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Effects of an online tailored decision aid to promote informed decision making about maternal pertussis vaccination in the Netherlands: A randomized controlled trial

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A B S T R A C T

Introduction: In 2019, maternal pertussis vaccination (MPV) during pregnancy was introduced in the Netherlands. New interventions to promote informed decision making (IDM) about vaccinations are highly needed, especially for new vaccinations. Decision aids (DAs) have the potential to support IDM. This study evaluates the effects of an online DA on IDM and MPV uptake.

Methods: Pregnant individuals, recruited for the randomized controlled trial (RCT), who gave informed consent (N = 1,236) were randomly assigned to the control (N = 650; no information) or intervention condition (N = 586; DA at 18 weeks pregnancy). MPV uptake and IDM were primary outcomes, decisional certainty and psychological determinants of MPV uptake were secondary outcomes. Measures were taken at 18 weeks of pregnancy (baseline) and at 20 weeks of pregnancy (post-test); intervention use was logged. Data were analysed using intention-to-treat analyses, logistic regression, and linear mixed regression models.

Results: Uptake of MPV was high in our sample (92.3 %). No significant effect of the DA condition on MPV uptake was found compared to the control condition. We found that the DA increased IDM ($\beta = 0.24$, $p < .004$) and one of its components level of knowledge about MPV ($\beta = 0.31$, $p < .004$). We also found an increase in decisional certainty ($\beta = 0.24$, $p < .004$), perceived susceptibility ($\beta = 0.24$, $p < .004$), severity of pertussis ($\beta = 0.41$, $p < .004$), and positive affect about MPV ($\beta = 0.15$, $p < .004$). There was a positive association between dose of the intervention and MPV uptake ($\beta = 0.05$, $p < .004$).

Discussion: The DA seemed effective in promoting IDM about and determinants of MPV uptake. No main effect was found on MPV uptake, but MPV uptake was related to the level of exposure to the DA. People with high intentions towards MPV were overrepresented in the sample. However, effects on IDM were consistent among participants with different levels of MPV intention at baseline.

1. Introduction

Pertussis, commonly known as whooping cough, is ranked as the 9th leading cause of death and disability among children aged 0–9 in 2019 globally. Reported cases of pertussis stand at around 150,000 per year globally, but actual cases are estimated to be much higher [1,2]. In the Netherlands, from 2015 onwards, incidence rates of pertussis cases were close to 30 per 100,000, and reached 36 in 2019 [3]. In December 2019, maternal immunisation during pregnancy (i.e., 'maternal pertussis vaccination' or MPV) with the TDaP vaccine, containing Tetanus, Diphtheria an acellular pertussis, was introduced in the National Immunisation Programme (NIP) in the Netherlands to protect infants from pertussis in their first months of life, by providing passive immunity to the baby via transplacental transport of antibodies [4]. Currently, the obstetric care provider informs pregnant individuals about the possibility of getting MPV and provides them with an information leaflet and invitation letter. The pregnant woman can make an appointment at the Preventive Child and Youth Healthcare Services, where the MPV consists of one injection and is administered free of charge at 22 weeks of pregnancy.

Upon introduction in 2019, uptake of MPV in the Netherlands was a suboptimal 70 % in 2020 [5]. Getting MPV is a voluntary decision. Hesitancy about vaccination decisions, meaning a level of indecisiveness [6], leads to lower uptake of vaccinations [7]. Therefore, it is important to facilitate informed decision making (IDM) regarding MPV, because an informed decision ensures that the patient's choice is in line with their values, helps to avoid future feelings of regret, and makes people less prone to misinformation [8,9]. Furthermore, informed choice is preferred by people deciding about MPV, wanting to have sufficient information [10,11] and deliberating what the information means for them personally [12]. IDM has been defined as: "a decision that is based on relevant knowledge, consistent with the decision-maker's values and behaviourally implemented" [9,13]. Both refusing or accepting a vaccination can be an informed decision.

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We have developed an online, tailored decision aid to promote IDM about MPV. A decision aid is a tool aimed at preparing people to make a (medical) decision, complementary to and not as a replacement of an interaction with a health-care professional. In line with the IPDAS international guidelines for DA's, the DA stated the decision that needs to be made and the options to choose from. It contained evidence-based information about the related health condition(s), the options and the associated risks and benefits. Furthermore, it aimed to provide insight in the values related to decision and the options to choose from [14].

In the context of screening, compared to usual care, decision aids have shown to result in greater knowledge among users, lower decisional conflict, fewer people who were passive in the decision making, and fewer people who still felt undecided after already having made the decision [15]. In the context of vaccination, few studies are available. So far, these studies have shown that decision aids potentially decrease IDM and decrease decisional conflict and hesitancy. However, the effects on uptake of MPV are inconclusive [16,17].

The aim of this randomised controlled trial (RCT) is to evaluate the effectiveness and dose-outcome relationship of the decision aid compared to usual care on IDM and MPV uptake (primary outcomes), decisional certainty, and determinants of MPV uptake targeted in the intervention (secondary outcomes). We hypothesise that IDM and MPV uptake will be higher among participants in the intervention condition compared to those in the control condition, and we expect positive effects of the intervention on the secondary outcomes as well.

2. Methods

2.1. Design

This study is an RCT with two conditions: a control condition (receiving no additional information in addition apart from usual care) and an intervention condition (additionally receiving an online tailored decision aid at 18 weeks of pregnancy). The study has received ethical approval from the TNO institutional review board of human research (reference number 2018-01). The RCT was registered at https://trialsearch.who.int/Trial2.aspx?TrialID=NL8811. The study was conducted online from November 2020 until April 2022.

2.2. Participants

The target population for this study was pregnant individuals in the Netherlands with a command of the Dutch language. Initially, we planned to recruit participants through midwifery practices. The midwife informed potential participants before or at 17 weeks of pregnancy and provided them with an information sheet. Participants could then register via a website link. We recruited a total of 62 midwifery practices, but due to COVID-19 measures, the enrolment was lower than expected and required significant effort from the midwifes, partly due to online consults with pregnant clients. Therefore, we decided to additionally recruit participants via social media advertisements (Facebook and Instagram). Pregnant individuals could participate if they were less than 18 weeks pregnant and resided in the Netherlands.

2.3. A priori power calculation

To detect a 10 % difference in vaccination uptake with 90 % power and a two-sided alpha of 0.05, and expecting a 10 % drop-out, a minimum of 444 participants per condition was needed at baseline. We used an expected 10 % point difference in MPV uptake because we anticipated that the uptake of 70 % in 2020 could be improved (to 80 %) [18].

2.4. Procedure

Participants could enrol in the study if they were less than 18 weeks pregnant. They could follow a website link in the invitation letter that directed them to a website with study information and an informed consent form. Informed consent involved giving permission to participate in the questionnaires and random assignment to the control or intervention condition, as well as permission to request vaccination status from Praeventis, which is the national vaccination register. Those who provided informed consent were assigned a unique participant code and were immediately directed to the online baseline questionnaire, which assessed socio-demographics, IDM, and psychological determinants of MPV uptake targeted in the intervention (see Table 1 for an overview of the measurements). Participants who did not complete the baseline questionnaire at 17 weeks of pregnancy, received a reminder via After completing the baseline questionnaire, participants were randomised to either of the two conditions.

