

# Promoting informed decision making about maternal pertussis vaccination

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Promoting informed decision  
making about maternal  
pertussis vaccination

CHARLOTTE ANRAAD



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## **Colofon**

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**PROMOTING INFORMED DECISION MAKING  
ABOUT MATERNAL PERTUSSIS VACCINATION**

PROEFSCHRIFT

ter verkrijging van de graad van doctor aan de Universiteit Maastricht,  
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volgens het besluit van het College van Decanen,  
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# Chapter 1

General Introduction



Infectious diseases have been troubling humankind ever since we started civilisations. Today, we have vaccinations to protect ourselves against many of those diseases. The recent COVID-19 pandemic has shown us again how much we depend on vaccinations to control the damage and spread of infectious diseases. To make sure vaccinations are used when available, it is crucial to understand how people decide about vaccinations. Only then can we help people to make an informed decision, and eventually, help prevent infectious diseases from spreading and causing illness through a sufficient uptake of vaccinations. This is the challenge that this thesis focuses on. Specifically, it focuses on factors associated with uptake of maternal pertussis vaccination during pregnancy, the decision-making process of pregnant individuals, and ultimately, finding ways to promote informed decision making.

### **Pertussis**

Pertussis, commonly known as whooping cough, is an infection of the respiratory tract caused by the bacterium *Bordetella Pertussis*. Pertussis spreads by droplet transmission. In adults, the disease usually starts with cold-like symptoms and a mild cough or fever. After 1-2 weeks, fits of many, rapid coughs occur that can lead to exhaustion and vomiting. This ‘whooping cough’ can last up to 10 weeks. Babies younger than 1 year old may also have difficulty breathing, causing about half of young babies that get pertussis to need hospital care (Mooi & de Greeff, 2007). In rare cases, pertussis in babies may lead to seizures, brain damage or death (McIntyre & Wood, 2009). Pertussis was ranked as the 9<sup>th</sup> leading cause of death and disability among children aged 0-9 in 2019 globally (Vos et al., 2020). In 2016, the World Health Organisation reported 139,535 pertussis cases globally, and estimated that there were 89,000 deaths (*Global Health Observatory Data Repository Pertussis - Reported Cases by WHO Region*, 2022). However, a study modelling pertussis cases and deaths estimates that there were 24.1 million pertussis cases and 160,700 deaths in children younger than 5 years in 2014 worldwide (Yeung et al., 2017). Reported cases are around 150,000 per year globally (*Global Health Observatory Data Repository Pertussis - Reported Cases by WHO Region*, 2022). In the Netherlands, from 2015 onwards, incidence rates of pertussis cases confirmed in a laboratory were close to 30 per 100,000, and reached 36

in 2019 before COVID-19 regulations caused a drop in incidence (*Atlasinfectieziekten.NI*, n.d.). The actual pertussis-incidence was likely to be higher than that.

Since the introduction of childhood pertussis vaccinations in many countries, the burden of pertussis has declined. However, new-born babies are not protected until they get their first vaccination at 2 or 3 months of age, when they are particularly vulnerable to a severe progression of pertussis. To address this immunity gap, in 2007, the Global Pertussis Initiative recommended vaccination against pertussis of parents of a new-born child as part of the 'cocooning' strategy to prevent transmission of pertussis to the baby (K. D. Forsyth et al., 2007; Visser, 2018). Later, a vaccination during pregnancy was found to be more effective, and Maternal Pertussis Vaccination (MPV) was introduced in the UK in 2012, followed by Australia in 2014. MPV is a pertussis vaccination given during the 2<sup>nd</sup> or 3<sup>rd</sup> trimester of pregnancy. It has been found to be safe and effective for both the mother and the child, by providing passive immunity to the baby via transplacental transport of maternal antibodies (Vygen-Bonnet et al., 2020).

### **Netherlands' National Immunisation Programme**

The Netherlands' National Immunisation Programme offers vaccinations free of charge to all children. Vaccinations include Pertussis, Diphtheria, Tetanus, Poliomyelitis, Haemophilus influenza type b, Hepatitis B, Mumps, Measles, Rubella, Meningococcal ACWY, and HPV. The first vaccination is offered at 3 months of age, and there is a total of 8 vaccination moments, the last one at 14 years old. All vaccinations are voluntary. The NIP is managed by the National Institute of Public Health and the Environment (RIVM), that is also responsible for providing information about the NIP to child vaccine providers and parents. The Youth Health Centres offer preventive care to all children and are responsible for consulting about and administering child vaccinations. This kind of centralised organisation of vaccination provision is different than many other European countries, where child vaccinations are often provided by general practitioners or paediatricians.

Until recently, participation in the programme was high with an uptake of over 95% for pertussis and most other vaccines for children up to 2 years old. However, since 2011, participation decreased, down to an uptake of 92.6% of pertussis vaccination in 2015, where it stabilised (van Lier et al., 2017).

### **MPV in the Netherlands**

The Minister of Health, advised by the Dutch Health Council, decides whether a new vaccine will be included in the NIP, and for which target groups. The Health Council advised in 2015 that to protect infants aged 5 months and younger, pregnant individuals should be offered MPV at 22 weeks of pregnancy. MPV was implemented in the NIP in 2019 and is

given as a combination vaccine containing Tetanus and Diphtheria in addition to pertussis, because a single pertussis vaccination is not available.

In the Netherlands, pregnant individuals on average have 13 consultations during pregnancy with an obstetric care provider. This is usually a midwife or a gynaecologist. Some obstetric care clinics also provide group-care called Centering Pregnancy (CP). In this form of antenatal care, individual consultations are replaced with group-sessions including 8-12 pregnant individuals.

The obstetric care provider notifies pregnant individuals about the possibility of getting the vaccine and hands out an information leaflet at or before 16 weeks of pregnancy. The leaflet includes a link to the website of the RIVM, and instructions on how to make an appointment at the Youth Health Centre via internet or telephone to get the MPV. The Youth Health Centres have the task to inform about the MPV as well as to administer the vaccine. In practice, many midwives and other obstetric providers also counsel about MPV.

### **Vaccine acceptance and hesitancy**

The success of any vaccination programme relies on the uptake of the vaccines. In most countries, childhood vaccinations are voluntary. Because of sub-optimal vaccine acceptance rates and vaccine hesitancy all over the world, the WHO Strategic Advisory Group of Experts (SAGE) on vaccine hesitancy was formed in 2014 (*Report of the SAGE Working Group on Vaccine Hesitancy*, 2014). The group defined vaccine hesitancy as ‘delay in acceptance or refusal of vaccines despite availability of vaccine services’. But vaccine hesitancy also occurs among those eventually choosing to accept vaccination, so it cannot be defined by behaviour only. More recently, a new definition has been proposed by Bussink-Voorend and colleagues based on a thorough literature review (Bussink-Voorend et al., 2022). They define vaccine hesitancy as ‘a psychological state of indecisiveness that people may experience when making a decision regarding vaccination’.

The state of indecisiveness can occur for many reasons and among many different sub-populations. One way of classifying vaccination decisions is proposed by Peretti-Watel and colleagues. They argue that decisions to refuse vaccines can be active or passive. In addition, decisions to accept vaccines can also be passive or active. Active decisions tend to be more engaged, deliberated and more stable. Passive decisions tend to be more uninformed and reliant on social norms (Peretti-Watel et al., 2015).

### **Informed decision making**

A decision-making process described above as highly engaged, when based on relevant information, can be categorised as an informed decision. Informed decision making is de-

defined as: “a decision that is based on relevant knowledge, consistent with the decision-maker’s values and behaviourally implemented” (O’Conner & O’Brien-Pallas, 1989). In recent years, there has been increasing focus and attention for autonomy and shared decision making in healthcare. As people become more involved in decisions about their health, informed decision making is essential to ensure a decision based on facts and values. Furthermore, an informed choice is preferred by people deciding about MPV, wanting to have sufficient information (Kilich et al., 2020; Qiu et al., 2021) and deliberating what the information means for them personally (de Munter et al., 2020). We argue that informed decision making will eventually lead to an increased uptake of MPV, because if one has access to evidence-based information, they are likely to decide in favour of MPV. This thesis will focus on informed decision making as a vehicle to improve uptake of MPV.

### **(Health) Literacy**

When talking about vaccination decisions, it is important to note that some people are more at risk of being missed by vaccination programmes than others.

Literacy has been defined as ‘the ability to identify, understand, interpret, create, communicate and compute, using printed and written materials associated with varying contexts’ (UNESCO Institute for Statistics, 2022). In the Netherlands, there are an estimated 2.5 million people with low-literacy skills, with a higher prevalence among low-educated people, migrant and elderly (Algemene Rekenkamer (2016), 2016; Buisman et al., 2013; Heijmans et al., 2016). One of the contexts in which low literacy can influence decision making is the health and healthcare domain. Health literacy is defined as ‘an individuals’ ability to find health information, interpret it, and apply it to health-related decisions. Recently it has been emphasised that the definition of (health) literacy should be more society-focused rather than solely focused on the skills of the individual. Health literacy does not just represent a lack of skills in an individual but rather a mismatch between how health information is conveyed and how it is received (Ancker et al., 2020). Therefore, it is important to make efforts to make health information as fitting and accessible as possible.

Active engagement in health and healthcare-decisions is lower among those with low (health) literacy and a lower educational background (Barton et al., 2014; Goggins et al., 2014; S. K. Smith et al., 2014; Yin et al., 2012). There are indications that people with low socio-economic status and low health-literacy more often refuse vaccinations (Lorini et al., 2018). Furthermore, they more often make vaccinations decisions that are uninformed or passive (Peretti-Watel et al., 2014). Therefore, we will have extra attention for those groups throughout this thesis and we will aim to make interventions that are produced inclusive and accessible.

### **Social-psychological framework for vaccine decision making**

Vaccine acceptance and hesitancy can be psychologically described using several theories. First, the Theory of Planned Behaviour (TPB) (most recent version: Reasoned Action Approach (Fishbein & Ajzen, 2010)) states that behaviour is most proximally determined by intention to perform a that behaviour (i.e. accepting the vaccination), and intention can be explained by attitude towards that behaviour, subjective norms and self-efficacy (Ajzen, 1991). Attitude is defined as “the degree to which a person has a favourable or unfavourable evaluation or appraisal of the behaviour in question” (Ajzen, 1991). Subjective norms are constituted by descriptive norms and injunctive norms. Descriptive norms refer to the expected behaviour of other people. In this case, whether other people are expected to receive vaccination. Injunctive norms refer to perceptions of what is approved or disapproved by others, i.e. the opinions about vaccination of important others. Self-efficacy or perceived behavioural control is the perceived ability to perform the behaviour. For vaccination behaviour, this translates to the perceived ability to inform oneself, talk about and decide about vaccination, as well as getting the vaccination (Ajzen, 1991). It should be noted that although intention is a strong predictor of behaviour, there is a gap between intention and behaviour in which barriers play a role, such as the availability, ease of access and if applicable, affordability of the vaccination (DiBonaventura & Chapman, 2005).

In addition to the TPB, the Health Belief Model (HBM) argues that people’s specific beliefs about risks, in this case perceived severity and susceptibility of the disease and the perceived benefits and risks of the vaccine, also relate to health behaviour (Janz & Becker, 1984). In the case of vaccinations, risk perception is twofold: on the one hand there is the risk of side effects of the vaccine, and on the other hand the risk of getting the disease without vaccination. Research has identified that the public underestimates the risks of getting a disease and overestimates the risk of side effects of vaccines (Hobson-West, 2003).

In addition to cognitive factors like attitude, social norms and risk perceptions, affective factors and emotions are also of influence on vaccination decisions (Dubé et al., 2018; Gavaruzzi et al., 2021; Tomljenovic et al., 2020). For example, worry and anxiety about the consequences of accepting or refusing vaccination, and anticipated regret about accepting or refusing vaccination are found to play a role in decision making about vaccine uptake (Chapman & Coups, 2006; Chou & Budenz, 2020). Affective states such as indifference can also be of influence (Dubé et al., 2018). Tomljenovic and colleagues argue that emotions are expected to influence vaccine uptake both directly and via cognitive factors such as attitude (Tomljenovic et al., 2020). Emotional competences are found to influence all dimensions of attitudes towards vaccines (Gavaruzzi et al., 2021). Emotions can influence vaccinations in both the direction of accepting or refusing vaccination. As

Foster and colleagues stated in a study about parental decision making about vaccination: "Fear, worry and guilt surrounding vaccination led some parents to decide against it or to defer the decision, whereas it motivated others to vaccinate. Parents described anticipating that they would regret vaccinating, while others anticipated regretting not vaccinating and some felt torn between the two" (Forster et al., 2016).

