Be.

At the end of the experiment, we conducted semi-structured interviews with the participating physicians, composed of five fixed questions, with the possibility of following-up if the physician raises an interesting issue they want to share with the researcher:

1. How satisfied were you using the MI/ERI/discussing vaccination with your patients?
2. What kind of difficulties and advantages did you encounter?
3. How confident and comfortable were you when applying MI/ERI/discussing vaccination with your patients?
4. How did the patients react to MI/ERI/when discussing vaccination?
5. How do you think MI/ERI/your current skills to discuss vaccination with your patients can be improved to better fit the needs of patients and HCPs?

We encouraged physicians to use real examples in their responses, always maintaining the anonymity of patients.

The interviews were conducted and analysed by Dr. Alexandra Deliu. Dr. Deliu completed her PhD in Sociology in 2015 at the University of Bucharest, with a thesis focused on identity construction in migration. In 2014, she became a member of the research team at the Research Institute for Quality of Life. Her work experience consists of both scientific and consultancy projects for international organisations such as UNICEF, UNHCR or The World Bank. A report of the main outcomes of this qualitative analysis will be delivered by Dr. Deliu in English to the rest of the team.

Impact of ERI/MI training on physicians' psychosocial resources regarding vaccination

The effectiveness of training in MI or ERI was assessed by examining the outcomes of physician-patient interactions. Physicians conducted semi-directive interviews focused on the vaccines against HPV or influenza, with a minimum of 10 patients who were hesitant to receive a vaccination (data collected between February 12 and May 16, 2024). The pre-consultation questionnaire for patients included a Romanian version of the 7C scale for vaccination readiness (Geiger et al., 2021) and initial willingness to get vaccinated. The post-consultation questionnaire included, besides the 7C scale and the same question on willingness to get vaccinated, a question asking if the patient scheduled an appointment to get vaccinated and 6 questions to assess satisfaction with the interaction with the physician. Comparisons of the patients' evaluations between the pre and post phase serve to evaluate the effects of ERI, MI, and the control group (with no training).

Field test among patients

In this field experiment, physicians conducted semi-directive interviews with a minimum of 10 patients who were hesitant to receive a vaccination. Comparisons of the patients' evaluations between the pre

and post phase serve to evaluate that empathetic refutational interviewing and motivational interviewing have a stronger effect on interpersonal communication than the baseline condition. Furthermore, comparisons of the patients' evaluations between the empathic refutational interviewing and the motivational interviewing serve as the evaluation criteria for different effects on interpersonal communication—that is, one or the other could be effective for some aspects of the outcome measures. Perceptions of healthcare professionals, which are obtained through semi-structured interviews, reveal how useful the approaches are perceived by active practitioners.

Number of patients

Sample size calculations for the group comparisons in the main outcome variables were performed to estimate a minimal desirable size of patients of 252. This minimum sample size was exceeded in the study, as the groups had a minimum of 102 patients, with a final sample of 334 patients (105 in the ERI group, 126 in the MI group, and 102 in the control group).

Results

The questionnaires sent by the nurses by email or postal service were manually processed by Angelo Fasce to obtain an Excel spreadsheet used to conduct data analyses in SPSS (v. 27).

Results of the training among physicians

We conducted a series of paired samples t-tests to evaluate the outcomes of the training sessions in ERI and MI. Table 15 displays the pre-training and post-training comparisons on the Pro-VC-Be, ERISI, MISI, and difficulties to address anti-vaccination arguments. The analyses indicate that both training sessions produced significant positive changes in knowledge about the respective technique (and in related behaviors, in the case of MI). However, observed differential effects were also observable in proactive efficacy and difficulties to address arguments, as only physicians in the ERI group increased their self-efficacy and commitment to vaccination, and increased their confidence in refuting arguments during consultations.

To further explore intergroup differences between ERI and MI, we conducted independent samples t-tests on the post-training measures of the following comparable variables of interest: confidence in vaccines, proactive efficacy, difficulties to address arguments, and perceived competence in the trained technique (see Table 16). The results suggest that the ERI group finished the training with lower levels of perceived difficulty for addressing anti-vaccination arguments and a greater perception of competence in the trained technique compared to the MI group. Even though the effect size in proactive efficacy is large (Hedges' $g > 0.8$), the difference is not statistically significant ($p = 0.06$), which could be attributable to the small sample size.