Participants who were recruited online were randomised into the intervention and control condition. Participants recruited via midwifery clinics were randomised at the clinical practice-level to minimize spillover effects of the intervention via the midwife. Participants in the intervention condition received an e-mail with a link to the intervention along with their personal participant code at 18 weeks of pregnancy. They could visit the intervention as often as they wanted until they received an invitation and link via e-mail to complete the post-test measurement at 20 weeks of pregnancy. At the post-test, IDM, decisional certainty, and determinants of MPV uptake were measured again. Those who had not completed the post-test measurement at 21 weeks, received a reminder via Participants who had, for any reason, already received MPV when completing the post-test were excluded because this may influence their answers.

At 22 weeks, all participants had the opportunity to receive the MPV according to usual care. We did not expect to be able to make a complete match with the MPV uptake data from the national vaccination register because not all vaccinations are registered, and it is not registered when someone is not vaccinated. Therefore, at 28 weeks of pregnancy, participants also received an invitation and a link to a second post-test measurement to assess self-reported MPV uptake. If they reported not having received MPV, they were given the option to answer this question again at 38 weeks of pregnancy.

All participants who completed the questionnaire at 28 weeks of pregnancy received a 5-euro gift card via Once all participants had completed their pregnancies, we requested their vaccination status from the national vaccination register. Personal data and research data were saved separately and were linked using the unique participant codes only when requesting vaccination uptake data from the national vaccination register.

2.5. Control condition: Standard information

The control condition received no additional information besides standard care. As part of standard care, the midwife provided an information leaflet and an invitation letter during one of the consultations with the pregnant individual. If the participant decided to get MPV, they could make an appointment at the Preventive Child and Youth Healthcare Services, where the MPV is administered free of charge at 22 weeks of pregnancy, and additional counselling is provided if needed.

2.6. Intervention condition: Decision aid

Participants in the intervention condition received, in addition to standard care, an invitation to visit and use an online tailored decision aid. This was a mobile-first (progressive) web application that could be accessed on any device or saved as an app on a mobile phone. The systematic development of the decision aid has been described elsewhere in detail [19]. The decision aid targeted relevant and changeable determinants of MPV uptake and IDM, derived from a survey amongst pregnant individuals [18,20], which were mapped to behaviour change methods and translated into practical applications. This resulted in three main components of the intervention: a component with information

Table 1
Overview of outcome measures, their scores or scales and internal consistencies.

Measures and items	Score/scale	Cronbach alpha (α) or Pearson r (r)[2]
Primary outcome		
MPV uptake Uptake of the MPV is derived from national register and gaps in data were filled with available subjective MPV uptake data.	0 = rejected MPV, 1 = received MPV	NA
Secondary outcomes		
IDM Consistency scale between attitude and MPV uptake Knowledge about MPV (see below)	1 = low IDM (least informed) to 40 = high IDM (most informed)	NA
Knowledge (7 items) The MPV is meant to protect the baby. A painful arm is a common side-effect of MPV. Whooping cough is never serious for young babies. (R) The MPV only protects against whooping cough, and not against other diseases. (R) After getting MPV, the baby can skip their first vaccination after birth. Whooping cough can be transmitted by coughing. The MPV protects only my baby, and not me, against whooping cough. (R)	Sum score of correct answers 0 = low knowledge about MPV to 7 = high knowledge about MPV. (total number of correct answers)	NA
Decisional Certainty (3 items) It is clear to me what the best decision for me is regarding the MPV.I feel certain about my decision about MPV. I find it easy to make a decision about MPV.	1 = low decisional certainty to 5 = high decisional certainty	0.93
Intention (3 items) I plan to get MPV. I expect to get MPV. It is probable that I will get MPV.	1 = low intention of getting MPV to 5 = high intention of getting MPV	0.98
Attitude (4 items) I find MPV: very bad – very good very unimportant – very important very undesirable – very desirable very unnecessary – very necessary	1 = negative to 5 = positive	0.93
Perceived susceptibility of pertussis (1 item) The chance that my baby will get whooping cough (without the MPV) is ….	1 = very small to 5 = very big	NA
Perceived severity of pertussis (2 items) Whooping cough in a baby is … If you baby gets whooping cough, how likely do you think it is that it will have serious effects?	1 = not likely at all – 5 = very likely	0.62
Beliefs safety (3 items) MPV has been sufficiently tested in pregnant women. MPV is safe for pregnant women. MPV is safe for the baby.	1 = very unsafe to 5 = very safe	0.71
Beliefs effectiveness (3 items) MPV decreases the chance of whooping cough in babies. Babies are better protected against whooping cough with MPV than without MPV. There is less whooping cough in babies because of MPV.	1 = very ineffective to 5 = very effective	0.78
Moral norm (2 items) I find it my responsibility to get vaccinated for whooping cough. I find it the responsibility of pregnant women to get MPV.	1 = low moral norm to 5 = high moral norm	0.59
Injunctive norm (2 items) I think my partner wants me to get MPV. I think my obstetric care provider wants me to get MPV.	1 = low injunctive norm to 5 = high injunctive norm	0.44
Affect (5 items) About the MPV I feel: Comfortable Relaxed Angry (R) Certain Scared (R)	1 = negative to 5 = positive	0.89
Perceived control/self-efficacy (5 items) I can manage the following situations: Assessing information about MPV. Having a conversation about MPV. Making a decision about MPV. Making an appointment to get MPV. Going to the Youth Health Centre to get MPV.	1 = low perceived control to 5 = high perceived control	0.83

pages, an interactive component called ‘my choice’, and a ‘make an appointment’ component.

The information pages were grouped as clusters of information tiles to chunk information in relevant and logical categories. Active learning and information comprehension were stimulated by providing recall quiz-like questions with tailored feedback, as well as by using three different modes of delivery: video, text, and audio/text-to-speech facilitation. The information provided included details on how MPV works what pertussis is and what the risks are in babies, and about safety and side-effects of MPV.

The second main component, ‘My choice’, was divided into three subcomponents. The first, ‘Knowledge test’, used a quiz-like strategy to promote active learning and to provide feedback for the most basic and relevant information about the vaccine [21–24]. The second subcomponent, ‘Weighing pros and cons’, aimed to improve decisional certainty by providing a tailored overview of the participant’s considerations about the MPV using a decisional balance [25]. The third subcomponent was a chat-like conversational module, where participants prepared for a conversation with a significant other, indicating what they wanted to gain from a conversation with an important social referent or healthcare provider, and expressing their feelings, needs, and questions were regarding MPV. The subcomponent targeted dealing with social pressure and injunctive norm with regard to MPV by applying resistance to social pressure [26] and using non-violent communication [27].