## **MPV decision making**

### ***Determinants of MPV uptake***

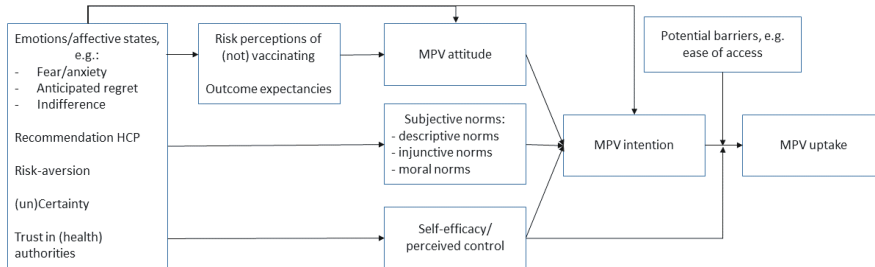
MPV is not like other vaccinations; one takes it to protect their unborn baby rather than (just) themselves. Therefore, it is important to understand the factors underlying hesitancy and decisions about MPV specifically, as well as potential barriers and facilitators of MPV uptake. A review and meta-analysis on factors that influence decision making about vaccinations during pregnancy showed that the most influential factor associated with uptake of MPV was recommendation from a healthcare professional; uptake was 10-fold among those who received a recommendation, compared to those who did not (Kilich et al., 2020). In line with the Health Belief Model described earlier, beliefs about safety of the vaccine were another influential factor on MPV uptake, as well as perceived risk and severity of the disease. In line with the TPB, attitudes and social norms such as cultural values were found to be of influence. Furthermore, emotions such as worry and fear about the disease, the safety of the vaccination and pain, uncertainties around the decision and anticipated regret played a role (Kilich et al., 2020). Another review studied factors associated with vaccination uptake during pregnancy specifically in high-income countries and confirmed the role of safety concerns and risk perceptions surrounding the disease. Additionally, they found that information provision was often inadequate, and when this was the case, this negatively influenced the uptake of vaccinations (Qiu et al., 2021). These studies focused on both maternal influenza vaccination and MPV.

To learn more about uptake of MPV in the Netherlands, we can look at a study that was done when cocooning was the preferred method of pertussis prevention in babies. This survey study in the Netherlands found that parents' intention to get vaccinated against pertussis was associated with attitude, anticipated negative affect of refusing or accepting the vaccination, decisional (un)certainty, moral norms about getting vaccinated, risk perceptions around the baby getting pertussis, and beliefs about the effectiveness of the vaccination strategy (Visser, Kraan, et al., 2016).

Figure 3 shows an overview of factors related to MPV uptake based on literature, complemented with theories mentioned in the section above (the TBP, HBM, and classification of vaccination decisions). It is important to note that in reality, factors may be influencing



each other in more ways than visible in the Figure. For example, trust in authorities could influence emotions and affective states.



**Figure 3.** Overview of factors related to MPV uptake, based on literature.

### ***The decision-making process***

As mentioned, decision making about vaccinations varies across people and groups. Not everyone has doubts – some people accept the vaccine if it is recommended by their health-care professional and do not experience much hesitancy (*Report of the SAGE Working Group on Vaccine Hesitancy, 2014*). Others need more information or experience uncertainty. A qualitative study about MPV among vaccine-hesitant, religious pregnant individuals found that the decision making process can be divided into three stages: orientation, deliberation and the final decision (de Munter et al., 2020).

In the current situation in the Netherlands, the obstetric care provider notifies pregnant individuals about MPV. Usually this is when the orientation phase starts. During the orientation phase, participants have a need for basic information as well as tailored information provided by a health-care professional, additional written information, and information using viewpoints matching on their personal values (in this study, religious and ethical values). Additionally, there is a need for conversation about the vaccination with the partner, and relatives, friends and peers, as well as with the health-care professional (de Munter et al., 2020).

Online information is widely used during pregnancy (Lagan et al., 2011). A study in the UK showed that about 40% of pregnant individuals seek information specifically about MPV online, in addition to information provided by their health-care professional (Clarke, 2020). Even before the COVID-19 pandemic, social media changed the way people seek and share health information (Li et al., 2018). Online information on social media about

vaccination is widely spread, and has been found to influence opinion about vaccination and public trust in vaccines (Betsch & Sachse, 2012; ECDC, 2012) and vaccine uptake (Dunn et al., 2017). How pregnant individuals search for information about vaccinations is of valuable insight to the development of healthcare programmes that target the online environment. In the Netherlands, it has not yet been researched which specific types of information pregnant individuals look for online in the context of MPV, how they judge the reliability of online information, and how they prefer the information to be offered to them.

After acquiring satisfactory information about MPV, the information is considered during the deliberation phase. Participants in the Dutch study among hesitant individuals indicated needing time to reflect on how what they have learned relates to parental responsibility, their (religious) values, and health. Participants in the study indicated needing enough time in both the information and deliberation phase to make a decision (de Munter et al., 2020). After the deliberation stage, in the final stage, the decision is made.

### **Increasing uptake of MPV**

Despite efforts to promote vaccine acceptance and decrease hesitancy about vaccines, MPV uptake remains sub-optimal in most countries where it is offered and funded. In the USA, where MPV was introduced in 2011, uptake was 48.8% in 2016, and 23.3% was not recommended or offered the vaccine (CDC, 2017). In the UK, where MPV was introduced in 2012, uptake balanced around 70% in 2017. In the Netherlands, uptake of MPV was 70% in 2020 (van Lier et al., 2021).

Bisset and Paterson (2018) have reviewed interventions aimed at increasing uptake of vaccination during pregnancy in high-income countries, including influenza and pertussis vaccinations. They describe that although there is limited high quality evidence for strategies in high-income countries to increase coverage of pertussis and influenza vaccination, some strategies seem to be promising. These included reminders for vaccine providers, and the midwives providing the vaccinations. They further added that patient education is most effective when provided by the midwife, and education of providers of vaccination is just as important as educating patients (Bisset & Paterson, 2018). Information for patients should include information on efficacy, safety, benefits and timing of vaccination, as well as practical information on how and where to get the vaccine. In 2019, Mohammed et al. reviewed interventions specifically aimed at increasing uptake of MPV, and found that although most interventions struggled to improve uptake, provider awareness and cues to action such as reminders in the electronic patient record were effective (Mohammed et al., 2019). A 2021 review by Patel et. al confirmed that cues to action for providers like standing orders and opt-in orders, and provider education, on-site vaccination and interactive patient education were most effective (Patel et al., 2021). Standing orders meant

making the MPV part of the status quo and were slightly more effective than opt-in orders. This shows how important it is to embed MPV in usual care settings. Whereas the review mentions provider education in general, we believe that all health-care professional that are involved should be included in the definition of 'provider'. This includes obstetric care providers in the Dutch context, who are responsible for notifying pregnant individuals about the option to get the MPV.

In the usual care situation, individuals are offered a leaflet with information by the obstetric care provider, and they are referred to the Youth Health Services for counselling about MPV and getting MPV. This thesis focuses on additional interactive patient education and communication about MPV to increase uptake of MPV in the Dutch context. There are few interventions promoting MPV that have been systematically developed, and therefore, it is difficult to assess which components of interventions were successful in meeting the needs of the target group. Therefore, we will use Intervention Mapping as a tool to systematically research and develop interventions to increase uptake of MPV in the Netherlands.

### **Intervention Mapping**

Intervention Mapping is a 6-step protocol to systematically develop interventions for health promotion and behavioural change. It provides a framework that facilitates the design, planning, implementation, and evaluation of health promotion interventions. Step 1 concerns the formation of a logic model of the problem. In this step, the behavioural and environmental causes of the problem are identified, and the underlying determinants reflected as cognitions, beliefs, and feelings of members of the at-risk population and environmental decision-makers. In Step 2, performance objectives (POs) are formulated. These are the (sub)behaviours that must be performed by the target group in order to reach the intervention goal. Also, for each PO and its determinants, change objectives are formulated. Step 3 concerns the design of the intervention programme and its themes, components, scope, and sequence. This step includes the selection of theory-based intervention methods and the translation of these methods into practical applications, considering the parameters for the effectiveness of these methods. In Step 4, the methods and practical applications are being creatively translated into a coherent intervention during the production phase, including pretesting of prototypes. In this phase, we used the user-centred design approach (Kristensson et al., 2008) to make sure the interventions fit the needs and wishes of the target group. Involving members of the target group in the development of an intervention is a crucial part of the IM protocol (Bartholomew Eldredge et al., 2016). In Step 5, the use of the intervention in real-life settings is carefully planned to ensure that the intervention will be adopted by the intended users and implemented according to the protocol to ensure sustained, long-term use of the intervention. Finally,

Step 6 concerns the planning of the process and effect evaluation of the intervention to measure programme implementation and outcomes (Bartholomew Eldredge et al., 2016).

In line with the IM protocol, this thesis starts with a needs assessment (**Chapter 2 and 3**). Then, the intervention development will be described (**Chapter 4 and 5**). Finally, the evaluation of the interventions will be described (**Chapter 6, 7 and 8**). Below, I briefly introduce these three components of the thesis.

### **The needs assessment**

MPV is administered to pregnant individuals, therefore they will be the target group. Despite focusing on the group as a whole, we will have extra attention for those extra at risk of not being included in MPV programmes. In high-income countries like the Netherlands, MPV uptake is typically lower among younger people, with more children, and a lower educational background, and belonging to minorities such as those with a non-Western migration background (Bödeker et al., 2014; Byrne et al., 2018; Campbell et al., 2015; Laenen et al., 2015; McAuslane et al., 2018; McQuaid et al., 2016). Throughout our studies, we will aim to include representative samples including these groups.

In the needs-assessment, we studied the determinants of MPV intention in the Netherlands (**Chapter 2**). We also studied the preferences of pregnant individuals for the organisation of MPV and information around MPV (**Chapter 3**). Furthermore, focus-group interviews with pregnant individuals (reported as part of the systematic description of the intervention development in **Chapter 5**) provided more in-depth insight into decision making about MPV. Insights from these studies led us to the development of two interventions. The first is an online decision aid, given that literature showed the extensive use of the internet for information seeking, and the need for comprehensive, reliable information online (Clarke, 2020). The second is a group-based antenatal care (CP) intervention, because of the importance of the interaction between midwives and pregnant individuals, and the success of CP interventions to reach at-risk populations that may be missed by online interventions.

### **The intervention development**

#### *Online decision aid*

A decision aid is a tool aimed at preparing people to make a (medical) decision, while functioning complementary to and not as a replacement of an interaction with a health-care professional. A decision aid aims to provide clarity about the decision that needs to be made by providing relevant information about the available options and outcomes, and interpreting these in the light of personal values (*IPDAS Voting Document*, 2005). In the

context of decisions about screening, decision aids result in greater knowledge among users, lower decisional conflict, less people who were passive in the decision making, and less people who still felt undecided after already having made the decision compared to usual care conditions (Stacey et al., 2011). In the context of vaccination decisions, although studies are few, decision aids have similarly shown to decrease decisional conflict. The effects of decision aids on uptake of MPV are as yet inconclusive (Bruehl et al., 2020). This thesis aims to address this knowledge gap.

Because the internet is an accessible and much used source of information during pregnancy (Clarke, 2020), a decision aid for MPV decisions could reach many people if available in an online format. Additionally, an online format makes it possible to make the decision aid interactive and tailored to the needs of each person. Both of these strategies have been found to be effective in online interventions (Patel et al., 2021; Rimer & Kreuter, 2006).

Little is known about how to address affect and emotions in online interventions about vaccinations, even though many online information sources that are negative about vaccinations often used emotional appeals (Betsch et al., 2010). Therefore, aside from applying user-centred design and pre-tests in the development of the intervention as a whole, we experimentally pre-tested online instructions to use emotion-regulation strategies to deal with negative affect regarding MPV decision making. The results from this experiment are described in **Chapter 4**. **Chapter 5** describes the involvement of the target group and the pre-tests for the development of the decision aid.

Although online decision aids are suitable for a significant part of the target group, not everyone benefits from this form of decisional support. Online health interventions have shown to be less successful in access, uptake, adherence and effectiveness among socio-economically disadvantaged groups, while we need to reach these groups especially because they are at risk of not being included in vaccination programmes. That is why, in addition to making the online decision aid as accessible as possible, we developed an additional intervention more suitable for all sub-groups and focused on the interaction between health-care professional and patient: a CP intervention.

### ***Group-based antenatal care: Centering Pregnancy***

CP is group-based prenatal care where individual consultations during pregnancy are replaced with 10 group sessions, led by a midwife or other obstetric-care provider (Massey et al., 2006). There are 8-12 participants in a group. Because the group sessions are much longer (90-120 minutes) compared to individual sessions, there is more time for education, self-management, skills building, and building trust between caregiver and clients (Ickovics et al., 2007; Lorig & Holman, 2003; Zantinge et al., 2009).