Table 15
Paired samples t-test between the pre-test and the post-test of the training sessions.

	ERI				MI			
	Pre-test M (SD)	*Post-test M (SD)*	*t*	Hedges' *g*	*Pre-test M (SD)*	*Post-test M (SD)*	*t*	Hedges' *g*
Confidence in vaccines	4.08 (0.33)	4 (0)	0.709	0.215	3.95 (0.37)	4.1 (0.32)	-1.406	-0.426
Proactive efficacy	4.5 (0.24)	4.85 (0.24)	**-4.583*** **	-1.388	4.35 (0.24)	4.6 (0.32)	-2.236	-0.677
Trust in authorities	4.8 (0.42)	5 (0)	-1.50	-0.454	5 (0)	5 (0)	-	-
Openness to patients	4.3 (0.95)	4.7 (0.48)	-1.809	-0.548	3.6 (1.74)	4.1 (1.20)	-1.342	-0.406
Perceived constraints	2.50 (1.43)	2 (1.41)	1.103	0.334	2.7 (1.7)	2.5 (1.27)	0.688	0.208
Reluctant trust	3.11 (1.15)	3.67 (1.66)	-1.644	-0.522	3.7 /1.34)	2.9 (1.85)	1.309	0.397
Knowledge about the technique	8.7 (2.26)	13.1 (1.29)	**-6.41*** **	-1.941	4.1 (1.1)	7.1 (1.60)	**-5.031*** **	-1.524
Behaviors related to the technique	-	-	**-**	-	3.88 (0.66)	4.64 (0.51)	**-3.389** **	-1.026
Difficulties to address arguments	2.33 (0.6)	1.45 (0.38)	**3.639** **	1.102	2.53 (0.69)	2.29 (0.92)	0.89	0.27

Note. Significant differences in bold. * $p < .05$, ** $p < .01$, *** $p < .001$

Table 16

Independent samples t-test between the post-test of the training sessions in comparable variables of interest.

	ERI M (SD)	*MI M (SD)*	*t*	Hedges' *g*
Confidence in vaccines	4.00 (0)	4.10 (0.32)	-1.000	-0.428
Proactive efficacy	4.85 (0.22)	4.60 (0.32)	1.987	0.851
Difficulties to address arguments	1.45 (0.38)	2.29 (0.92)	**-2.647***	-1.134
Perceived competence in the technique	9.47 (0.4)	7.90 (1.7)	**2.626***	1.211

Note. Significant differences in bold. * $p < .05$, ** $p < .01$, *** $p < .001$

Differences in attitudes toward vaccines and willingness to get vaccinated

We conducted a repeated measures analysis of variance to assess the differences within and between subjects in the two variables with pre and post measures. Table 17 displays the results of the analysis for attitudes toward vaccines (i.e., 7C scale), with a graphical representation in Figure 6. Strong increases in positive attitudes towards vaccines were observed between the pre-test and the post-test measures of both experimental groups: ERI = 31.03% and MI = 20.09% (5.14% in the control group). This analysis revealed significant differences in the baseline of the three groups, so that raw comparisons between groups in the post-test measure are not guaranteed by randomization (i.e., despite ERI having the strongest impact within subjects, the post-test mean of this group remains lower than those of the MI and control groups because patients in the ERI group were particularly hesitant and, therefore, the intervention departed from worse attitudes toward vaccines).