The third main component ‘Appointment’ aimed to facilitate those in favour of getting MPV by providing a post code-based location finder of a vaccination location, allowing participants to make an MPV

appointment. Fig. 1 shows screenshots from the different components of the decision aid.

2.7. Measurements

Fig. 2 provides an overview of the measurement moments. Table 1 shows an overview of all outcome measurements, the number of items, their scales and internal reliabilities.

2.7.1. MPV uptake

MPV uptake was measured objectively by requesting MPV uptake data from the national vaccination register Praeventis. We provided the register with a list of participant codes and personal data, and they provided a list with only the participant codes and uptake data, ensuring that research data and personal data remained separate. The national register only registers a vaccination status when a person is vaccinated, and not when they are not vaccinated. Therefore, there was no distinction in this dataset between people whose data were missing but who were vaccinated and non-vaccinated participants. Because objective MPV uptake data is expected to be incomplete, MPV uptake was additionally assessed subjectively by asking participants if they had received the MPV at 28 weeks of pregnancy, and if needed, at 38 weeks gestational age. Participants were either not vaccinated (vaccination status = 0) or had received MPV (vaccination status = 1).

2.7.2. IDM and decisional certainty

IDM and decisional certainty were measured at baseline (before 18 weeks of pregnancy) and post-test (between 20 and 22 weeks of pregnancy). Initially, we wanted to construct a measure of IDM based on the two components of an informed decision according to Marteau and colleagues [9]: (1) knowledge and (2) the consistency between the person's attitude and their behaviour (uptake of MPV). Following recommendations by Ghanouni and colleagues [28], we decided not to use cut-off values for attitude consistency and adequate knowledge, and report these separately as well as multiplied into one score representing IDM. First, we computed a consistency score by recoding the attitude scale ranging from 1 to 5 to −2 (negative) to 2 (positive) and multiplying this value by −1 if a participant did not get vaccinated, or 1 when they did get vaccinated. A neutral score on the attitude scale was considered to be in line with either both getting the MPV and not getting the MPV and was recoded to −1 or 1, according to MPV status. The resulting consistency value was recoded to range from 1 (least) to 5 (most consistent) and multiplied by the total score on knowledge about MPV. The knowledge score consisted of 1 plus the number of correct answers to the 7 knowledge questions, to avoid multiplying by 0. The result was a scale ranging from 1 (low IDM) to 40 (high IDM).

Decisional certainty was measured with the sub scale of the Decisional Conflict Scale [29] using a 5 point Likert scale.

2.7.3. Targeted determinants of uptake

To measure the determinants targeted in the intervention, we calculated composite scores (see Table 1). Determinants included intention and attitude towards MPV, perceived susceptibility of the baby getting pertussis and perceived severity of pertussis for babies, beliefs about the safety and effectiveness of MPV, moral and injunctive norms, affect towards MPV, knowledge about MPV and perceived control of deciding about MPV and getting MPV. To assess internal validity, Cronbach's alpha was used for scales consisting of more than 2 items, and Pearson's r was used for scales consisting of 2 items. Negatively formulated items were reverse coded (marked with and R in Table 1).

2.7.4. Socio-demographics

Socio-demographics were measured to assess whether the sample is representative of your target population and to assess whether effects are different among socio-demographic groups. Age, highest completed educational level, country of birth, whether the participant had children and affiliation with religion were measured at baseline. Educational level was classified as low (less than secondary or vocational education), intermediate (secondary and vocational education), or high (higher or university education). Country of birth was divided into the Netherlands or other.

2.7.5. Intervention use

Intervention use was objectively measured according to computer logs. Intervention use was measured in three ways: the number of clicks, time spent on the intervention and number the of visited components. Every time a participant used the intervention, a record linked to their assigned unique participant number was created.

Number of intervention clicks was calculated. Every time a participant clicked on something was logged, creating a record of which components and pages were visited, as well as which answers were given to questions in interactive components.

The number of seconds spent on the intervention was calculated by summing the difference in time between each logged event for a

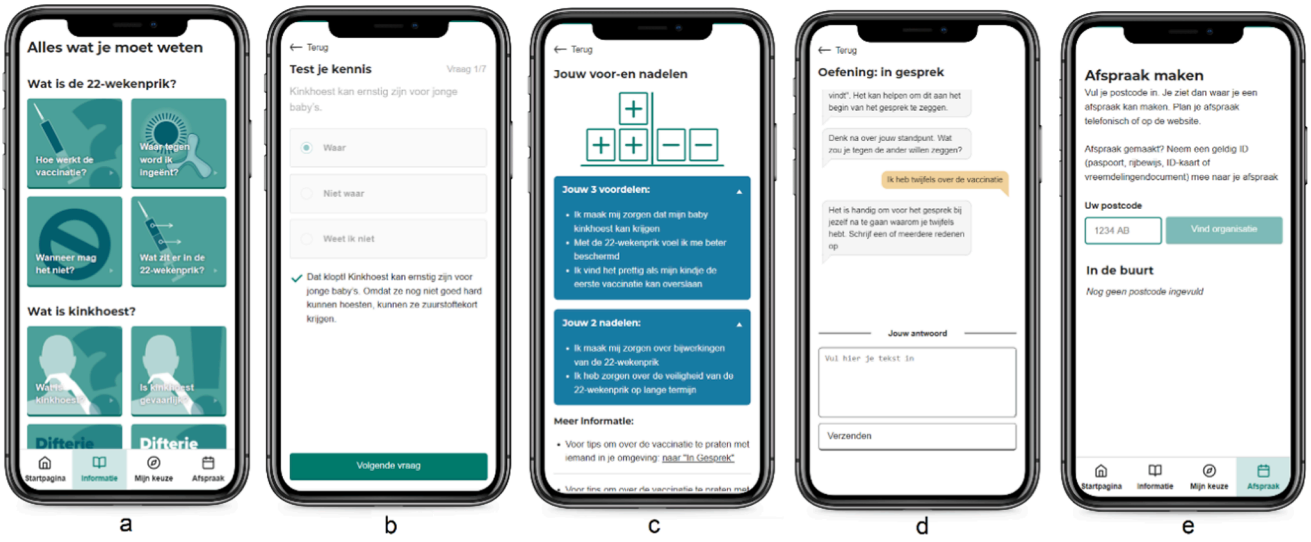

Fig. 1. Screenshots of a selection of components from the online tailored decision aid: an overview of the information topics (a), an example of a 'test your knowledge' question and tailored feedback (b), an overview page of the decisional balance with tailored pros and cons (c), the 'prepare a conversation' subcomponent (d), the 'make an appointment' page (e).