CP is associated with better pregnancy outcomes and an increase in the initiation of breastfeeding compared to individual care. Pregnant individuals felt more able to voice opinions about care and indicated that they were more likely to feel that their wishes were listened to by care providers (Rijnders et al., 2019). CP has been found a successful method to reach at-risk populations (Grady & Bloom, 2004; Picklesimer et al., 2012; Rijnders et al., 2019).

Each CP session has an overall plan, but emphases and topics are based on the needs of each group. Because of the long sessions and the opportunity to socialise, group cohesion takes shape, and an environment is created where participants can support each other. The leadership of the midwife is transparent and facilitative. Participants are involved in check-ups and self-care activities, so they learn to understand how their body is changing during pregnancy. These principles of CP are founded by the Midwifery Model of Care, and derived from social-cognitive theory, targeting social support and self-efficacy enhancement (Rising et al., 2004).

With CP already implemented in the Dutch care setting in approximately 35% of midwifery clinics, the ideal context for discussing MPV is created. Therefore, we decided to create a CP module focused on MPV decision making that can be implemented in the existing care setting.

**Chapter 5** describes the development of the CP intervention and the online decision aid, the theoretical rationales and the involvement of the target group and relevant stakeholders in the process of the intervention design.

### **Evaluation of the interventions**

Interventions need to be evaluated to see whether they reached their aims, and to assess if they should be implemented on a larger scale, and with which potential adjustments. Additionally, the effective components of the interventions need to be identified to inform the future development of health-promotion interventions, and the conditions under which strategies that are used are effective. We aimed to perform extensive evaluations for both the online decision aid and the CP intervention, but due to COVID-19 regulations and to protect the safety of participants and midwives during the pandemic, the CP intervention could not be studied in a large-scale randomised controlled trial (RCT) within the timeframe of the project. As an alternative, we performed a smaller-scale feasibility study once a small amount of data-collection was possible.

### ***Feasibility study***

Feasibility studies help determine whether an intervention should be recommended for efficacy testing. Key areas of focus for feasibility studies of interventions can be implementation of the intervention, acceptability, demand and practicality of the intervention, as well as adaptation, integration, expansion and if possible a limited measure of efficacy (Bowen et al., 2009). We chose to focus on (1) to what extent the intervention was implemented as intended, (2) how the intervention was perceived by CP participants and facilitators, thereby assessing acceptability, demand and practicality of the intervention, and (3) efficacy, to see if we can identify, despite a small sample, whether the intervention shows promising outcomes on MPV attitude and intentions. With this study, we aim to assess whether the intervention meets the needs of the target group and can be scaled up in its current form (**Chapter 8**).

### ***Effect evaluation***

The effect evaluation compares the outcomes between groups with and without exposure to the intervention, in our case the online decision aid, in an RCT. The pre-defined outcomes in this project are MPV uptake, informed decision making about MPV, and determinants of MPV uptake. Aside from comparing effects between the control and the intervention conditions, we will also investigate whether a dose-response relationship occurs (in this case, dose refers to extent of use of the intervention). In addition, we are interested in the generalizability of the outcomes of the RCT for the target group, which tells us how effective the intervention would be if implemented across the Netherlands. Therefore, we will look at whether any potential effects are consistent across different groups based on baseline characteristics. The results of the RCT with the online decision aid intervention are described in **Chapter 6**.

### ***Process evaluation***

Aside from the effects of the interventions, we are also interested in why the interventions have the effects they have. This is why we also did a process evaluation for the decision aid, which "can be used to assess fidelity and quality of implementation, clarify causal mechanisms and identify contextual factors associated with variation in outcomes" (Moore et al., 2015). This is particularly relevant for the future development of similar interventions, and the implementation of the existing interventions in different contexts. A process evaluation reports on the intervention reach, as well as the dose (in this case, extent of use) of the intervention, as well as on a dose-response relationship. Because we addressed the dose-response relationship as part of the effect evaluation, we focused on reach, use and acceptability (subjective evaluation) of the intervention in the process evaluation. **Chapter 7** describes the process evaluation of the online decision aid.

## Thesis outline

This thesis describes the systematic development and evaluation of two interventions intended to increase MPV uptake and improve informed decision making about MPV. **Chapter 2** describes a study about the determinants associated with intention to accept MPV in the Netherlands, before MPV was implemented in the NIP. **Chapter 3** is a study about the preferences of pregnant individuals surrounding the organisation of MPV and information provision about MPV. **Chapter 4** focuses on affect in the context of MPV and describes an experiment using emotion regulation strategies in a group of pregnant individuals experiencing negative affect surrounding the MPV decision. **Chapter 5** is a detailed description of the intervention development and design rationales. **Chapter 6** reports the outcomes of the RCT with the online decision aid. **Chapter 7** is a study about the use of the online decision aid, and what the use of the intervention tells us about MPV decision making. **Chapter 8** describes the feasibility study of the CP intervention. Finally, in the general discussion (**Chapter 9**), we will critically reflect on the main findings of the studies and the implications for research and practice.







# Chapter 2

## Social-psychological determinants of maternal pertussis vaccination acceptance during pregnancy among women in the Netherlands

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## Abstract

**Background:** Maternal Pertussis Vaccination (MPV) during pregnancy became part of the National Immunisation Programme in the Netherlands late 2019. This study aims to identify social-psychological factors associated with MPV acceptance among Dutch women to add to the current understanding of vaccine hesitancy worldwide, and to inform the development of communication and information campaigns about MPV.

**Methods:** We conducted a cross-sectional study using an online survey among 611 women (174 pregnant women, 205 women who had given birth in the past two years and 232 women of 20-35 years old). The primary and secondary outcomes were vaccination intention and attitude towards MPV, respectively. Pearson's correlation and regression analyses were used to examine social-psychological and socio-demographic determinants of the outcomes.

**Results:** Vaccination intention was most explained by attitudes towards MPV, beliefs about safety, moral norm and the belief about the effectiveness of MPV ( $R^2 = .79$ ). Other factors associated were injunctive norm, anticipated regret of vaccinating, and decisional certainty. Attitudes towards MPV were further explained by descriptive norm, risk perceptions of side effects, and risk perceptions of the baby getting pertussis when not vaccinating, and fear of MPV and of the disease ( $R^2 = .76$ ). Finally, pregnant women had a significantly lower intention and less positive attitude towards MPV than non-pregnant women.

**Conclusions:** Communication about MPV should address the most important determinants of MPV intention and attitude, i.e. beliefs about safety and effectiveness and moral norms. Furthermore, such information may benefit from taking into account affective feelings of pregnant women such as anticipated regret and fear towards MPV. Further research could explore this. The timing of communication about MPV can be important as determinants of MPV acceptance may vary depending on pregnancy status.

## Introduction

Pertussis, commonly known as whooping cough, is an infection of the respiratory tract caused by the bacterium *Bordetella Pertussis*. Pertussis is most severe among infants younger than six months, who are too young to be (fully) protected by vaccination. About half of young infants who get pertussis require hospital care and in rare cases, pertussis in babies may lead to convulsion, encephalopathy and even death (McIntyre & Wood, 2009). Pertussis incidence in the Netherlands has increased since 1996, with a rate of up to 63 per 100,000 during an outbreak in 2011-2012 (van der Maas et al., 2013). From 2005 until 2014, 1,711 cases of pertussis were reported in Dutch infants. Of these cases 1,279 were five months of age or younger with 1,020 being admitted to hospital and five mortalities (Health Council of the Netherlands, 2015). 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 (Health Council of the Netherlands, 2015).

The Netherlands has seen a decline in vaccination uptake since 2003, which stabilised at 90.2% of children completely enrolled in the programme in 2018. There is however vaccine-specific hesitancy, with for example a lower uptake of HPV vaccination (45.4% in 2018). DTaP vaccination for children had an uptake of 92.5% in 2018, with a lower uptake in religious areas (Van Lier et al., 2019). Besides the vaccination against H1N1 influenza (2009) during an outbreak, there is no experience with vaccination of pregnant women in the Netherlands (Health Council, 2009). The uptake of H1N1 vaccination among pregnant women was 63%. It appeared that mothers' beliefs about the protection of the child and possible harmful effects of the vaccine for the unborn child, and the government's, GP's and midwife's advice best predicted vaccination status (van Lier et al., 2012). In the UK, where MPV was introduced in 2012 in response to increased pertussis incidence, uptake stabilised around 70% in 2017 (Public Health England, 2018). In the United States of America, coverage was 54.4% in 2017 (Kahn et al., 2018). In Australia, coverage was estimated at 85.2% in 2017 (Van Buynder et al., 2019).

To effectively communicate and facilitate an informed choice regarding MPV among pregnant women, it is important to gain further understanding of reasons that might hamper or promote MPV acceptance. Even more so because choices and experiences surrounding maternal vaccination appear to impact later decision making processes on childhood vaccination (Danchin et al., 2018). A literature review by Wilson et al. (2015) found that factors associated with vaccine uptake during pregnancy were beliefs about the vaccine safety and effectiveness (Hayles et al., 2016; Hill et al., 2018; Ko et al., 2015; Varan et al.,

2014), a desire to protect the baby (Winslade et al., 2017), perceived risk (i.e., perceived susceptibility of the baby to get pertussis if not vaccinated, and perceived severity of the disease) (Hayles et al., 2016; Hill et al., 2018), the opinion of the partner (Campbell et al., 2015), the recommendation by a healthcare professional to get the vaccine (Bödeker et al., 2014; Hill et al., 2018; Ko et al., 2015; Laenen et al., 2015; McQuaid et al., 2016; O'Shea et al., 2018; Varan et al., 2014; Winslade et al., 2017), and the logistic convenience to get the vaccine (Winslade et al., 2017). In the Netherlands, insights into the reasons for MPV acceptance are lacking. A study on the acceptance of a cocooning strategy among parents (where the parents get vaccinated to prevent infecting the child) found attitude, anticipated regret, and decisional certainty to be associated with vaccine acceptance (Visser, Kraan, et al., 2016). It is unclear which factors are of influence at different moments in the decision-making process, for example before or during pregnancy. Insights in these factors could guide the development of communication about MPV to facilitate informed decision making and decrease decisional conflict.

This study aims to identify social-psychological factors associated with MPV acceptance among Dutch women who are pregnant and who are not pregnant or have recently given birth. These determinants are theoretically based on social cognitive theories to explain human behaviour, in particular the Health Belief Model (HBM) and the Theory of Planned Behaviour (TPB) (Ajzen, 1991; Janz & Becker, 1984). Besides, factors such as beliefs about safety and effectiveness, decisional certainty, moral norms, and risk perception are suggested to be critical by the existing literature on vaccine acceptance in pregnancy and by focus groups on vaccine acceptance in a cocooning strategy (Hayles et al., 2016; Hill et al., 2018; Ko et al., 2015; O'Shea et al., 2018; Pot, Paulussen, et al., 2017; Varan et al., 2014; Visser, Kraan, et al., 2016; Winslade et al., 2017). We included both pregnant and non-pregnant women to examine whether the findings for pregnant women are different compared to non-pregnant women, as different factors may be of influence during different moments of the decision-making process.

## **Methods**

### ***Study design***

This is a cross-sectional, survey-based study.

### ***Participants***

A questionnaire was set out in April 2017 among two existing, online panels organised via Flycatcher, a private, ISO 26362 certified research company. People could join the panel online and by participating in online questionnaires, the panel members could collect

points that can be exchanged for gift vouchers. Panel members were recruited via e-mail if they represented women who (a) were pregnant and therefore in the position to decide about maternal vaccination, (b) had given birth within the last two years and could imagine how they would have felt making the decision, or (c) did not have children, but were of childbearing age (20-35). Participants were excluded if response rate was insufficient or if they explicitly indicated that they did not have a wish to become pregnant. They were also excluded if they had already received MPV during their current pregnancy, because this could cause confirmation bias, i.e., people are more likely to be positive about the vaccination if they have already received it.

### ***The online questionnaire***

The survey was based on two general theoretical frameworks, the Theory of Planned Behaviour (TPB) and the Health Belief Model (HBM). The Theory of Planned Behaviour (TPB) argues that intention (i.e. the intention to perform a certain behaviour) is the main predictor of behaviour, which is in turn predicted by attitude and perceived social norms (Ajzen, 1991). According to the Health Belief Model (HBM), a decision to engage in certain health behaviour is determined by risk perception. Risk perception results from the extent to which one perceives oneself susceptible to a health threat ('perceived susceptibility') and the extent to which one perceives the threat as severe ('perceived severity'). In addition, the likelihood to perform the behaviour depends on the perceived benefits of and barriers to that behaviour (Conner & Norman, 2007; Janz & Becker, 1984).