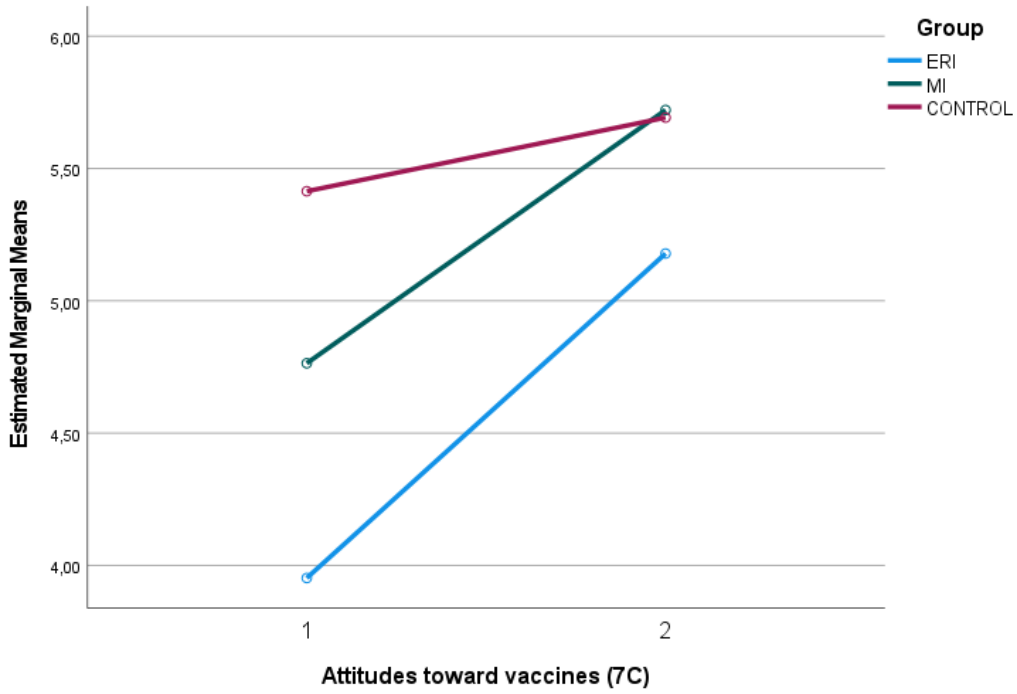
Table 17

Repeated measures analysis of variance and pairwise comparisons test for differences within and between groups in the 7C scale.

Within groups	Between groups	Pairwise comparison	Mean difference	*p*
F (2, 331) = 26.063, $p <$ .001	F (2, 331) = 21.727, $p < .001$	ERI-MI	-0.677	< .001
		ERI-CONTROL	-0.988	< .001
		MI-CONTROL	-0.311	> .05

Note. p-values corrected using the Bonferroni method.

Figure 6.
Mean of attitude towards vaccines in dependence of intervention group.



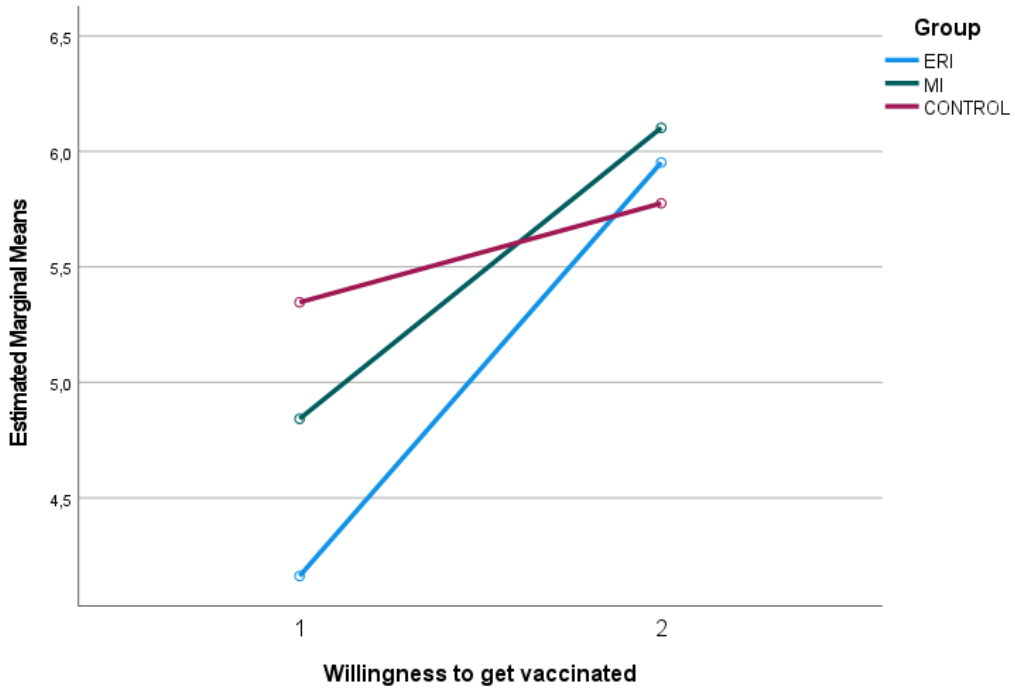
A similar repeated measures analysis of variance was conducted to calculate the differences in willingness to get vaccinated (see Table 18 and Figure 7), also resulting in strong increases in both experimental groups in the pre-test and post-test measures: ERI = 43.03% and MI = 26.03% (8.04% in the control group). Once again, we observed significant differences in the baseline of the three groups, which will be addressed in the following subsection.