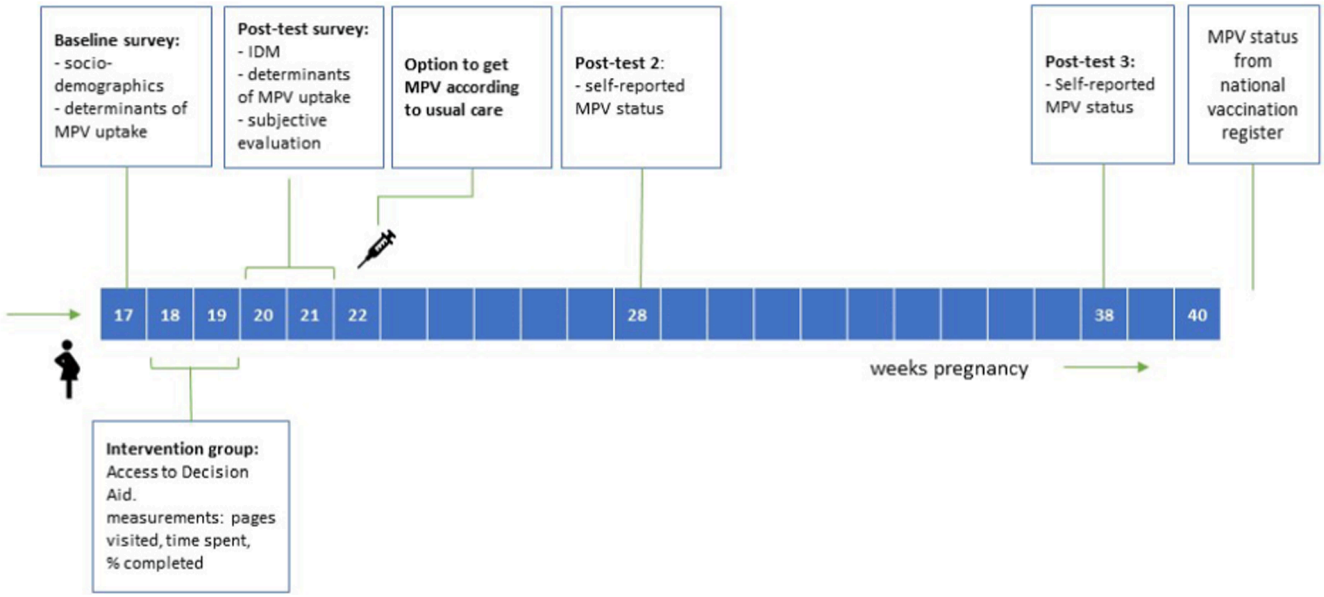

Fig. 2. Overview of the measurement moments.

participant. If a participant did not click on anything for more than 4 min, it was assumed that they were not paying attention to the web-app anymore and this duration was not included in the total sum of time.

The number of intervention components visited was calculated from the main components and subcomponents of the interactive 'My choice' elements ('Homepage', 'Information', 'Weighing pros and cons', 'Knowledge test', 'Conversation preparation' and 'Appointment').

2.7.6. Intervention dose

Since neither the number of clicks, time spent (in seconds), nor the number of components visited give a full indication of intervention use, these measures were combined by multiplying them to create a measure for the delivered dose. This scale was then transformed with a log transformation due to its skewedness to the right, resulting in a score from 0 (not used) to 15 (completely used).

2.8. Analyses

All analyses were conducted using R version 4.1.2. Descriptive statistics were used to describe the baseline sample [30]. Differences between those who completed the second measurement and those who did not, as well as differences between the intervention and control condition, were assessed to check if drop-out occurred randomly or based on socio-demographics. Chi-squared and independent samples t-tests were used to assess differences. Similarly, differences between the intervention and control condition were checked for.

To analyse effects, Intention to Treat (ITT) analyses were used: all randomised participants who completed the baseline measurement were included in the analyses. First, the missingness of data on MPV uptake was assessed, using all objective uptake data and using subjective uptake data to fill in the gaps where possible. For the analysis of intervention effects on MPV uptake, logistic regression analysis was used, with MPV uptake as the dependent variable and condition as the independent variable. We added recruitment channel as factor variable in the analyses to correct for differences between the social media sample and clinic sample. The odds ratio was used as an indicator for the effect size of the intervention on MPV uptake. Odds ratios of 1.68, 3.47 and 6.71 are considered as small, medium and large effect sizes respectively [31]. The analyses were repeated using the assumption that participants with missing uptake data did not receive MPV, because the most common reason for not having MPV status registered is not having received the vaccination.

For IDM, a linear regression model was used. Because linear and logistic regression models without multiple levels cannot handle missing data accurately, imputation was used for missing data for IDM. Knowledge and attitude were imputed separately, and IDM was constructed as described above. Multiple imputation by chained equations was used to impute missing data [32,33], generating 30 imputed datasets using the predictive mean matching algorithm in the MICE package in R [34]. Results from these datasets were pooled together using Rubin's rules [35], and iteration plots were inspected to check convergence of the imputations.

For the determinants of MPV uptake, linear mixed regression models were used because there were two timepoints (baseline and post-test). Mixed models adequately handle missing data at one measurement, even if the missingness is non-random. Condition and time were added to the model, as well as the interaction between condition and time. The control condition was coded as 0 and the intervention condition as 1, with timepoints coded as 1 and 2. The effect of the interaction indicates the additional effect of the intervention compared to the control condition over time. Recruitment channel was added again as a factor variable to correct for differences between the social media sample and the clinic sample. The distribution of residuals was assessed to ensure that linear models were suitable.

The inclusion of socio-demographics in the model and the moderation of intervention effects by socio-demographic variables were checked. Interaction effects of condition and socio-demographics were added to the models to see if the intervention was effective across socio-demographic conditions.

Furthermore, it was examined whether decisional certainty and intention levels at baseline moderated intervention effects. Two groups with different intention levels and two groups with different decisional certainty levels were created based on a cut-off value of the median score. This resulted in a group of participants with a maximum intention score of 5 and a group of no maximum intention score (a score below 5) for the same was done for decisional certainty. The analyses conducted for the main effects were repeated for these different groups to assess whether effects were present among participants with maximum or no maximum intention or decisional certainty scores at baseline.

Finally, the dose-outcome relationship between intervention use and the primary and secondary outcomes was examined by repeating the regression analyses among the participants in the intervention condition

only, using the combined measure of dose as the dependent variable instead of condition. The natural logarithm of the dose was used in the model since the dose was skewed to the right.

To correct for multiple testing, an effect was considered significant when P <.004 (Bonferroni corrected alpha = 0.05/13 factors).

3. Results

3.1. Response rates

A flow diagram illustrating the response rates is presented in Fig. 3. Out of the 1,618 individuals who gave informed consent, 194 were excluded as they did not meet the inclusion criterion (i.e., being less than 18 weeks pregnant). In total, 1,236 participants (76.4 % of those eligible who gave informed consent) completed the baseline questionnaire and were randomly assigned into the intervention or control condition. Among them, 74.3 % (N = 976) started the first post-test questionnaire (at 20 weeks of pregnancy), and 67.0 % completed it (N = 829). At the post-test, 82 participants were excluded because they had already received MPV.