Attitude is defined as "the degree to which a person has a favourable or unfavourable evaluation or appraisal of the behaviour in question" (Ajzen, 1991). Social influences are constituted by descriptive norms and injunctive norms. Descriptive norms refer to the expected behaviour of other people, i.e. whether other pregnant women are expected to receive MPV.

Risk perceptions (i.e., perceived severity and susceptibility) of side effects for the mother and the child, and the baby getting whooping cough when not vaccinating were included in this study. This also accounts for outcome expectancies, referring to a person's estimation of the benefits and barriers of accepting MPV, beliefs about the vaccine's effectiveness and safety, as well as beliefs about alternative strategies for the prevention of whooping cough. Because some people may hold both positive and negative beliefs about the vaccination, the concepts of outcome expectancies and beliefs about the safety of the vaccine are based on weighing both beliefs in favour and in disfavour of the vaccine.

In the case of vaccine acceptance (Chapman & Coups, 2006), research has shown that decisions are not only influenced by cognitive biases (Tversky & Kahneman, 1974). Since

affective factors appear important too (Slovic et al., 2007), we also included anticipated regret of vaccinating, fear of MPV or of the baby suffering from whooping cough, feelings of trust in the NIP, the government and the Dutch National Institute for Public Health and the Environment, i.e. the RIVM (Chapman & Coups, 2006). Previous experiences with other vaccinations and with whooping cough, and the feeling that it is the moral responsibility of a pregnant woman to get MPV, i.e. moral norm, have been found to influence vaccine acceptance and were included in our study (Dubé et al., 2018).

Because decisional certainty, i.e. the extent to which someone found it easy to make the decision or had doubts, has shown to influence vaccination behaviour (Visser, Kraan, et al., 2016), we included a subscale of the complete decisional conflict scale by O'Connor (1995). This subscale consists of three items: 'deciding on MPV is something I have to give a lot of thought' (1=completely disagree to 7=completely agree), 'I find deciding on MPV ...' (1=very easy to 7=very hard) and 'about the MPV decision I feel ...' (1=very certain to 7=very uncertain) (O'Connor, 1995a).

Socio-demographics included were age, having children, country of birth, working in the healthcare sector, highest completed education (low and intermediate level versus high level of education), and affiliation with religion, homeopathy, natural care and/or anthroposophy.

Table 1 provides an overview of all constructs measured, the number of items used for each construct, an example of an item that was used, the scales used, and the internal validity of each construct. Items targeting attitude, descriptive and injunctive norm, outcome expectancies, beliefs about safety of the vaccine, anticipated regret, fear of MPV or of the baby suffering from whooping cough and trust were measured on 7-point Likert scales. Perceived effectiveness of strategies to prevent pertussis in infants was measured on a 10-point scale. Items with the same underlying theoretical construct were averaged into a composite score when internal consistency was sufficient (Cronbach's alpha  $\alpha > 0.60$  or Pearson correlation coefficient  $r > 0.50$ ).



**Table 1.** Psychosocial variables and their internal reliability.

<i>Variable</i>	<i>Nr of items</i>	<i>Reliability</i>	<i>Example question</i>
Intention 1=low – 7=high	3	$\alpha=.98$	I would be willing to get vaccinated against whooping cough during pregnancy. 1=completely disagree to 7=completely agree
Attitude MPV 1= negative – 7=positive	5	$\alpha=.95$	I think vaccination against whooping cough during pregnancy is: 1=not important at all to 7=very important
Attitude vaccines in general 1=negative – 7=positive	4	$\alpha=.92$	In general, I think vaccination is: 1=very unnecessary to 7=very necessary
Outcome expectancies 1=negative – 7=positive	7	$\alpha=.87$	Vaccination against whooping cough during pregnancy leads to less pertussis among babies. 1=completely disagree to 7=completely agree
Moral norm 1=low – 7=high	2	$r=.89$	I think that it is my responsibility as a pregnant woman to get vaccinated against whooping cough during pregnancy to protect my baby. 1=completely disagree to 7=completely agree
Risk Perception of pertussis in baby if not vaccinating 1=low – 42=high	2 (multiplied*)	NA	How severe is whooping cough according to you? 0=not severe to 6=very severe
Risk Perception side effects vaccine 1=low – 42=high	2 (multiplied*)	NA	Imagine you get vaccinated against whooping cough during pregnancy, what do you think the chance is that you will get side effects? 0=very small to 6=very big
Risk Perception side effects vaccine for the child 1=low – 42=high	2 (multiplied*)	NA	Imagine you get vaccinated against whooping cough during pregnancy, what do you think the chance is that your baby gets side effects? 1=very small to 7=very big
Belief Safety 1=unsafe – 7=safe	7	$\alpha=.89$	I think whooping cough vaccination during pregnancy is safe. 1= completely disagree to 7 =completely agree
Injunctive norm 1=low – 7=high	2	$r=.60$	The people who are important to me will appreciate if I get vaccinated against whooping cough during pregnancy. 1=completely disagree to 7=completely agree
Descriptive norm 1=low – 7=high	1	NA	Most pregnant women will get vaccinated against whooping cough during pregnancy. 1=completely disagree to 7=completely agree
Anticipated regret of vaccinating 1=low – 7=high	1	NA	Imagine you get vaccinated against whooping cough during pregnancy and your baby gets side effects, how much regret would you feel about your decision to get vaccinated? 1=no regret at all to 7=a lot of regret

**Table 1.** (Continued)

<i>Variable</i>	<i>Nr of items</i>	<i>Reliability</i>	<i>Example question</i>
Decisional certainty 1=uncertain – 7=certain	3	$\alpha=.89$	Deciding whether to get vaccinated against whooping cough during my pregnancy is: 1=very difficult to 7=very easy
Trust in NIP and healthcare professionals 1=low – 7=high	3	$\alpha=.88$	How much trust do you have in information you get about pertussis vaccination during pregnancy from your midwife (or other caregiver)/ the RIVM/ the government? 1=No trust at all to 7=A lot of trust
Past experience pertussis 1=no – 2=yes	1	NA	I have experienced that someone in my environment had whooping cough. No/Yes
Past experience pertussis in a baby 1=no – 2=yes	1	NA	I have experienced that a baby in my environment had whooping cough. No/Yes
Past experience vaccine side effects baby 1=no – 2=yes	1	NA	I have experienced that a baby in my environment had side effects from a vaccine. No/Yes
Fear vaccination 1=low – 7=high	1	NA	When I think about getting vaccinated during pregnancy, I feel fear. 1=completely disagree to 7 =completely agree
Fear disease 1=low – 7=high	1	NA	When I think about my baby getting whooping cough, I feel fear. 1=completely disagree to 7=completely agree
Belief effectiveness MPV 1=low – 10=high	1	NA	Is, according to you, whooping cough vaccination during pregnancy an effective way to protect your baby against whooping cough? 1=not effective at all to 10=very effective
Belief effectiveness having Pertussis 1=low – 10=high	1	NA	Is, according to you, the baby going through having whooping cough an effective way to protect your baby against whooping cough? 1=not effective at all to 10=very effective
Belief effectiveness breastfeeding 1=low – 10=high	1	NA	Is, according to you, breastfeeding an effective way to protect your baby against whooping cough? 1=not effective at all to 10=very effective
Belief effectiveness healthy lifestyle 1=low – 10=high	1	NA	Is, according to you, living in a healthy manner an effective way to protect your baby against whooping cough? 1=not effective at all to 10=very effective

Note. NA = not applicable,  $r$  = Pearson  $r$ ,  $\alpha$  = Cronbach's alpha.

\* Multiplication of perceived severity and perceived susceptibility. Perceived susceptibility had a score from 1-7, and perceived severity had a score from 0-6 because if the proposed risk (in this case of the baby getting pertussis) is perceived to be not severe at all, the susceptibility to it is irrelevant. These were multiplied, and this resulted in a scale varying from 0-42 in which 0 is a low-risk perception and 42 is high risk perception.

After giving informed consent, participants had access to the online questionnaire via a personalised link. Women who did not respond were sent a reminder one week after the start of the study. The online questionnaire consisted of 54 questions (see Table 1 for exemplary items). Non-pregnant women were asked to imagine how they would answer the questions in the case that they were pregnant. The questionnaire started with a brief introduction about whooping cough and the planned introduction of MPV during pregnancy, aimed to protect new-borns against whooping cough.

### **Data analysis**

Data was analysed using IBM's SPSS version 25. First, we analysed means and standard deviations and Pearson's  $r$  between study variables. Factors that by univariate analysis appeared significantly ( $p < 0.05$ ) associated with intention were included in a stepwise linear regression analysis on that criterion (backward selection). Social-psychological variables were added in the first step. Socio-demographic variables were added in the second step to correct for demographic variation. We report both the start and end-model of the regression analysis. Because attitude towards MPV appeared to be the strongest predictor of intention, we then repeated the same regression strategy with attitude towards MPV as criterion variable.

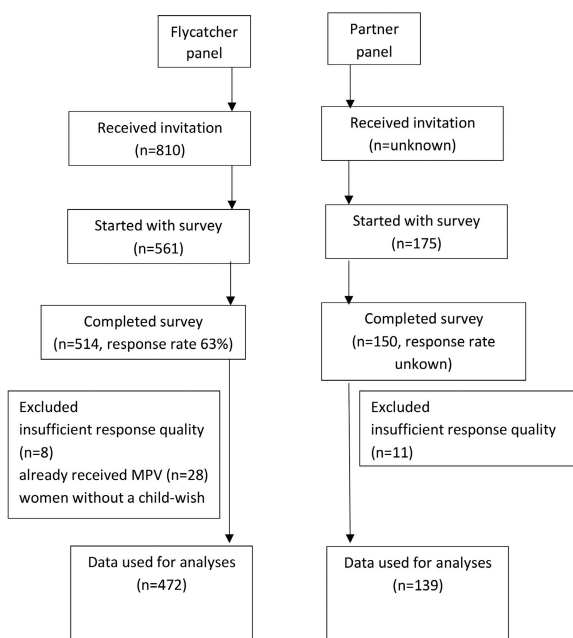
Decisional certainty is somewhat complex to interpret in a linear analysis because the scale only refers to the certainty of the decision and not to the extent to which someone is positive or negative about MPV. It has a possible moderating effect on the relationship between vaccination intention and its determinants, because the extent to which determinants are of influence on health behaviour may depend on the extent to which these determinants are certain (Sparks et al., 2001). Therefore, moderation of the associations between determinants of intention and intention by decisional certainty was explored by adding interaction terms to the linear regression models, with the interaction terms made with the centred values for decisional certainty and the variable associated with intention. If the  $R$  change was positive and the interaction term and  $F$  change were significant ( $p < 0.05$ ), moderation was further explored in a multivariate model with decisional certainty and the concerning dependent variables. The most persistent moderators were then looked at in more detail using simple slopes analyses (Aiken et al., 2003). We computed slopes for the regression of those attitudinal variables on intention at three levels of the moderator variable decisional certainty: one standard deviation above or below the mean (low and high) and the mean level (moderate). The simple slope analyses were done using PROCESS version 3.1 by Andrew Hayes (model 1), using centred variables and 5000 bootstrap samples.

Because we found that pregnancy status was significantly associated with the criterion in our regression models (i.e., vaccination intention), differences in mean scores on all variables were tested between pregnant and non-pregnant women by independent sample t-tests, using 95% confidence intervals.

## Results

### Sample

Figure 1 shows the inclusion of participants. In total 736 women started with the survey and 664 women completed it. Women were excluded when response quality was insufficient ( $n=19$ ), when they had already received MPV during their current pregnancy ( $n=28$ ), or when they explicitly indicated that they did not want to become pregnant ( $n=6$ ). In total 611 women were included in the analyses, including pregnant women ( $n=174$ , of which 68 did not yet have children), women who had given birth to a child within the two years preceding the questionnaire ( $n=205$ ), women aged 20-35 who were not pregnant and did not have children yet ( $n=232$ ). Participants were on average 30 years old. Women who were born in the Netherlands (96%), were highly educated (76%) and who worked in the healthcare sector (38%) were overrepresented.



**Figure 1.** Flow diagram of the recruitment and response of study participants.

Table 2 shows the mean scores on all social-psychosocial measures. Intention towards MPV was scored neutral ( $M=4.11$ ;  $SD=1.57$ ) while attitude was more positive about vaccination in general than about MPV in particular. One should be cautious with interpreting differential mean scores on beliefs about vaccines people are already familiar with for years versus beliefs about a new vaccine to be implemented by the NIP.