Table 18
Repeated measures analysis of variance and pairwise comparisons test for differences within and between groups in willingness to get vaccinated.

Within groups	Between groups	Pairwise comparison	Mean difference	*p*
F (2, 327) = 21.113, *p* < .001	F (2, 331) = 3.407, *p* < .05	ERI-MI	-0.415	> .05
		ERI-CONTROL	-0.504	< .05
		MI-CONTROL	-0.089	> .05

Note. P-values corrected using the Bonferroni method.

Figure 7.
Mean of willingness to get vaccinated in dependence of intervention group.



Covariance analysis for willingness to get vaccinated

To address the baseline differences between groups, we conducted another repeated measures analysis of variance with willingness to get vaccinated as the dependent variable, but this time we used the pre-test measure of the 7C scale as a control covariate. As can be seen in Figure 8, the baselines became homogeneous after controlling for patients' initial attitudes toward vaccines, without significant differences, which makes the adjusted means of the post-test measure comparable across groups. This analytical context boosted the differences of ERI and MI with the control group based on the greater slope of the within group differences in both experimental groups. As a result, substantial increases were observed again in relation to the pre-test (ERI = 30.59% and MI = 27%; 15% for the control group), as well as higher adjusted means compared to the control group in the post-test (ERI = 19,85% and MI = 13.32%; see Table 19).

Figure 8.

Mean of willingness to get vaccinated in dependence of intervention group and controlled for pre-test measures

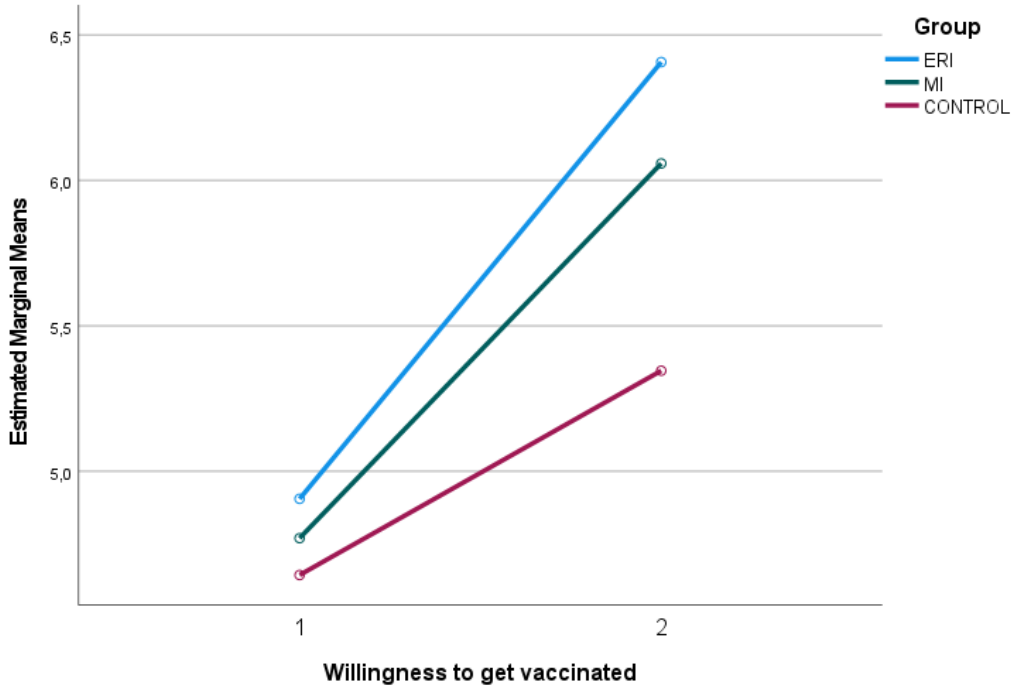


Table 19

Repeated measures analysis of variance and pairwise comparisons test for differences within and between groups in willingness to get vaccinated, with the 7C as a control covariate.

Within groups	Between groups	Pairwise comparison	Mean difference	*p*
F (2, 326) = 7.359, *p* < .001	F (2, 326) = 13.464, *p* < .001	ERI-MI	0.348	> .05
		ERI-CONTROL	1.061	< .001
		MI-CONTROL	0.712	< .001

Note: *p*-values corrected using the Bonferroni method.