The response rate for the survey at 28 weeks regarding MPV uptake was 82.8 % (N = 1021). The results of the dropout analyses are presented in Table 1 of the appendix. There was slightly higher dropout in the intervention condition compared to the control condition. Dropout rates were higher among those recruited via social media (35.2 %) compared to those recruited via a clinic (26.5 %, $\chi 2 = 8.27$, p = .004), and among participants with low (33.3 %) and intermediate education (43.0 %) compared to those with high education (30.2 %, $\chi 2 = 14.76$, p < .004). T-tests revealed that there was more dropout among participants with lower intention (mean = 4.45 versus 4.67 among those completed the post-test, 95 %CI = −0.32, −0.12) and attitude towards MPV (mean = 4.50 versus 4.67, 95 %CI = −0.26, −0.09), lower beliefs about safety (mean = 4.31 versus 4.50, 95 %CI = −0.29, −0.09) and effectiveness of MPV (mean = 4.49 versus 4.62, 95 %CI = −0.21, −0.05, p <.001), as well as lower moral norm (mean = 4.19 versus 4.36, 95 % CI = −0.28, −0.07), perceived control (mean = 4.54 versus 4.74, 95 % CI = −0.26, −0.13), and affect (mean = 4.25 versus 4.47, 95 %CI = −0.32, −0.12).

3.2. Sample description

Table 2 presents the sample characteristics based on recruitment method and assigned condition. Overall, there was an over-representation of highly educated women born in the Netherlands were overrepresented compared to the general population. Only 4.1 % of the sample was born outside the Netherlands, whereas this figure is 14 % in the general population. In our sample, 76.3 % had a high level of education, while the corresponding figure in the general population is 60.9 % among women of an average age of 32 in our sample [36]. On average, the participants in the study were 32 years old, and approximately half of them already had one or more children. The percentage of highly educated women was higher in the social media sample compared to the clinic sample. A randomisation check revealed differences between the control and intervention conditions in terms of country of birth, with more participants born outside the Netherlands in the control condition than in the intervention condition (p < .006). However, this difference was not significant after correcting for multiple testing. Significant differences were observed between the clinic sample and the social media sample in terms of age (p < .001) and education level (p < .001), thus recruitment channel was included in the models to account for these differences.

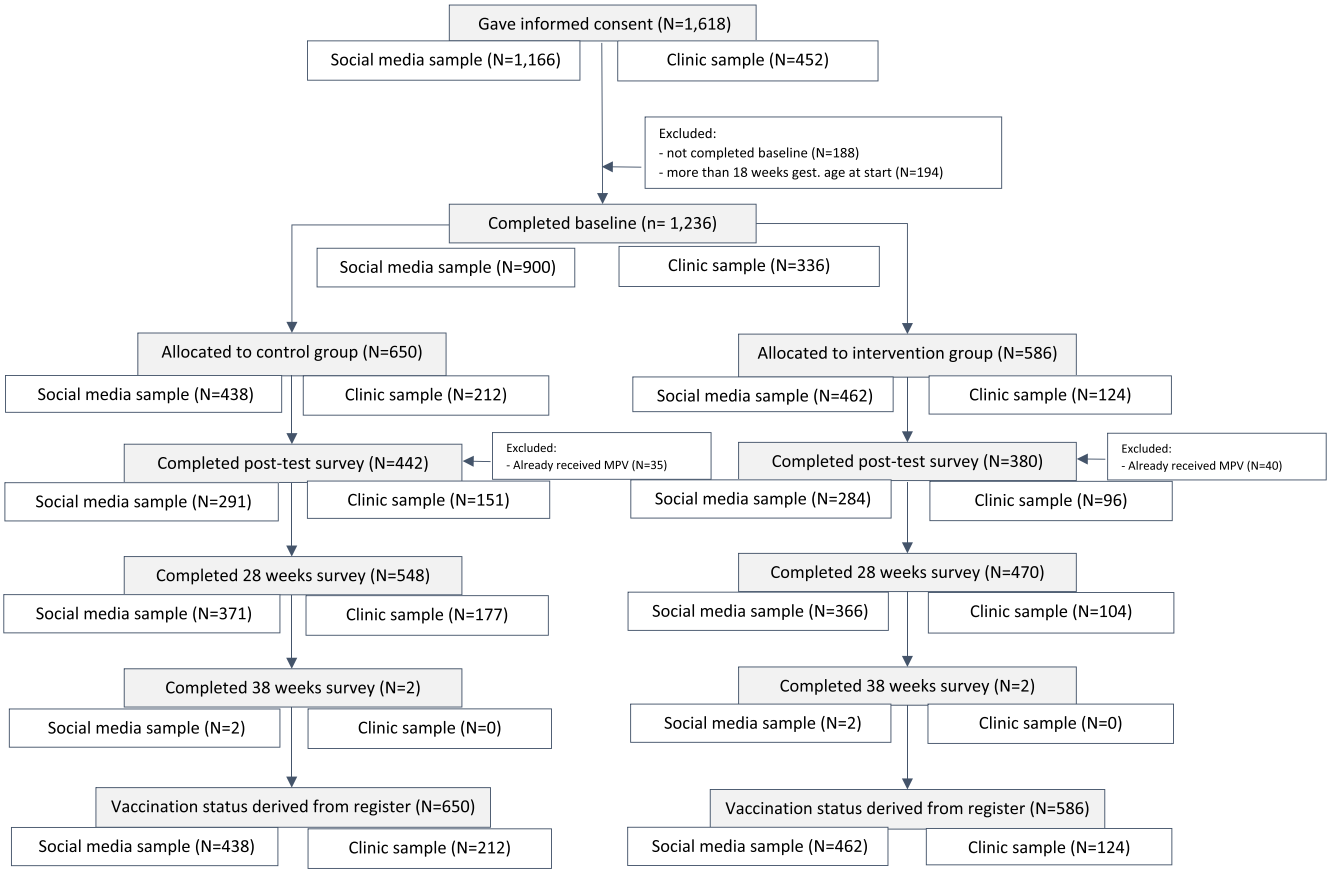

Fig. 3. Flow diagram of the recruitment and response of study participants.

Table 2
Sample characteristics by recruitment method and by randomised condition.

	Conditioned by recruitment channel(N = 1236)			Conditioned by condition (N = 1236)		
	Social media sample (N = 900)	Clinic sample (N = 336)		Control condition (N = 650)	Intervention condition (N = 586)	
Sociodemographic variables	Mean (standard deviation) for continuous variables and percentages for dichotomous or categorical variables		Chi-squared (p-value) or 95 %CI (p-value)	Mean (standard deviation) for continuous variables and percentages for dichotomous or categorical variables		Chi-squared (p-value) 95 % CI (p-value)
Age	32.42 (3.97)	31.46 (3.80)	CI = −1.53–−0.56 (<0.001) ***	32.06 (3.87)	32.21 (4.04)	CI = −0.60–0.29 (0.04)*
Has at least one child						
No	48.2 %	54.5 %	χ^2 = 3.56 (0.05)*	46.7%	53.2 %	χ^2 = 4.67 (0.03)*
Yes	51.8 %	45.5 %		53.1 %	46.8 %	
Country of birth						
Netherlands	95.9%	95.8%	χ^2 = <0.001 (1)	94.3%	97.6%	χ^2 = 7.69 (0.006)**
Other	4.1 %	4.2 %		5.7 %	2.4 %	
Highest education completed						
Low	0.6 %	0.3 %	χ^2 = 14.72[1] (<0.001)***	0.3 %	0.7 %	χ^2 = 2.29[1] (0.13)
Intermediate	18.6 %	29.2 %		23.4 %	19.3 %	
High	80.8 %	70.5 %		76.3 %	80.0 %	
Religion 1 = no affiliation – 7 = strong affiliation	2.04 (1.28)	2.50 (1.39)	CI = 0.04–0.39 (0.01)*	2.13 (1.33)	2.06 (1.29)	CI = −0.07–0.22 (0.33)

Note. [1]Low and intermediate versus high educational levels were compared. *p <.05, **p < 0.01, ***p < 0.004 (corrected for multiple testing by means of Bonferroni correction p < 0.004).