**Table 2.** Sample description.

<i>Sociodemographic variables</i>	<i>Mean (standard deviation) for continuous variables and percentages for dichotomous or categorical variables (n=611)</i>
Age	30.34 (4.64)
Has at least one child	
No	49.10%
Yes	50.90%
Pregnant	
No	71.52%
Yes	28.48%
Country of birth	
Netherlands	96.07%
Other	3.93%
Highest education completed	
Low or Intermediate	24.22%
High	75.78%
Work in healthcare sector	
No	62.03%
Yes	37.97%
Religion	
1 = no affiliation – 7 = strong affiliation	2.48 (2.01)
Homeopathy	
1 = no affiliation – 7 = strong affiliation	2.79 (1.65)
Natural Cure	
1 = no affiliation – 7 = strong affiliation	2.73 (1.65)
Anthroposophy	
1 = no affiliation – 7 = strong affiliation	2.15 (1.47)
<i>Social-psychological variables*</i>	
Intention	
1= low – 7= high	4.11 (1.57)
Attitude MPV	
1= negative – 7= positive	4.45 (1.18)
Attitude vaccines in general	
1= negative – 7= positive	5.78 (1.21)

**Table 2.** (Continued)

<i>Sociodemographic variables</i>	<i>Mean (standard deviation) for continuous variables and percentages for dichotomous or categorical variables (n=611)</i>
Outcome expectancies 1= negative – 7= positive	5.32 (1.02)
Moral norm 1= low – 7= high	4.33 (1.63)
Risk perception of pertussis in baby if not vaccinating 1= low – 49= high	9.83 (6.49)
Risk perception side effects vaccine 1= low – 49= high	5.94 (6.05)
Risk perception side effects vaccine for the child 1= low – 49= high	5.76 (6.54)
Belief safety 1=unsafe – 7=safe	4.34 (1.20)
Injunctive norm 1= low – 7= high	4.55 (1.20)
Descriptive norm 1= low – 7= high	4.17 (1.23)
Anticipated regret of vaccinating 1= low – 7= high	4.82 (1.52)
Decisional certainty 1=uncertain – 7=certain	3.87 (1.51)
Trust in NIP and healthcare professionals 1= low – 7= high	5.05 (1.26)
Past experience pertussis	
No (reference)	74.14%
Yes	25.86%
Past experience pertussis in a baby	
No (reference)	93.94%
Yes	6.06%
Past experience side effects vaccine	
No (reference)	71.69%
Yes	28.31%
Past experience side effects vaccine in a baby	
No (reference)	73.49%
Yes	26.51%
Fear vaccination 1= low – 7= high	3.30 (1.69)
Fear disease 1= low – 7= high	4.80 (1.62)

**Table 2.** (Continued)

<i>Sociodemographic variables</i>	<i>Mean (standard deviation) for continuous variables and percentages for dichotomous or categorical variables (n=611)</i>
Belief effectiveness MPV 1= low – 10= high	6.45 (2.09)
Belief effectiveness having pertussis 1= low – 10= high	4.55 (2.40)
Belief effectiveness breastfeeding 1= low – 10= high	5.82 (2.50)
Belief effectiveness healthy lifestyle 1=low – 10=high	5.73 (2.44)

Note. \* A higher score represents a stronger presence of the measured construct.

### **Correlations**

Table 3 shows the Pearson's  $r$  between social-psychological variables and MPV intention. Cohen (1988) argues that correlations of  $r=.10$  to  $.23$  are indicative for a small effect size,  $r=.24$  to  $.36$  for a moderate effect size, and  $r\geq .37$  for a large effect size (Cohen, 1988). Table 3 shows that large associations with intention were found for attitude, beliefs about safety, moral norms and beliefs about the effectiveness of MPV. Large effects were also found for outcome expectancies, injunctive norms, trust, attitude about vaccines in general, and fear of the vaccine. Weaker correlations, but still indicating large effects were found for decisional certainty, risk perceptions of side effects, descriptive norms, and fear of the disease. Moderate effect sizes were found for anticipated regret, and small effect sizes for beliefs about the effectiveness of a healthy lifestyle as a strategy to protect against whooping cough.

**Table 3.** Pearson correlations (n=611)

	1. Intention	2. Attitude MPV	3. Attitude vaccines in general	4. Outcome expectancies	5. Moral norm	6. Risk perception pertussis baby when not vaccinating	7. Risk perception side effects mother	8. Risk perception side effects child	9. Belief safety	10. Injunctive norm
1. Intention										
2. Attitude MPV	.844***									
3. Attitude vaccines in general	.560***	.602**								
4. Outcome expectancies	.637***	.657***	.621***							
5. Moral norm	.753***	.711***	.576***	.558**						
6. Risk perception pertussis baby when not vaccinating	.254***	.247***	.182***	.042	.301***					
7. Risk perception side effects mother	-.460***	-.486***	-.475***	-.640***	-.430***	.100*				
8. Risk perception side effects child	-.484***	-.511***	-.490***	-.634***	-.453***	.012	.807***			
9. Belief safety	.777***	.801***	.576***	.734***	.683***	.142***	-.610***	-.645***		
10. Injunctive norm	.635***	.611***	.434***	.534***	.626***	.154***	-.345***	-.340***	.589**	
11. Descriptive norm	.417***	.386***	.173***	.272***	.418***	.154***	-.196***	-.210***	.334**	.557***
12. Anticipated regret of vaccinating	-.324***	-.352***	-.270***	-.240***	-.337***	-.096*	.288***	.334**	-.452***	-.248***
13. Decisional certainty	.486***	.438***	.176***	.262***	.417***	.076	-.163***	-.186***	.509***	.384***
14. Trust	.615***	.657***	.653***	.649***	.596***	.180***	-.478***	-.524***	.641***	.456***
15. Past experience pertussis (Reference: no)	.110**	.100*	.112**	.059	.045	.022	-.068	-.072	.084*	.028
16. Past experience pertussis baby (Reference: no)	.062	.073	.068	.027	.052	.052	-.027	-.025	.089*	.009
17. Past experience side effects (Reference: no)	-.108**	-.105**	-.191***	-.094*	-.107**	-.092*	.141***	.153***	-.143***	-.055
18. Past experience side effects baby (Reference: no)	-.177***	-.162***	-.203***	-.149***	-.201***	-.114**	.152***	.199***	-.194***	-.155***
19. Fear vaccination	-.521***	-.527***	-.337***	-.406***	-.419***	-.071	.410***	.437***	-.635***	-.357***
20. Fear disease	.396***	.412***	.333***	.390***	.352***	.256***	-.171***	-.215***	.321***	.317***
21. Effect MPV	.717***	.746***	.536***	.679***	.642***	.135*	-.493***	-.494***	.678***	.575***
22. Effect pertussis	.010	.005	-.137***	-.213***	-.015	.036	.127**	.139**	-.086*	.024
23. Effect breastfeeding	-.074	-.040	-.164***	-.119**	-.068	-.065	.139***	.149**	-.127**	.002
24. Effect healthy lifestyle	-.188***	-.191***	-.161***	-.291***	-.153***	.022	.233***	.234***	-.265***	-.089*
25. Age	-.064	-.06	-.056	.004	-.084*	-.03	.068	.089*	-.091*	-.107**
26. Pregnant (Reference: not pregnant)	-.251**	-.125*	-.121**	-.191**	-.164**	.037	.172**	.130**	-.165**	-.193**
27. Children (Reference: no children)	-.095*	-.083*	-.079	-.067	-.133**	-.035	.062	.095*	-.099*	-.092*
28. Country of birth (Reference: Netherlands)	.009	.009	-.008	-.021	.024	.029	.03	.102*	0	.009
29. Education low or intermediate/high (Reference: low or intermediate)	.134**	.147**	.113**	.222**	.074	-.121**	-.155**	-.165**	.166**	.097*
30. Working in Healthcare (Reference: no)	.137**	.147**	.152**	.171**	.083*	-.041	-.189**	-.184**	.171**	.129**
31. Religion	-.094*	-.069	-.080*	-.097*	-.114**	-.026	.129**	.095*	-.120**	-.083*
32. Homeopathy	-.287**	-.308**	-.318**	-.315**	-.286**	-.022	.292**	.318**	-.370**	-.219**
33. Natural Cure	-.313**	-.329**	-.337**	-.347**	-.303**	-.045	.306**	.345**	-.366**	-.215**
34. Anthroposophy	-.212**	-.203**	-.286**	-.335**	-.198**	-.045	.224**	.271**	-.271**	-.101*

Note. \*p<.05. \*\*p<.01. \*\*\*p<.001.



11. Descriptive norm	12. Anticipated regret of vaccinating	13. Decisional certainty	14. Trust	15. Past experience pertussis (Reference: no)	16. Past experience pertussis baby (Reference: no)	17. Past experience side effects (Reference: no)	18. Past experience side effects baby (Reference: no)	19. Fear vaccine	20. Fear disease	21. Effect MPV	22. Effect pertussis	23. Effect breastfeeding	25. Age	26. Pregnant (Reference: not pregnant)	27. Children (Reference: no children)	28. Country of birth (not NL) (Reference: Netherlands)	29. Education Low or intermediate/High (Reference: low or intermediate)	30. Working in Healthcare (Reference: no)	31. Religion	32. Homeopathy	33. Natural Cure	
-.100'																						
.326***	-.325***																					
.236***	-.286***	.253***																				
-.018	-.058	.051	.094'																			
.009	-.057	.100'	.068	.383***																		
-.007	.078	.023	-.148***	.077	.084'																	
-.098'	.040	.025	-.189***	.103'	.127**	.552***																
-.238***	.402***	-.574***	-.414***	-.053	-.042	.125**	.105*															
.185***	-.089'	.084'	.375***	.068	.048	-.015	-.013	.005														
.339***	-.251***	.313***	.607***	.063	-.022	-.065	-.182***	-.411***	.394**													
.104'	.042	.093'	-.081'	.061	.111**	.114**	.044	-.058	-.075	.030												
.049	.138***	.091'	-.124**	.044	-.001	.119**	.063	.019	-.040	.005	.222***											
-.006	.170***	-.043	-.202***	-.095'	-.113**	.018	-.013	.144***	-.058	-.130**	.174***	.428***										
-.059	-.016	-.014	.031	.044	.129**	.226**	.072	.069	-.06	-.091'	-.064	-.105**										
-.170**	.080'	-.106**	-.041	.007	-.01	.04	.107**	-.079	-.208**	-.055	.018	.014	.063									
-.112**	.005	-.032	.027	.043	.094'	.375**	.063	.008	-.127**	-.069	.003	-.065	.502**	.126**								
-.090'	-.01	.03	-.004	.019	-.015	.012	.008	.015	.009	-.053	.035	.001	.032	.04	.03							
.029	-.103'	.136**	.063	.047	.067	.071	-.145**	.119**	.156**	.002	.057	-.101'	.142**	-.185**	.01	.016						
.026	-.141**	.132**	.162**	.183**	.04	.065	-.109**	.065	.105**	.097'	.061	-.143**	-.068	-.06	.047	-.037	.096'					
-.01	0	-.032	.035	.018	-.026	.030	.054	-.037	-.047	.02	.106**	.045	.009	.024	.082'	.061	-.049	.004				
-.02	.183**	-.284**	-.04	.012	.109**	.093'	.247**	-.156**	-.224**	.033	.159**	.135**	.084'	.052	-.005	.067	-.066	-.100**	.227**			
-.04	.145**	-.330**	-.090'	-.008	.114**	.071	.239**	-.144**	-.243**	.058	.220**	.199**	.045	.110**	-.023	.07	-.076	-.117**	.164**	.814**		
.068	.118**	-.254**	-.057	.016	.087'	.017	.182**	-.092'	-.179**	.132**	.181**	.145**	.045	.052	-.021	.037	-.042	-.059	.157**	.623**	.680**	

### **Regression analyses of intended MPV uptake**

Table 4 shows that the linear regression model explained 79% of the intention to accept MPV, both with and without a stepwise backwards selection of determinants. The Akaike Information Criterion (AIC) is lower for the model with backwards selection than for the model with all variables, indicating that the backwards model presents a better fit. In the model with backwards selection, attitude towards MPV appeared the strongest determinant of intention ( $\beta=0.45$ ), followed by moral norms ( $\beta=0.20$ ). Other determinants in the model were beliefs about safety, decisional certainty, injunctive norms, anticipated regret of vaccinating, beliefs about the effectiveness of MPV and breastfeeding as an alternative prevention strategy (all  $\beta$ 's $>0.60$ ; all p-values $<.05$ ).

The explained variance was 76% in the linear regression models predicting attitude towards MPV, and the AIC was lower for the backwards model, indicating a better fit model. Strongest associated with attitude towards MPV were beliefs about safety ( $\beta=0.39$ ) and the effectiveness of MPV ( $\beta=0.27$ ). Moral norms were also significantly associated with attitude towards MPV. Compared to model one, model two had lower significant betas for attitude about vaccines in general, risk perception of the child getting pertussis when not vaccinating, risk perception of the side effects for the child, descriptive norm, trust and fear of the vaccination and the disease (all  $\beta$ 's $\geq 0.06$  all p-values $<.05$ ).