Differences between groups in satisfaction, doubts, and vaccination appointments

As can be seen from Table 20, the results of a series of univariate analyses of variance with the 7C as a control covariate for differences between the outcome variables that were only measured in the post-test resulted in significant differences in scheduling an appointment to get vaccinated, with patients assigned to both the ERI and MI group scheduling more appointments than those in the control group (20.86% and 19.92% more, respectively). Also, and despite the more confrontational nature of ERI, there are no differences in satisfaction with the interaction with the physician.

Table 20

Univariate analyses of variance for differences between groups in satisfaction, doubts, and appointment, with the 7C as a control covariate.

Variable	Between groups	Pairwise comparison	Mean difference	*p*
Satisfaction	F (2, 329) = 1.508, *p* > .05	ERI-MI	0.057	> .05
		ERI-CONTROL	0.141	> .05
		MI-CONTROL	0.084	> .05
Doubts	F (2, 223) = 3.020, *p* > .05	ERI-MI	-0.084	> .05
		ERI-CONTROL	0.032	> .05
		MI-CONTROL	0.116	< .05
Appointment	F (2, 313) = 14.395, *p* < .001	ERI-MI	0.014	> .05
		ERI-CONTROL	0.309	< .001
		MI-CONTROL	0.295	< .001

Note. P-values corrected using the Bonferroni method.

Concluding remarks

The training of physicians led to good results in France and Romania, comparable for MI to previous studies in France and Quebec (Gagneur, Bergeron, et al. 2019). The effects in knowledge acquisition were similar between MI and ERI, although interesting differences emerged among the outcome measures of the Romanian training, with physicians assigned to the ERI training exhibiting lower levels of perceived difficulty for addressing anti-vaccination arguments and a greater perception of competence in the trained technique compared to their counterparts in the MI group. Moreover, the ERI training produced a greater increase in proactive efficacy (i.e., commitment to vaccination and self-efficacy).

Strong positive effects among patients were also observed in the Romanian experiment, with significant increases of 43.03% (ERI) and 26.03% (MI) in willingness to get vaccinated, and of 31.03% (ERI) and 20.09% (MI) in positive attitudes toward vaccines. Moreover, we found significant intergroup differences in the outcome variables compared to the control group, which indicates that ERI constitutes a promising technique to address vaccine hesitancy in face-to-face interactions between patients and physicians. Moreover, despite the more confrontational nature of ERI, no differences were observed in satisfaction with the interaction with the physician, and vaccination appointments increased by 20.86% (ERI) and 19.92% (MI) compared to the control group.

In contrast, the French field test resulted in small non-significant increases in vaccine readiness score (ERI group: 6%; MI group: 5%; Control: 4%). The general picture provided by these results are in line with previous studies in France with a similar design among patients:

- Health mediators using MI during an outreach approach: 6% increase of the vaccine readiness score (7C) among socioeconomically disadvantaged adults after the encounter with a health mediator (Cogordan et al. 2023);
- Midwifes at maternities, using MI after birth, about childhood vaccination: 33% decrease of vaccine hesitancy immediately after the encounter, also observed at follow-up at 7 months (Verger et al. 2023).

Additionally, the results of the large-scale experiment indicated that watching short interactions using an empathic communication technique (ERI, MI) increased patients' vaccination intentions and strengthened their trust in the doctor. This suggests the usefulness of such empathy-based techniques

in conversations with vaccine hesitant patients and indicates that ERI is at least as effective as MI. Further, the results strengthen previous evidence showing that the novel ERI is a promising intervention in promoting informed vaccination decisions.

One of the main limitations encountered by the French node were the limited numbers of participating residents and patients compared to expectations. Some of the reasons for this situation are: (1) high workload for the residents arriving in their new internship at a doctor's practice because of their new position as quasi-autonomous practitioners in their prescribing, and (2) few vaccination consultations and reduced consultation time devoted to vaccination when this subject was discussed in addition to the reasons for consultation. Given their arrival in a new internship with high workload and stress, it is possible that the residents were not able to immediately put into practice the skills and knowledge acquired during the ERI/MI training courses. Despite these limitations, the French results are surprising in view of the efforts invested in training the two groups of residents and probably reflect insufficient practice of the two techniques studied (ERI and MI) immediately after the trainings.