3.3. Intervention use

Among the participants in the intervention condition, 79.0 % accessed the decision aid (objective evaluation). The average number of clicks was 27.24 (SD = 25.08). On average, participants spent 4.25 min (4 min and 15 s) using the decision aid (SD = 4.39). The average number of visited (sub)components was 2.70 out of 6 (SD = 1.63), and the average number of information pages visited was 3.90 out of 19 (SD = 1.36).

3.4. Intervention effects

3.4.1. Primary outcomes: MPV uptake and IDM

Table 3 displays self-reported MPV uptake and uptake according to registered data. Examining the level of agreement between self-reported and objective data, it was found that 66.4 % had received MPV according to both data sources. In total, 8.0 % reported receiving MPV, although was not recorded in the register, and 4.8 % reported not receiving MPV despite it being recorded in the register. A small group (3.4 %) reported not receiving MPV, and had no record in the register, indicating either no MPV administration, or missing data. The remaining participants did not provide their MPV status in the survey (17.5 %). For the participants with no registered MPV status who did not complete the self-reported MPV status survey, it was assumed that they did not receive MPV.

Table 3
Overview of MPV status according to self-reported data and the national register (N and percentages).

		Self-reported data			
		Received MPV	Did not receive MPV	missing	Total (from objective data)
Registered data (from national register)	Received MPV	821 (66.4 %)	59 (4.8 %)	164 (13.3 %)	1044 (84.5 %)
	Did not receive MPV/ missing	99 (8.0 %)	42 (3.4 %)	53 (4.3 %)	194 (15.7 %)
	Total (from subjective data)	919 (74.4 %)	101 (8.2 %)	216 (17.5 %)	

Table 4 presents the outcomes of the intervention effects on objective MPV status, self-reported MPV status, and a combination of the two, where a positive self-reported MPV status or a registered MPV status indicated that the participant received MPV. There was a 1.31 %-point difference in MPV uptake between the control and intervention conditions (91.69 % in the control condition and 93.00 % in the intervention condition, B = 0.22, 95 %CI = −0.09–0.53). However, this difference was not significant.

Table 4 displays the average IDM score and its components (knowledge and consistency between attitude about MPV and uptake) for the control and intervention conditions. For knowledge, the difference over time is presented for both groups, since it was assessed at both baseline and post-test. Overall, a positive effect of the intervention on IDM (β = 0.24, p < .001) was observed. Knowledge increased more between baseline and post-test in the intervention condition than in the control condition (β = 0.31, p < .001). Consistency (i.e. alignment between attitude and behaviour) did not differ significantly between the intervention and control conditions (β = 0.04, p > .05). Additionally, it is noteworthy that consistency was lower among unvaccinated participants (mean = 2.77, SD = 1.41) than vaccinated participants (mean = 4.57, SD = 0.94), indicating that participants who chose not to receive MPV often did so despite having a positive attitude towards MPV.

Table 4
Effects of the intervention outcome measures, correct for recruitment channel (via a clinic or via social media).

	Control N (percentage)		Intervention N (percentage)		B (standard error)	95 % Confidence interval	Beta (standard error)	t-value	Odds Ratio
	Pre-test (N = 650)	Post-test (N = 650–444)	Pre-test (N = 586)	Post-test (N = 586–392)					
MPV status (objective data) *Has not received MPV/missing (reference)* *Has received MPV*	NA	110 (16.92 %) 510 (83.08 %)	NA	84 (14.33 %) 502 (85.67 %)	0.22 (0.16) (p = .17)	−0.09 – 0.53	NA	NA	1.29
MPV status (self-reported data) *Has not received MPV (reference)* *Has received MPV* *Missing*[1]	NA	57 (8.77 %) 493 (75.85 %) 100 (15.38 %)	NA	44 (7.51 %) 427 (72.87 %) 115 (19.62 %)	0.20 (0.21) (p =.36)	−0.22 – 0.62	NA	NA	1.12
MPV status (combined data) *Has not received MPV/missing (reference)* *Has received MPV*	NA	54 (8.31 %) 596 (91.69 %)	NA	41 (7.00 %) 545 (93.00 %)	0.25 (0.22) (p = .25)	−0.18 – 0.68	NA	NA	1.20

	Control Mean (SD)		Intervention Mean (SD)		B (standard error)	95 % Confidence interval	Beta (standard error)	t-value	R squared (adjusted)
	Pre-test (N = 650)	Post-test (N = 650–444)	Pre-test (N = 586)	Post-test (N = 586–392)					
IDM	NA	29.54 (8.62)	NA	31.50 (8.91)	2.11 (0.62)**	0.88–3.34	0.24 (0.07)	3.37	0.02
Knowledge (1–7)	4.94 (1.53)	5.59 (1.15)	4.68 (1.53)	5.94 (1.11)	0.58 (0.09)**	0.41–0.75	0.31 (0.05)	6.67	0.56
Consistency between attitude at post-test and MPV status (N = 844)	NA	4.52 (0.97)	NA	4.55 (0.97)	0.05 (0.07)	−0.08–0.19	0.04 (0.07)	0.81	0.01
Decisional certainty (1–5)	4.43 (0.95)	4.67 (0.70)	4.39 (0.95)	4.80 (0.47)	0.18 (0.05)**	0.08–0.28	0.17 (0.05)	3.60	0.61
MPV Intention (1–5)	4.59 (0.81)	4.79 (0.63)	4.61 (0.73)	4.88 (0.50)	0.08 (0.04)*	0.01–0.15	0.09 (0.04)	2.22	0.76
MPV Attitude (1–5)	4.62 (0.67)	4.70 (0.58)	4.61 (0.65)	4.75 (0.48)	0.07 (0.03)*	0.01–0.13	0.08 (0.04)	2.38	0.75
Perceived susceptibility of pertussis (1–5)	2.64 (0.78)	2.58 (0.84)	2.63 (0.80)	2.83 (0.97)	0.26 (0.05)**	0.16–0.37	0.24 (0.05)	4.81	0.52
Perceived severity of pertussis (1–5)	4.40 (0.61)	4.34 (0.60)	4.38 (0.66)	4.67 (0.48)	0.32 (0.04)**	0.25–0.40	0.41 (0.05)	8.39	0.56
Beliefs safety of MPV (1–5) (N =)	4.46 (0.82)	4.62 (0.68)	4.41 (0.81)	4.69 (0.58)	0.09 (0.05)*	<0.01–0.19	0.10 (0.05)	2.02	0.57
Beliefs effectiveness of MPV (1–5)	4.58 (0.63)	4.67 (0.56)	4.58 (0.59)	4.72 (0.47)	0.04 (0.04)	−0.03–0.12	0.06 (0.05)	1.17	0.55
Moral norm (1–5)	4.30 (0.86)	4.39 (0.75)	4.31 (0.82)	4.42 (0.74)	<0.01 (<0.01)	−0.08–0.11	0.02 (0.05)	0.33	0.62
Injunctive norm (1–5)	4.10 (1.01)	4.21 (0.98)	4.09 (0.98)	4.26 (0.91)	<0.01 (<0.01)	−0.10–0.13	0.01 (0.05)	0.32	0.60
Affect about MPV (1–5)	4.41 (0.80)	4.48 (0.74)	4.39 (0.78)	4.61 (0.59)	0.15 (0.04)**	-0.07 – 0.23	0.15 (0.04)	3.46	0.65
Perceived control/self-efficacy (1–5)	4.67 (0.49)	4.74 (0.44)	4.67 (0.48)	4.78 (0.38)	0.06 (0.03)*	0.01–0.11	0.10 (0.04)	2.39	0.67