Among the socio-demographics, being pregnant had a significant effect in both models, with a negative effect in model one and a small but positive effect in model two ( $\beta=-0.11$ ;  $p<.001$  versus  $\beta=0.05$ ;  $p<.05$ , respectively). This means that pregnant women had a significantly lower vaccination intention and a significantly higher attitude towards MPV. Affiliation with natural cure and anthroposophy had a small but significant association with attitude towards MPV ( $\beta=-0.08$  and  $\beta=0.06$ , respectively;  $p<.05$ ).

**Table 4.** Regression analyses of MPV intention (model 1) and attitude about MPV (model 2). N=611.

	Model 1a. Multivariate regression with intention	Model 1b. Multivariate regression with backwards selection with intention	Model 2a. Multivariate regression with attitude about MPV	Model 2b. Multivariate regression with backwards selection with attitude about MPV
R <sup>2</sup> (adjusted R <sup>2</sup> )	0.80 (0.79)	0.80 (0.79)	0.77 (0.76)	0.77 (0.76)
F	78.50***	145.13***	67.42***	98.16***
AIC	-378.33	-387.81	-637.34	-650.02
Social psychological variables	Unstandardised beta (standard error)	Standardised beta	Unstandardised beta (standard error)	Standardised beta (standard error)
Attitude MPV	0.56 (0.05)	0.45***	NA	NA
Attitude vaccines in general	-0.01 (0.04)	-	0.08 (0.03)	0.09**
Outcome expectancies	0.02 (0.06)	0.01	-0.03 (0.05)	-0.02
Moral norm	0.19 (0.03)	0.19***	0.07 (0.02)	0.10**
Risk perception pertussis child when not vaccinating	0.01 (<0.01)	0.03	0.01 (<0.01)	0.06**
Risk perception side effects vaccine mother	0.01 (<0.01)	0.02	0.01 (<0.01)	<0.01
Risk perception side effects vaccine child	<0.01 (0.01)	0.01	0.01 (0.01)	0.05
Belief safety	0.19 (0.06)	0.18**	0.37 (0.04)	0.38***
Injunctive norm	0.06 (0.04)	0.05	0.04 (0.03)	0.04
Descriptive norm	0.02 (0.03)	0.02	0.04 (0.02)	0.04
Anticipated regret of vaccinating	0.04 (0.02)	0.04	<0.01 (0.02)	0.01
Decisional certainty	0.08 (0.03)	0.08**	0.02 (0.02)	0.03
Trust	<0.01 (0.04)	<0.01	0.07 (0.03)	0.07*
Past experience pertussis No (reference)	0.11 (0.07)	0.03	0.05 (0.06)	0.02
Yes	-	-	-	-

Table 4. (Continued)

	Model 1a. Multivariate regression with intention	Model 1b. Multivariate regression with backwards selection with intention	Model 2a. Multivariate regression with attitude about MPV	Model 2b. Multivariate regression with backwards selection with attitude about MPV
R <sup>2</sup> (adjusted R <sup>2</sup> )	0.80 (0.79)	0.80 (0.79)	0.77 (0.76)	0.77 (0.76)
F	78.50***	145.13***	67.42***	98.16***
AIC	-378.33	-387.81	-637.34	-650.02
Social/psychological variables	Unstandardised beta (standard error)	Unstandardised beta (standard error)	Unstandardised beta (standard error)	Unstandardised beta (standard error)
	Standardised beta	Standardised beta	Standardised beta	Standardised beta
Past experience side effects vaccine	-0.04 (0.08)	-	<0.01 (0.07)	-
No (reference)	-0.01	-	<0.01	-
Yes	-	-	<0.01	-
Past experience side effects vaccine in a baby	-0.05 (0.09)	-	0.06 (0.07)	-
No (reference)	-0.02	-	0.02	-
Yes	-	-	0.02	-
Fear vaccination	-0.03 (0.03)	-	-0.04 (0.02)	-0.05 (0.02)
Fear pertussis	0.04 (0.02)	-	0.05 (0.02)	0.05 (0.02)
Effectiveness MPV against pertussis	0.06 (0.02)	0.08**	0.15 (0.02)	0.15 (0.02)
Effectiveness healthy lifestyle	<0.01 (0.01)	-	<0.01 (0.01)	-
Sociodemographic variables				
Age	<0.01 (0.01)	<0.01 (<0.01)	<0.01 (0.01)	<-0.01 (0.01)
Pregnant	-0.38 (0.07)	-0.11***	0.13 (0.06)	0.13 (0.05)
No (reference)	-0.11***	-0.11***	0.05*	0.05*
Yes	-	-	-	-

**Table 4.** (Continued)

	Model 1a. Multivariate regression with intention	Model 1b. Multivariate regression with backwards selection with intention	Model 2a. Multivariate regression with attitude about MPV	Model 2b. Multivariate regression with backwards selection with attitude about MPV				
R <sup>2</sup> (adjusted R <sup>2</sup> )	0.80 (0.79)	0.80 (0.79)	0.77 (0.76)	0.77 (0.76)				
F	78.50***	145.13***	67.42***	98.16***				
AIC	-378.33	-387.81	-637.34	-650.02				
Social psychological variables	Unstandardised beta (standard error)	Standardised beta	Unstandardised beta (standard error)	Standardised beta	Unstandardised beta (standard error)	Standardised beta		
Has at least one child No (reference) Yes	0.03 (0.07)	0.01	0.01 (0.07)	<0.01	<0.01 (0.06)	<0.01	0.03 (0.06)	0.01
Country of birth Netherlands (reference) Other	0.02 (0.15)	<0.01	0.02 (0.15)	<0.01	<0.01 (0.12)	<0.01	0.01 (0.12)	<0.01
Highest education completed Low or intermediate (reference) High	-0.04 (0.07)	-0.01	-0.05 (0.07)	-0.01	0.04 (0.06)	0.02	0.05 (0.06)	0.02
Work in healthcare sector No (reference) Yes	0.02 (0.06)	0.01	0.01 (0.06)	<0.01	0.03 (0.05)	0.01	0.04 (0.05)	0.02
Religion	-0.01 (0.02)	-0.02	-0.01 (0.02)	-0.01	0.01 (0.01)	0.02	0.01 (0.01)	0.02
Homeopathy	0.03 (0.03)	0.03	0.03 (0.03)	0.04	0.01 (0.03)	0.01	0.01 (0.03)	0.01
Natural cure	<0.01 (0.03)	<-0.01	-0.01 (0.03)	-0.01	-0.06 (0.03)	-0.08*	-0.06 (0.03)	-0.08*
Anthroposophy	-0.02 (0.03)	-0.02	-0.02 (0.03)	-0.02	0.05 (0.02)	0.06*	0.05 (0.02)	0.06*

Note. \*p<.05. \*\*p<.01. \*\*\*p<.001.

### **Moderation by decisional certainty**

Small moderation effects of decisional certainty on the relation between each variable and intention were found for all social-psychological variables (Table 1 of the appendix) in the univariate analyses and were most persistent for attitude towards MPV, outcome expectancies, and moral norms in the multivariate analyses. Because it may provide a direction for future research, we presented the simple slopes of the three moderated variables that were most strongly moderated in multivariate analyses in Table 5. This table shows that attitude towards MPV had a lower effect on intention under low decisional certainty ( $B=0.94$ ) than under moderate decisional certainty ( $B=1.00$ ) and under high decisional certainty ( $B=1.05$ ). This means that the effect of attitude towards MPV on vaccination intention is larger when participants are more certain about their decision. For attitude towards MPV there is no significant difference in unstandardised beta for the different levels of certainty, but for outcome expectancies and moral norm, there is.

**Table 5.** Simple slope analysis. Values are unstandardised regression coefficients for intention ( $n=611$ ) with 95% confidence intervals at different levels of decisional certainty.

Variable	Level of decisional certainty		
	Low	Moderate	High
Attitude MPV	0.94 (0.83-1.04)	1.00 (0.93-1.07)	1.05 (0.99-1.11)
Outcome expectancies	0.49 (0.35-0.63)	0.76 (0.67-0.85)	0.98 (0.89-1.08)
Moral norm	0.45 (0.38-0.52)	0.61 (0.56-0.67)	0.75 (0.69-0.80)

### **Average differences between pregnant women and non-pregnant women.**

Looking at pregnancy status, the intention to vaccinate was significantly lower among pregnant women than among non-pregnant women (mean difference=0.87). Table 6 shows that pregnant women scored lower on most determinants of intention. Their risk perceptions of side-effects of the vaccine for mother and child were significantly higher (mean differences=-2.30 and -1.87 respectively).

**Table 6.** Mean differences between pregnant women (n=174) and non-pregnant women (n=437).

Variable	Mean (standard deviation) pregnant women	Mean (standard deviation), non-pregnant women	Mean difference	95% interval of the difference	
				Lower	Upper
Intention 1= low - 7= high	3.49 (1.47)	4.36 (1.54)	0.87*	0.60	1.14
Attitude MPV 1= negative - 7= positive	4.22 (1.08)	4.54 (1.21)	0.33*	0.13	0.52
Attitude vaccines in general 1= negative - 7= positive	5.54 (1.26)	5.87 (1.18)	0.33*	0.11	0.54
Outcome Expectancies 1= negative - 7= positive	5.01 (0.96)	5.44 (1.01)	0.43*	0.25	0.61
Moral norm 1= low - 7= high	3.91 (1.53)	4.50 (1.63)	0.59*	0.31	0.87
Risk Perception of pertussis in baby if not vaccinating 1= low - 49= high	10.21 (7.10)	9.68 (6.23)	-0.53	-1.67	0.62
Risk Perception side effects vaccine 1= low - 49= high	7.59 (6.42)	5.29 (5.77)	-2.30*	-3.35	-1.25
Risk Perception side effects vaccine for the child 1= low - 49= high	7.10 (6.46)	5.23 (6.50)	-1.87*	-3.02	-0.74
Belief Safety 1= unsafe - 7= safe	3.94 (1.06)	4.35 (1.23)	0.41*	0.21	0.61
Injunctive norm 1= low - 7= high	4.19 (1.16)	4.70 (1.18)	0.51*	0.31	0.72
Descriptive norm 1= low - 7= high	3.84 (1.15)	4.30 (1.24)	0.46*	0.25	0.68
Anticipated regret of vaccinating 1= low - 7= high	5.02 (1.43)	4.75 (1.54)	-0.27	-0.54	0.00

Table 6. (Continued)

Variable	Mean (standard deviation) pregnant women	Mean (standard deviation) non-pregnant women	Mean difference	95% interval of the difference	
				Lower	Upper
Decisional certainty 1=certain – 7=uncertain	3.62 (1.32)	3.96 (1.57)	0.34*	0.09	0.59
Trust in NIP and healthcare professionals 1= low – 7= high	4.84 (1.21)	5.14 (1.27)	0.30*	0.08	0.52
Past experience Pertussis 1=no – 2=yes	0.23 (0.42)	0.27 (0.44)	0.04	-0.04	0.12
Past experience pertussis in a baby 1=no – 2=yes	0.06 (0.24)	0.06 (0.24)	0.00	-0.05	0.04
Past experience vaccine side effects baby 1=no – 2=yes	0.29 (0.46)	0.25 (0.44)	-0.04	-0.12	0.04
Fear vaccination 1= low – 7= high	3.59 (1.66)	3.19 (1.69)	-0.40*	-0.70	-0.11
Fear disease 1= low – 7= high	4.60 (1.71)	4.88 (1.58)	0.28	0.00	0.57
Belief effectiveness MPV 1= low – 10= high	5.76 (2.07)	6.73 (2.04)	0.97*	0.60	1.32
Belief effectiveness having Pertussis 1= low – 10= high	4.34 (2.29)	4.63 (2.44)	0.29	-0.13	0.72
Belief effectiveness breastfeeding 1= low – 10= high	5.89 (2.59)	5.79 (2.46)	0.10	-0.54	0.34
Belief effectiveness living healthily 1=low – 10=high	5.79 (2.42)	5.71 (2.44)	0.08	-0.51	0.35

Note. \* Indicates a significance of the mean difference at the level of the 95% confidence interval.



## **Discussion**

### ***Main findings***

This study explored the determinants of intention to accept MPV during pregnancy among a sample of pregnant and non-pregnant women. Univariate analyses showed that attitude towards MPV had the strongest correlation with intention, followed by moral norms with regard to MPV, outcome expectancies, beliefs about safety and the effectiveness of MPV, injunctive norms, and trust in the NIP and the RIVM.