Regarding MI, the literature indicates that isolated training would not enable the learning acquired to be integrated into everyday practice (Walters et al. 2005). The addition of feedback and supervision are necessary to foster the acquisition of the ability to use MI (Miller et al. 2004). Training health professionals in MI therefore represents a significant investment of time, which may not be compatible with their availability, and represents a challenge if we wish to train a large number of professionals. This is why, in the EMMIE programme in Quebec, the Ministry of Health opted instead to train vaccination advisers, who then use MI on a regular and frequent basis. Initial training remains an interesting option, if supervision is possible, and if students have the opportunity to apply this technique with patients, in the field of vaccination (as well as in other fields). In any case, the MI technique can only be truly effective as long as the professionals have a good mastery of the "content" (i.e. in this case, solid, regularly updated knowledge of vaccination).

In addition, we observed a decrease of the intention to vaccinate in the French ERI group, the reasons for which are unclear. One hypothesis could be that some residents would have concentrated on the task of refutation itself and were not successful in establishing a relationship of empathy with their patients, which could have led to some reactance. At this stage, it is difficult to draw firm conclusions, given the limited number of patients in the ERI group recruited for the French experiment. However, the very positive results obtained in Romania, where a similar quantitative study was implemented with experienced GPs, indicated that further research is needed to better understand the differences between both countries and experimental protocols. We hope to address this issue in the short term through the training of a second promotion of French residents. In this regard, a new wave of patient inclusions was initiated in January 2024.

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Appendix – French node

Table A1

MISI scoring

Dimensions	Type of question	Coding
MI knowledge acquisition	6 multiple-choice questions	1 point for each correct answer and 0 for any wrong answers.
MI skills application[a]	12 items based on 6-point Likert frequency scales	For MI-consistent behaviours, only the two highest category responses ("Frequently" and "Extremely") were attributed 1 point For MI-inconsistent behaviours, only the lowest category response ("Not at all") was attributed 1 point.
Self-confidence in using MI in clinical practice	7 items based on 10-point Likert-scale	Coded according to the number of points scored

"Don't know" answers and refusals were considered as missing values.

Table A2

ERISI scoring

Dimensions	Type of question	Coding
ERI knowledge acquisition	5 multiple-choice questions and 1 open-response question	Regarding the multiple-choice question about attitudinal roots: ratio between 0 and 1: (Number of correct selected roots – Number of wrong selected roots)/11 correct selected roots Other 4 multiple-choice questions: 1 point for each correct answer and 0 for any wrong answers. Open-response question: 1 point for one of the possible attitudinal roots cited, 1 point for sensible explanation given, 0 otherwise
Self-confidence in using ERI in clinical practice	7 items based on 10-point Likert-scale	Coded according to the number of points scored
Perceived difficulty to rebute anti-vaccination arguments	11 items based on 5-point Likert-scale	Coded according to the number of points scored

"Don't know" answers and refusals were considered as missing values.

Table A3

Sociodemographic characteristics and vaccine readiness and intention of patients at baseline, according to the resident group (n=150)

	All		Resident group						P[a]
			Motivationnal interviewing		Empathic refutational interviewing		Control		
	N=150	%	N=51	col. %	N=35	col. %	N=64	col. %	
Questionnaires completed									0.05
T0+T1	120	80.0	39	76.5	30	85.7	51	79.7	
T1 only	5	3.3	5	9.8	0	0.0	0	0.0	
T0 only	25	16.7	7	13.7	5	14.3	13	20.3	
Gender									0.07
Men	50	33.3	19	37.3	6	17.1	25	39.1	
Women	100	66.7	32	62.8	29	82.9	39	60.9	
Age [19;86] – *mean (SD)*	149	51.5 (18.0)	51	52.4 (18.1)	34	50.4 (19.6)	64	51.3 (17.4)	0.88
Vaccine readiness at T0									
Confidence: I am convinced that the state only authorizes vaccines that are safe and effective.									0.67
Refuse to answer	6	4.1	2	4.3	0	0.0	4	6.3	
Strongly agree	35	24.0	15	31.9	6	17.1	14	21.9	
Somewhat agree	40	27.4	14	29.8	10	28.6	16	25.0	
Don’t know	35	24.0	10	21.3	11	31.4	14	21.9	
Somewhat disagree	18	12.3	4	8.5	4	11.4	10	15.6	
Strongly disagree	12	8.2	2	4.3	4	11.4	6	9.4	
(Lack of) complacency: I get vaccinated because it is too dangerous to get sick from diseases.									0.97
Refuse to answer	8	5.5	3	6.4	1	2.9	4	6.3	
Strongly agree	53	36.3	17	36.2	11	31.4	25	39.1	
Somewhat agree	56	38.4	18	38.3	13	37.1	25	39.1	
Don’t know	8	5.5	3	6.4	3	8.6	2	3.1	