*p-value < 0.05, and **p-value <0.004 (Bonferroni: 0.05/13 = 0.004). The effect size B is the interaction effect between condition and time and indicates the added effect of the intervention compared to the control condition, over time. We found positive significant effects on knowledge, decisional certainty, perceived susceptibility and severity of pertussis, and affect about MPV. [1]Missings in subjective data were not included in the regression analysis.

3.4.2. Secondary outcomes

Table 4 provides an overview of the intervention effects on the secondary outcomes. On average, participants already had a positive attitude and intention towards receiving MPV at baseline (mean scores > 4.5 on a 5-point scale). The intervention showed a significant, positive effect (after Bonferroni correction) on knowledge about MPV ($\beta = 0.31$, $p < .004$), indicating that participants in the intervention condition exhibited a greater increase in knowledge about MPV compared to those in the control condition. In the intervention condition, participants had a significantly higher level of decisional certainty compared to the control condition ($\beta = 0.24$, $p < .004$), as well as more positive affect about MPV ($\beta = 0.15$, $p < .004$). Furthermore, significant effects were found on perceived susceptibility ($\beta = 0.24$, $p < .004$) and severity of pertussis ($\beta = 0.41$, $p < .004$) for babies, with those higher scores observed in the intervention condition compared to the control condition. No effects were found on beliefs about effectiveness of MPV, moral norm and injunctive norm.

3.4.3. Influence of socio-demographic factors

We found no significant effects of socio-demographic variables on the intervention effects and there were also no moderation effects by socio-demographics, which suggests that the effects of the intervention did not differ by age, country of birth, whether a participant already had children, education level, and affiliation with religion (data not shown).

3.4.4. Moderation of decisional certainty and MPV intention at baseline

Table 5 shows the results of the moderation analyses. Differences in the effects of the intervention (indicated by a significant interaction between time and intervention condition) on perceived susceptibility of the baby getting pertussis are seen between different levels of intention

Table 5
Results of analyses checking for moderation no maximum and maximum intention and decisional certainty scores at baseline. B's or Betas (SE) and significance levels are shown (*p-value <0.05, and **p-value <0.004). Betas represent the interaction between time and control versus intervention group, except for MPV uptake and IDM, for which Betas represent only the difference between control and intervention group. Analyses were done in the same manner as above for the main effects.

	No high decisional certainty (score < 5) (N = 482)	High decisional certainty (score = 5) (N = 754)	No high Intention (score < 5) (N = 359)	High intention (score = 5) (N = 877)
		B (SE)		
MPV uptake (objective and subjective data combined)	0.12 (0.28)	0.50 (0.36)	0.27 (0.27)	0.23 (0.41)
		Beta (SE)		
IDM (1–40)	0.27 (0.11)*	0.25 (0.09)*	0.31 (0.13)*	0.24 (0.08)*
Knowledge (1–7)	0.32 (0.08)**	0.31 (0.06)**	0.32 (0.09)**	0.32 (0.06)**
Decisional certainty (1–5)	0.28 (0.08)**	NA[1]	0.36 (0.09)**	0.09 (0.07)
MPV Intention (1–5)	0.10 (0.06)	0.05 (0.04)	0.15 (0.07)*	NA[1]
MPV Attitude (1–5)	0.05 (0.07)	0.12 (0.05)*	0.12 (0.08)	0.08 (0.06)
Perceived susceptibility of pertussis (1–5)	0.42 (0.09)**	0.14 (0.06)*	0.42 (0.10)**	0.18 (0.06)**
Perceived severity of pertussis (1–5)	0.44 (0.08)**	0.40 (0.06)**	0.46 (0.09)**	0.41 (0.06)**
Beliefs safety of MPV (1–5)	0.12 (0.08)	0.10 (0.07)	0.18 (0.10)	0.10 (0.07)
Beliefs effectiveness of MPV (1–5)	0.09 (0.09)	0.03 (0.06)	0.07 (01)	0.06 (0.06)
Moral norm (1–5)	0.06 (0.08)	−0.02 (0.06)	0.07 (0.09)	<−0.01 (0.06)
Injunctive norm (1–5)	−0.05 (0.07)	−0.06 (0.06)	−0.09 (0.08)	0.07 (0.06)
Affect about MPV (1–5)	0.29 (0.08)**	0.05 (0.07)	0.32 (0.09)**	0.11 (0.06)
Perceived control/self-efficacy (1–5)	0.15 (0.07)	0.08 (0.06)	0.13 (0.08)	0.11 (0.06)

[1]Analyses were not done for high decisional certainty and high intention groups in samples with the maximum scores on those variables, because scores could not be improved.

and decisional certainty. There was a larger increase in the perceived susceptibility in the intervention group among those having no high decisional certainty at baseline compared to those who had maximum decisional certainty (β = 0.42 versus β = 0.14 respectively) or no high MPV intention versus maximum MPV intention (β = 0.42 versus β = 0.18 respectively). The intervention also seems to positively impact affect regarding MPV, but only in the groups with no high decisional certainty (β = 0.19, p < .004) and no high intention (β = 0.32, p < .004).

3.4.5. *Dose-outcome relationship*

Table 6 shows the outcomes of the dose-outcome analysis (N = 586). There was a significant relationship between intervention dose and uptake of MPV (β = 0.05, p < .004). There was also an association between dose and knowledge (β = 0.36, p < .004).