The multivariate analyses showed that the regression models were adequate in explaining intention (79% of the variance) and attitude (76%) towards MPV. Intention towards MPV was explained by attitude about MPV, moral norm, beliefs about safety, decisional certainty, injunctive norm, anticipated regret of vaccinating, and beliefs about the effectiveness of MPV. Attitude towards MPV was explained by beliefs about safety and the effectiveness of MPV, moral norm, attitude about vaccines in general, risk perception of the child getting pertussis when not vaccinating, risk perception of the side effects of MPV for the child, descriptive norm, fear of the vaccination and the disease and being pregnant. Pregnant women had a significantly lower intentions than non-pregnant women.

These findings align with earlier findings from other countries, suggesting that social-psychological factors associated with vaccine acceptance include beliefs about safety and effectiveness, as well as risk perception of the disease (Hayles et al., 2016; Hill et al., 2018; Ko et al., 2015; Varan et al., 2014). The association between injunctive norms and vaccination intention corresponds to earlier findings that the opinion of the partner of the respondent and recommendation by a healthcare professional influence acceptance of vaccines during pregnancy (Bödeker et al., 2014; Campbell et al., 2015; Hill et al., 2018; Ko et al., 2015; Laenen et al., 2015; McQuaid et al., 2016; O'Shea et al., 2018; Varan et al., 2014; Winslade et al., 2017). Moral norms towards MPV have been found to be of influence in a qualitative study on pertussis vaccine acceptance in a cocooning strategy (Visser, Hautvast, et al., 2016). Aside from attitude towards MPV and beliefs about the effectiveness of MPV, moral norm was the most robust determinant of vaccination intention, both in the univariate analyses and the multivariate regression analyses. According to norm-activation theory (Schwartz, 1977), moral norms will influence behaviour when individuals are aware of the consequences of their actions for others and when they accept personal responsibility for those actions (Rivis et al., 2009a). In the case of MPV, the choice to accept or refuse MPV may have consequences for the child once it is born and might be activated when women become aware of the risks of accepting or refusing the vaccine. Contrarily, non-pregnant women appeared to feel more of a moral obligation to vaccinate than pregnant women.

This may be due to a lower risk perception of side-effects of the vaccine in non-pregnant women than in pregnant women.

We found moderating effects of decisional certainty for almost all variables in the univariate analyses, with stronger effects on intention under high certainty than under low certainty, although these effects did not persist in multivariate regression models. However, low decisional certainty can be a sign of attitudinal ambivalence (holding both positive and negative beliefs on a subject simultaneously) and this has been found to moderate the attitude-behaviour relationship in research studying other health behaviours (Conner et al., 2003). Measurements of intention, attitude and decisional certainty may have some level of interdependence, and independent measurements are needed to firmly state that effects of attitude are lower under a low decisional certainty than under high decisional certainty. Therefore, it would have been ideal to include behaviour instead of intention in the moderation analysis. Attitudinal ambivalence can lead to negative affect surrounding decision making (van Harreveld et al., 2015) and individuals with high attitudinal ambivalence towards specific behaviour are more pliable and less stable over time in performing these behaviours (Armitage & Conner, 2000).

Intention and associated variables were lower among pregnant women than among non-pregnant women. The regression analyses and mean differences show a larger difference in intention than attitude towards MPV between pregnant and non-pregnant women. A possible explanation for these differences is the so-called hot-cold empathy gap. 'Cold' being the group of non-pregnant women, who do not have to make the decision yet, 'hot' being the group of pregnant women who are closer in time to the decision on MPV. Cold-to-hot empathy gaps in medical decision making were first described by Loewenstein (2005) as: "... people mis-predict their own behaviour and preferences across affective states. When people are in an affectively 'cold' state, they fail to fully appreciate how 'hot' states will influence their own preferences and behaviour" (Loewenstein, 2005). In this context, vaccination intention and its determinants are lower among pregnant women, for whom the choice is more urgent compared to non-pregnant women.

### **Limitations**

This study has limitations. First, the size of the group pregnant women (n=174) within the sample is small to make robust statements about the extent to which different factors are key in the decision-making process, but this study does provide an exploratory view on the differences in factors related to the intention to accept MPV between pregnant and non-pregnant women. A second limitation is the generalizability of the sample from the panel, of which most women were highly educated and born in the Netherlands, and a relatively high percentage working in healthcare. We left sociodemographic factors in the

regression models to correct these factors. Third, this is a cross-sectional study, whereas a longitudinal study would be ideal to be able to measure the influence of the factors over time and to infer causality and also to include MPV uptake instead of vaccination intention. Finally, it would be ideal to measure vaccination uptake as well as vaccination intention, but this was not possible at the time of the study because MPV was not yet implemented in the NIP.

### ***Implications for future research***

First, because in our study, cognitive social-psychological variables associated with vaccination intention score lower among pregnant women than among non-pregnant women, affect-related factors could be at play. Further research could aim to understand in what way affect-related determinants influence maternal vaccination acceptance during pregnancy. Second, future studies identifying determinants of vaccine uptake could also include possible moderation on the attitude-intention relationship by decisional certainty, because we found that this may be occurring. Third, in this study we measured the moral norm of accepting the vaccine, whereas some women may find it their moral responsibility to refuse the vaccine.

Because we found striking differences between non-pregnant women and pregnant women in socio-psychological determinants, longitudinal studies are needed to explain the decision-making process of pregnant women from preconception to postnatal. Additionally, different communication strategies can be tested based on the determinants found, including strategies that have more attention to affect and emotions, rather than fact-based information.

### ***Implications for practice***

First, our study found that attitude towards MPV is key for vaccination intention and that both are significantly associated with moral norms, beliefs about the effectiveness and safety of MPV, outcome expectancies, injunctive norm, trust in the NIP, decisional certainty and risk perceptions. To promote informed choice and to meet the information need of pregnant women, these key factors should be addressed in future communication about MPV. It is important to note that the two components of risk perception, i.e., perceived severity of and perceived susceptibility to pertussis, should both be addressed individually in risk communication

Second, we recommend clinicians to encourage and facilitate pregnant women to actively make an informed decision on MPV. Being certain about their choice will provide pregnant women with a more robust attitude about vaccination and will make them less vulnerable to misinformation. Because vaccination for pregnant women is a subject that

involves emotions such as anticipated regret, fear for the vaccine and fear of the disease, taking their emotions and concerns seriously is important to facilitate an informed decision-making process.

Our study shows that it is difficult to determine an MPV decision of women who are uncertain about MPV. When a pregnant woman is in doubt about MPV, clinicians can provide help by actively checking whether potential misperceptions are present about safety of the vaccine, side-effects of the vaccine, and risk perceptions of the baby getting pertussis.

Furthermore, because pregnant women were found to have a lower attitude towards MPV and a lower vaccination intention than non-pregnant women, information provision may benefit from careful timing. Communication could address more cognitive factors when the decision is further in time ("cold", before pregnancy, e.g. addressing beliefs about safety and effectiveness and risk perception, whereas it could be more relevant to pay attention to possible concerns and related emotions that may arise when closer to the moment of decision ("hot", during pregnancy; e.g. addressing physical discomfort or feeling more protective about the unborn child on information given to pregnant women). This strategy could promote a robust attitude towards MPV before getting pregnant or early in pregnancy and ultimately, an informed decision.





# Chapter 3

Maternal pertussis vaccination: information needs and preferences for organisation among pregnant women in the Netherlands

Based on:

Charlotte Anraad, Hilde M. van Keulen, Birthe A. Lehmann, Liesbeth Mollema, Pepijn van Empelen & Robert A.C. Ruiter. Kinkhoestvaccinatie tijdens de zwangerschap: Wensen voor informatievoorziening en organisatie. TSG - Tijdschrift voor gezondheidswetenschappen volume 98, pages 101–106 (2020)

## **Abstract**

### **Introduction**

We studied the information and care need of pregnant women regarding maternal pertussis vaccination (MPV).

### **Methods**

We conducted a cross-sectional study using an online survey among 202 pregnant women. They were asked what kind of information they would want to receive about the vaccination, at which moment and from whom, as well as from whom they would like to receive the vaccine.

### **Results**

Participants wanted to receive information about side-effects for themselves and the baby, the effectiveness of the vaccine, and the risk for babies to get pertussis with or without a vaccination. They prefer receiving information about the vaccine from their midwife, followed by their gynaecologist or general practitioner (GP), and prefer to be informed ahead of getting the vaccine, at the beginning of pregnancy or at 20 weeks of pregnancy. Participants indicated that they would prefer to receive the vaccine from their obstetric care provider or their GP.

### **Conclusion**

This study provides practical implications for the development of communication about and the organisation of MPV. The obstetric care provider is seen to be the most preferred source of information about the vaccine. They could play an important part in the communication about the vaccine.



## **Introduction**

Whooping cough is a respiratory infection caused by the *Bordetella Pertussis* bacteria. About half of new-borns who develop whooping cough are hospitalised for it (McIntyre & Wood, 2009). In rare cases, whooping cough in new-borns leads to convulsions, encephalopathy or even death (McIntyre & Wood, 2009). From 2005 to 2014, 1,711 cases of whooping cough were reported, of which 1,279 occurred in infants less than 5 months old. Of the 1,279 infants, 1,020 (80%) were hospitalised and 5 of them died (Health Council of the Netherlands, 2015). Vaccinating pregnant women to protect their babies in the first months after birth has proven to be an effective and safe method to prevent whooping cough (Gkentzi et al., 2017). On the advice of the Health Council, vaccination against whooping cough during pregnancy (maternal pertussis vaccination, or MPV) will be included in the National Immunisation Programme (NIP) at the end of 2019. The vaccination is currently administered at the Youth Health Centres.

The introduction of new vaccinations, such as the HPV vaccination, has been the subject of much controversy in recent years, resulting in a low vaccination rate for this vaccine (45.5%) (Van Lier et al., 2018). It is therefore important that the information needs of the target group are carefully considered when introducing new vaccinations into the NIP. Understanding these needs makes it possible to better align the organisation and provision of information with the wishes of the target group, to promote informed decision making and to reduce possible barriers to participation in the NIP.

Research in the United Kingdom and Australia on information provision about vaccination during pregnancy indicates that midwives can play a major role in the provision of information, as pregnant women, especially in their first pregnancy, trust them most (Wiley et al., 2015) (Danchin et al., 2018; Wiley et al., 2015). Existing interventions aimed at increasing the uptake of vaccination during pregnancy were most effective when the vaccination was administered by the midwife and the midwives received digital reminders to bring up the vaccination during the consultation (Mohammed et al., 2019).

A systematic review indicates that barriers to acceptance of MPV are strongly dependent on context and population (Wilson et al., 2015). So far, no research has been done in The Netherlands into the care and information needs of pregnant women in relation to MPV. Care is organised differently in The Netherlands than in many other countries, so results from abroad cannot be directly translated to The Netherlands. In the Netherlands, for instance, the provision of information and the organisation of vaccinations are the responsibility of youth health services. Therefore, it is important to consult health care users in the Netherlands about their wishes, in order to remove any barriers to the use of health care.

This study aims to map the wishes of pregnant women with respect to care and information provision around MPV. We will investigate how they would like to receive the information, which topics are important to them, when they would like to be informed, from whom they would like to receive the information and the vaccination, and how they would like to be assisted in their choice about the vaccination. We will compare the wishes of the participants with the current care and information provision of the MPV, as implemented since December 2019.

## Methods

### *Participants and questionnaire*

We conducted a cross-sectional study among pregnant women using an online questionnaire. The questionnaire was based on previous research among mothers who were asked to consider whooping cough vaccination within a cocooning strategy, in which parents get vaccinated to prevent their baby from becoming infected with whooping cough through them (Visser, Hautvast, et al., 2016). In April 2017, pregnant women who were part of an online consumer panel of research company Flycatcher (ISO 26362 certified) were invited to participate. The Flycatcher consumer panel is an existing panel with panel members from all over the Netherlands. Participants were given access to the online questionnaire after giving their permission via an online informed consent form. They received a reminder if they had not completed the questionnaire after one week. Participants received points for their participation in the panel, which they could exchange for gift vouchers. The participants answered questions about which subjects they would like to receive information about, by whom and in which way they would like to be informed and from whom they would like to receive the whooping cough vaccination. Several answers were possible to these questions. Questions were asked about any desired help in making a decision about MPV and about possible barriers to vaccination or reasons for vaccination. A 7-point Likert scale was used, with 1 indicating 'strongly disagree' and 7 indicating 'strongly agree'. For these questions, the results section reports the percentage of participants who chose a score of 5-7, and thus agreed or disagreed with the statement.

### *Data analysis*

The data analysis was done in SPSS (version 25). The analyses involved descriptive statistics. For the information wishes, the percentage of participants who chose each option is reported. For the questions about the barriers or reasons for vaccinating, averages and standard deviations are reported. Because a relatively large number of participants work in the care or welfare sector and are highly educated, we looked additionally at differences

in the wishes for care provision between participants who do and do not work in the care or welfare sector, and between highly educated and non-highly educated.