Somewhat disagree	15	10.3	4	8.5	5	14.3	6	9.4	
Strongly disagree	6	4.1	2	4.3	2	5.7	2	3.1	
(Lack of) perceived constraints: Vaccinations are so important to me that I prioritize getting vaccinated over other things.									0.89
Refuse to answer	7	4.8	3	6.4	1	2.9	3	4.7	
Strongly agree	21	14.4	7	14.9	3	8.6	11	17.2	
Somewhat agree	39	26.7	13	27.7	9	25.7	17	26.6	
Don't know	22	15.1	7	14.9	4	11.4	11	17.2	
Somewhat disagree	30	20.6	8	17.0	11	31.4	11	17.2	
Strongly disagree	27	18.5	9	19.2	7	20.0	11	17.2	
Calculation: I only get vaccinated when I am sure that the benefits are greater than the risks.									0.07
Refuse to answer	2	1.4	2	4.3	0	0.0	0	0.0	
Strongly agree	58	39.7	19	40.4	10	28.6	29	45.3	
Somewhat agree	62	42.5	23	48.9	16	45.7	23	35.9	
Don't know	9	6.2	3	6.4	2	5.7	4	6.3	
Somewhat disagree	6	4.1	0	0.0	2	5.7	4	6.3	
Strongly disagree	9	6.2	0	0.0	5	14.3	4	6.3	
Collective responsibility: I see vaccination as a responsibility in order to protect others.									0.37
Refuse to answer	6	4.1	2	4.3	2	5.7	2	3.1	
Strongly agree	71	48.6	26	55.3	13	37.1	32	50.0	
Somewhat agree	46	31.5	11	23.4	16	45.7	19	29.7	
Don't know	8	5.5	3	6.4	0	0.0	5	7.8	
Somewhat disagree	6	4.1	3	6.4	2	5.7	1	1.6	
Strongly disagree	9	6.2	2	4.3	2	5.7	5	7.8	
Compliance: It should be possible to punish people by law if they are not vaccinated.									0.32
Refuse to answer	16	11.0	6	12.8	1	2.9	9	14.1	
Strongly agree	13	8.9	3	6.4	2	5.7	8	12.5	
Somewhat agree	14	9.6	3	6.4	5	14.3	6	9.4	

Don’t know	29	19.9	13	27.7	6	17.1	10	15.6	
Somewhat disagree	21	14.4	5	10.6	9	25.7	7	10.9	
Strongly disagree	53	36.3	17	36.2	12	34.3	24	37.5	
Conspiracy: Vaccines are more dangerous than diseases.									0.76
Refuse to answer	9	6.2	4	8.5	2	5.7	3	4.7	
Strongly agree	2	1.4	0	0.0	0	0.0	2	3.1	
Somewhat agree	9	6.2	2	4.3	2	5.7	5	7.8	
Don’t know	47	32.2	12	25.5	11	31.4	24	37.5	
Somewhat disagree	31	21.2	10	21.3	10	28.6	11	17.2	
Strongly disagree	48	32.9	19	40.4	10	28.6	19	29.7	
Vaccine readiness score at T0 [0 ;100] – *mean (SD)*	120	63.6 (21.8)	39	66.8 (20.7)	30	58.9 (19.6)	51	63.9 (23.7)	0.33
If today, a health care professional recommended you a vaccine (COVID-19 excluded), would you accept to get yourself vaccinated?									0.86
Refuse t answer	4	2.7	2	4.3	1	2.9	1	1.6	
Don’t know	44	30.1	14	29.8	11	31.4	19	29.7	
Totally yes	36	24.7	13	27.7	8	22.9	15	23.4	
Rather yes	47	32.2	14	29.8	11	31.4	22	34.4	
Rather no	5	3.4	1	2.1	3	8.6	1	1.6	
Totally no	10	6.9	3	6.4	1	2.9	6	9.4	
If today, a health care professional recommended you a vaccine (COVID-19 excluded), would you accept to get your child (<18 years ld) vaccinated?									0.35
Refuse t answer	8	5.5	2	4.3	2	5.7	4	6.3	
Don’t know	22	15.1	9	19.2	4	11.4	9	14.1	
Totally yes	15	10.3	6	12.8	2	5.7	7	10.9	
Rather yes	24	16.4	8	17.0	2	5.7	14	21.9	
Rather no	1	0.7	1	2.1	0	0.0	0	0.0	
Totally no	8	5.5	3	6.4	1	2.9	4	6.3	
No child <18 years old	68	46.6	18	38.3	24	68.6	26	40.6	