Table 6
Dose-outcome analysis (N = 586), using a combination number of clicks, time spent on the intervention and the number of components visited in the DA as independent variable and MPV uptake (logistic regression) and IDM (linear regression) as dependent variable.

	B (standard error)	95 % Confidence interval	Beta (standard error)	t-value	R^2
MPV uptake (objective and subjective data combined)	0.01 (<0.01)**	0.01–0.02	0.05 (0.01)	4.47	0.36
IDM (1–40)	0.06 (0.02)*	0.08–0.67	0.14 (0.06)	2.50	0.04
Knowledge (1–7)	0.07 (0.02)**	0.04–0.10	0.36 (0.80)	4.74	0.62
Decisional certainty (1–5)	0.02 (0.01)	<−0.01–0.04	0.18 (0.09)	1.92	0.48
MPV Intention (1–5)	<0.01 (<0.01)	−0.01–0.02	0.10 (0.07)	1.40	0.71
MPV Attitude (1–5)	0.01 (<0.01)*	<0.01–0.03	0.14 (0.07)	2.17	0.77
Perceived susceptibility of pertussis (1–5)	0.02 (0.01)*	<0.01–0.04	0.18 (0.09)	1.96	0.48
Perceived severity of pertussis (1–5)	<−0.01 (<0.01)	−0.02–0.02	−0.04 (0.09)	−0.45	0.54
Beliefs safety of MPV (1–5)	<0.01 (0.01)	−0.01–0.02	0.05 (0.09)	0.60	0.54
Beliefs effectiveness of MPV (1–5)	<0.01 (0.01)	−0.02–0.01	−0.05 (0.09)	−0.55	0.47
Moral norm (1–5)	<0.01 (0.01)	−0.01–0.02	0.07 (0.08)	−0.85	0.61
Injunctive norm (1–5)	−0.02 (0.01)	−0.04–<0.01	−0.18 (0.08)	−2.17	0.60
Affect about MPV (1–5)	<0.01 (0.01)	−0.03–0.01	0.08 (0.08)	−0.93	0.62
Perceived control/self-efficacy (1–5)	<0.01 (<0.01)	−0.01–0.01	0.05 (0.07)	0.75	0.71

*p-value <0.05, and **p-value <0.004.

4. Discussion

This study assessed the effects of an online DA for decision making about MPV among pregnant individuals. We found a difference of 1.3 % in uptake of MPV between the control and intervention condition. However, this difference was not statistically significant. Our study was not powered to find a difference that small as we expected a bigger difference. The lack of a significant difference in uptake could be explained by the high uptake and selectivity in our sample (92.3 %, across the whole sample, self-reported and register data combined), leaving less room for improvement. This is higher than in the general population, where uptake reported in the national register is 70 % compared to 82.7 % uptake in the national register among our sample [5]. MPV uptake was related to the dose of the intervention.

We found that the intervention increased IDM and its component knowledge about MPV, decisional certainty, perceived susceptibility, and severity of pertussis, and affect about MPV. This is in line with other studies about DAs for vaccination decisions, where positive effects on decisional certainty were found [16]. We found that MPV uptake and knowledge were related to the dose of the intervention that a participant was exposed to, showing a dose-outcome relationship. This implies that a successful strategy to increase the effectiveness of the DA, and potentially to establish a more robust effect on MPV uptake, could be by increasing the dose of the intervention. This could be done by adding more 'tunnelling' elements to the decision aid, to keep participants engaged when using it [37]. An example of a tunnelling element can be

redirection a participant from the end of one exercise to the beginning of another or from one information topic to the next, to keep them engaged.

A moderation analysis showed that the DA might have additional benefits for those who do not have high intentions about getting MPV and high decisional certainty before informing themselves, given that the intervention also improved (positive) affect regarding MPV in these groups. However, effects on IDM were stable across different baseline levels of intention to accept MPV and decisional certainty. This means that even though people had high intentions and did not change their decision, their decision became more informed. This could explain the lack of a significant effect on MPV uptake, while we did find an effect on IDM. Even if an increase in uptake is not seen immediately, more informed decisions lead to more stable vaccination choices in the future [38].

We used a measure of IDM based on the two components defined by Marteau and colleagues [9], using continuous scores for knowledge, and consistency between MPV uptake and the person's attitude about MPV. We noticed big differences between the vaccinated and unvaccinated groups in consistency between choice and MPV attitude (means of 4.57 and 2.77 respectively). The majority in both groups had positive attitudes about MPV, leading to a low average consistency score among unvaccinated participants. We suspect that despite a positive attitude or even intention towards MPV some participants do not follow up on that attitude or intention for various possible reasons. Perhaps they forgot to make the appointment to get MPV despite intending to. Perhaps their attitude about MPV is ambivalent; when MPV is brought to their attention, they evaluate it positively, but when they need to take the initiative to make an appointment, it might not be a priority. We also considered that perhaps affective factors caused the inconsistency, but when looking at consistency between affect instead of attitude about MPV and MPV status, the same trend was visible, with low consistency among unvaccinated participants compared to vaccinated participants (means of 2.56 and 4.42, respectively). One could argue that the participants who scored low on consistency did not make an informed decision because they did not get MPV despite finding it important, and that therefore, IDM was drastically lower among unvaccinated participants. But we find it important to note that the scale is quite rigorous in classifying decisions against MPV as inconsistent, thereby leading to a lower score on IDM. Therefore, we subscribe to the advice of Ghanouni and colleagues to additionally report each component of IDM separately [28]. Also, new ways of describing IDM that take into account attitudinal ambivalence could be a valuable addition to studies about vaccination decisions.

Another methodological consideration is that already at the baseline measurements, determinants of MPV uptake were very high (mean = 4.60, SD = 0.77) with a large proportion of the sample at the maximum score (71.0 %). This means that for a large part of the sample, a ceiling effect occurred, and it was impossible to improve scores from there. Subsequently, effect sizes were small. However, we believe that even small effect sizes can be of relevance on the population level.

A limitation of the study is that we had a selective sample in which high educated women who were born in the Netherlands were overrepresented. The high baseline levels of determinants of MPV uptake indicate that our sample was subject to selection bias. Caution should be exercised when interpreting the generalisability of this study's findings, particularly in terms of average scores, such as high attitudes and intentions towards MPV. This kind of selection bias is not uncommon in studies about vaccination uptake [39], but it is a problem because interventions are most needed among those in doubt and holding ambivalent beliefs about vaccinations. However, we found no differences in the effects of the intervention across socio-demographic groups, indicating that effects could be generalised to the a large part of the general population.

5. Conclusion

Since MPV is the first vaccination decision in a series of vaccination decisions during parenthood, especially for those in their first pregnancy, it is important to promote a robust attitude and decision [38]. We believe that a DA is a useful method to help IDM about vaccinations. The DA evaluated in this trial is a good addition to the standard information and counselling about MPV, as it increased IDM. Adding the DA to the standard information about MPV can help improve IDM about MPV across the general population. This is likely to benefit uptake of MPV, but further research is needed to confirm this.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

The authors do not have permission to share data.

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