[a] Chi² or Fisher tests for categorical variables, ANOVA for continuous variables

Table A4

Modelling of overall difference in the pre-post patients' vaccine readiness score changes, in ITT and PP analyses: results from mixed models with random intercepts

	ITT (n=149, 17)	PP (n=99,16)
	aβ [95% CI]	
Intercept (reference situation)	48.7 [36.9;60.5]	49.4 [35.1;63.7]
Post-intervention period (ref. Pre-intervention)	0.8 [-2.6;4.2]	0.5 [-3.0;4.0]
Group (ref. control)		
MI-based intervention	2.6 [-5.2;10.3]	2.6 [-8.0;13.2]
ERI intervention	-6.7 [-15.5;2.1]	-4.9 [-16.0;6.1]
Net difference in pre-post change (ref. pre-intervention and control group)		
MI-based intervention, post	0.4 [-4.8;5.5]	0.4 [-4.9;5.7]
ERI intervention, post	1.8 [-3.6;7.3]	1.9 [-3.7;7.4]
Age (continuous)	**0.3 [0.1;0.4]**	**0.3 [0.1;0.5]**
Women (ref. Men)	2.6 [-4.2;9.3]	1.6 [-6.5;9.6]

Reading: In ITT, the VR score increased slightly but non significantly by +0.8 points (95% confidence interval: [-2.6;4.2]) after consultation in the control group, compared to T0. Patients in the MI group had a non-significantly higher initial VR score at T0 (2.6 [-5.2;10.3]) than those in the control group, while those in the ERI group had a non-significantly lower initial VR score (-6.7 [-15.5;2.1]). The net impact of the MI intervention on the change in VR scores (MI*post) was not significant (+0.4 points [-4.8;5.5]); nor was the net impact of the ERI intervention (ERI*post: +1.8 [-3.6;7.3]). Similar results were found in PP analyses.

Table A5

Modelling of overall difference in the pre-post patients' vaccine intention changes, in ITT and PP analyses: results from GEE binomial models

	Themselves		Their children	
	ITT (n=148, 17)	PP (n=99,16)	ITT (n=84, 17)	PP (n=35,14)
	aβ [95% CI]			
Intercept (reference situation)	0.2 [0.0;0.4]	0.3 [0.1;0.5]	0.0 [0.0;0.0]	0.5 [-0.7;1.6]
Post-intervention period (ref. Pre-intervention)	0.0 [0.0;0.1]	0.0 [-0.1;0.1]	0.3 [-0.1;0.7]	0.0 [-0.1;0.2]
Group (ref. control)				
MI-based intervention	0.0 [-0.1;0.1]	0.0 [-0.1;0.2]	0.0 [0.0;0.0]	-0.1 [-0.5;0.3]
ERI intervention	0.0 [-0.2;0.1]	0.0 [-0.2;0.2]	-0.1 [-0.3;0.2]	-0.2 [-0.6;0.2]
Net difference in pre-post change (ref. pre-intervention and control group)				
MI-based intervention, post	0.0 [-0.2;0.1]	0.0 [-0.2;0.2]	0.0 [0.0;0.0]	0.0 [-0.3;0.2]
ERI intervention, post	**-0.2 [-0.3;-0.1]**	**-0.2 [-0.4;-0.1]**	0.0 [-0.3;0.2]	0.1 [-0.2;0.4]
Age (continuous)	**0.01 [0.002;0.01]**	**0.005 [0.001;0.01]**	0.0 [0.0;0.0]	0.0 [0.0;0.0]
Women (ref. Men)	0.1 [0.0;0.3]	0.1 [0.0;0.3]	0.0 [0.0;0.0]	0.1 [-0.3;0.5]