## Results

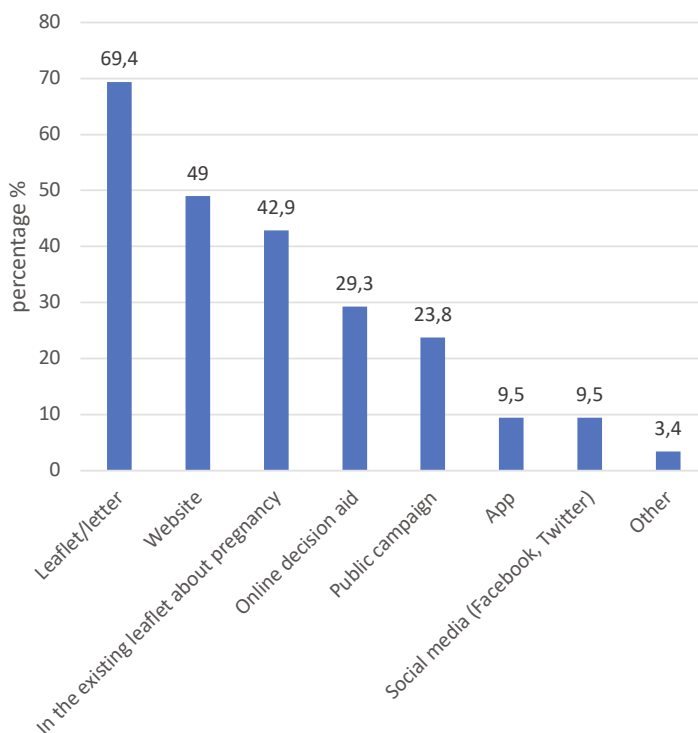
### Sample

The questionnaire was completed by 202 pregnant women. Table 1 shows the sample characteristics. Of the participants, 14% indicated that they had already achieved the MPV during pregnancy; 16% intended to do so. On average, participants were halfway through their pregnancy.

**Table 1.** Characteristics of the sample of pregnant women (n = 202) for the survey on wishes for information provision

Socio-demographic variables	n	Mean (standard deviation) / Percentage
Age	-	30,74 (3,70)
Number of weeks of pregnancy	-	20,31 (10,15)
Has had MPV		
- Yes	28	13,9%
- No	142	70,3%
- No, but is planning to get MPV	32	15,8%
Born in the Netherlands		
- Yes	192	95,0%
- No	10	5,0%
Level of education		
- Pre-vocational (VMBO)	21	10,4%
- Vocational (MBO)	48	23,8%
- Pre-university (HAVO/VWO)	18	8,9%
- Professional or university (HBO/WO)	113	56,0%
- Other	2	1,0%
Has one or more children		
- Yes	131	64,9%
- No	71	35,1%
Works in the healthcare sectors		
- Yes	75	37,1%
- No	127	62,9%
Receives obstetric care from		
- Midwife	156	77,2%
- Gynecologist	62	30,7%
- General practitioner	24	11,9%
- Clinical nurse	11	5,4%
- Physician assistant at the hospital	11	5,4%
- Other	1	0,5%

Of the 202 participants, 147 (72.8%) indicated that they would like to receive more information on the MPV. Figure 1 shows how the participants would most like to receive the information. The greatest preference was for a leaflet or letter (69.4%), followed by a website (49%) and or the existing leaflet on pregnancy (42.9%) (*Zwanger! Landelijke Folder Met Informatie En Adviezen van Verloskundigen, Huisartsen En Gynaecologen, 2019*).



**Figure 1.** Percentages of participants' preferences on how they would most like to receive the information.

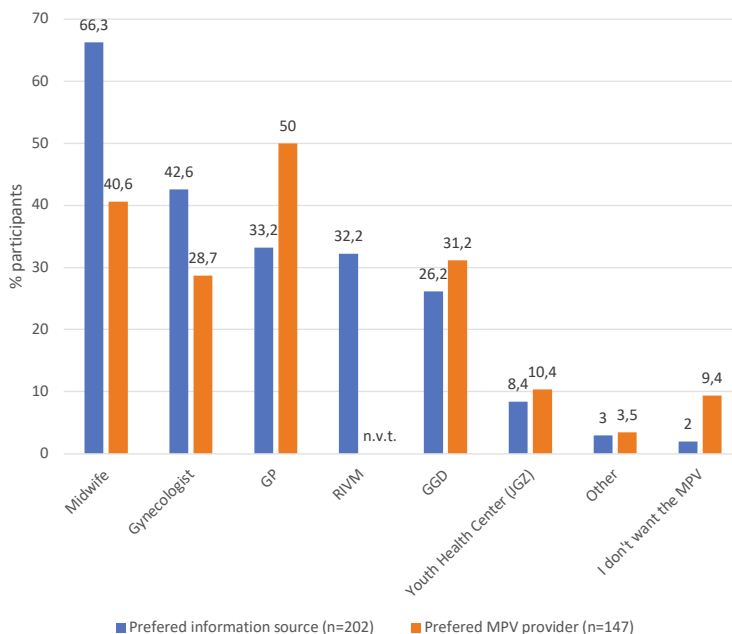
The topics about which participants want to be informed are listed in tab. 2. Most participants said they wanted information about the risk of side effects (71.4% of participants) and about the negative consequences of the vaccination for the baby (70.1%). The effectiveness of the vaccine (66%), the risk (63.9%) and the severity of whooping cough (60.5%) were also seen as important topics.

**Table 2** Desired topics in information provision (n = 147)

Topic of information that the participant wants to be informed about	n	% of participants
Risks of side-effects for the pregnant person	105	71,4
Risks of negative effects on the baby	103	70,1
Effectiveness of MPV	97	66,0
Risk of the baby getting whooping cough	94	63,9
Severity of whooping cough for a baby	89	60,5
Symptoms of whooping cough in babies	81	55,1
Severity of whooping cough during pregnancy	72	49,0
Alternatives to MPV	70	47,6
Symptoms of whooping cough during pregnancy	69	46,9
Scientific research on MPV	58	39,5
Experiences in other countries with MPV	50	34,0
Experiences of other pregnant women	46	31,3
What is in the vaccine?	44	29,9
Other	3	2,0

Of the participants, 12.9% said they would like to be informed about the MPV if they were thinking about becoming pregnant (results not shown in the table). Of the participants, 52.4% wanted to be informed at the beginning of the pregnancy, 33.3% wanted to be informed before the moment of vaccination, for example at 20 weeks, and 1.4% wanted to be informed at the moment of vaccination. More than half of the participants (55.4%, n = 112) indicated that, in addition to being informed, they would like to receive help in making the decision about the MPV. Of the participants, 58.9% would like help in the form of a consultation with a healthcare provider, 42% would like a digital decision aid, 38.4% would like the option of calling an expert with questions, 16.1% would like a consultation with other pregnant women, and 3.6% indicated that they would like help in some other way.

Figure 2 shows from which health care provider the participants wanted to receive the information on MPV during pregnancy and from whom they wanted to receive the MPV. The preference went to the general practitioner (50%) and the midwife (40.6%), and the least preference went to the youth health care centre (10.4%). Of the number of participants who had no children yet and were therefore not yet known to the Child Health Care Centre, 7.4% chose the Child Health Care Centre; among participants who already had one or more children this was 9.4%. This difference was not significant ( $p = 0.34$ ). In total, 9.4% indicated that they did not want to receive the vaccination.



**Figure 2.** Percentages of participants' preferences of which health care provider the participants receive the information on MPV during pregnancy from, and from whom they wanted to receive the MPV.

Analyses showed that there was no difference between participants who worked in the health and welfare sectors in terms of who they wanted to receive information from, and in what way. In the group of participants who worked in health care, 14% wanted to receive the MPV at the health care office, while this was 6% in the group who did not work in health care. This difference was not significant ( $p = 0.08$ ). There were no clear differences in preference for the other healthcare providers from whom the participants would like to receive the shot. Whereas 7% of the participants who worked in health care indicated that they did not want to be vaccinated during the pregnancy, this was 12% in the group who did not work in health care. This difference was also not significant ( $p = 0.29$ ).

There were also differences between the higher educated and the lower educated: 52% of the higher educated chose the RIVM as their source of information, as did 33% of the lower educated ( $p = 0.04$ ). Among the higher educated, 63% chose the midwife as their source of information, whereas this was 85% among the non-educated ( $p = 0.03$ ). The higher educated chose the consultation bureau less often than the lower educated (10%), but this difference was not significant ( $p = 0.27$ ). Whereas 6% of the higher educated indicated that they did not wish to be vaccinated, this was 18% of the non-educated. This difference was significant ( $p = 0.01$ ).

The main barrier to accepting the MPV was that the pertussis vaccination is a combination vaccine (20.5%). It was also a barrier for some participants if they had to see a healthcare provider other than the one they were being monitored by (18.7%) or if they had to make an extra appointment (11.1%). When asked if the possibility of being vaccinated during an existing appointment with their own health care provider would be a reason for them to get the MCR, 39.0% said yes. The fact that the MPV allows the child to start its own vaccinations a little later was a reason for 37.8% to take the MPV.

## **Discussion**

This study describes the care and information needs of pregnant women with respect to the MPV during pregnancy. At the time of the study, the MPV had not yet been introduced into the NIP and not all midwives were actively communicating about MPV. This explains why only 14% of the participants had already taken the MPV and 16% still wanted to do so. If the vaccination was offered, only 9.4% of the participants said they did not want the MPV. The study shows that 55.4% of the women in the sample wanted help in making a decision about the MPV. Most of them wanted help from a healthcare professional or a digital decision aid.

When it came to the question of which healthcare provider participants would like to receive information about the MCF, the preferred choice was the midwife, gynaecologist or general practitioner. In terms of administering the vaccination, half of the participants would prefer this to be done by the GP and 40.6% by the midwife. This is not in line with the current policy of having the vaccination administered by the youth health clinic - only 10.4% of the women in this study preferred this. The low popularity of the consultation centre may have something to do with the fact that many women without children are not yet familiar with the consultation centre, while they do know their general practitioner or obstetrician. This means that the information supply must pay attention to the possibilities offered by the Child Health Care Centre. Cooperation between obstetric care providers and the Child Health Care Centres can help in this respect. Table 3 contains a comparison of the results of our study with the current policy.

**Table 3.** Comparison of the results of the study with the current policy on MPV (22 *Wekenprik | Rijksvaccinatieprogramma.NI*, 2020; RIVM, 2019).

	Study results	Current policy.
Topics about which information is provided	Risks of side-effects for the pregnant person, risks of negative effects on the baby, effectiveness of MPV, risk of the baby getting whooping cough, severity and symptoms of whooping cough for babies and pregnant people, alternatives to MPV	The topics that arise in the current research are addressed in the information provision.
Moment of information provision	Some weeks before receiving MPV	Some weeks before receiving MPV
Potential barriers to MPV uptake	Having to make a separate appointment with a healthcare provider they do not know is perceived to be a barrier to getting MPV.	To get MPV, a separate appointment is required with the health clinic, where the pregnant woman is not under supervision at that time.
Medium for providing information	Flyer or information letter are most preferred.	Flyer and website
Healthcare professional providing information about MPV	Obstetric care provider	Obstetric care provider gives flyer, youth health nurse at the Youth Health Services (in Dutch: Jeugdgezondheidszorg) is contact person for questions.
Healthcare professional providing MPV	Obstetric care provider or general practitioner	Youth health nurse at the Youth Health Services (in Dutch: Jeugdgezondheidszorg)

Our findings are consistent with those in the literature. According to a systematic review on determinants of vaccination acceptance during pregnancy, the advice of the health care provider has a major influence on acceptance (Wilson et al., 2015). In addition, foreign studies show that when the midwife organises the FMU, acceptance is higher (Mohammed et al., 2019).

This study is the first study into the wishes of pregnant women concerning the provision of information and organisation of the maternal whooping cough vaccination. This study has the following limitations. The sample size of 202 pregnant women is relatively small. The sample contained a relatively large number of women who were born in the Netherlands (95%), were highly educated (56%) and worked in the care or welfare sector (37.1%). This may have led to an underestimation of the popularity of the Child Health Care Centre as a source of information, and an overestimation of the popularity of the Child Health Care Centre as a place to get the SSF. Also, the actual percentage of pregnant women who do



not want to get the vaccination is probably higher than 9.4%. In addition, the term 'youth health care/consultation bureau' in the questionnaire does not indicate that it refers to the youth physician or youth nurse. This may have influenced the participants' answers.

### **Conclusion**

This study provides practical tools for developing the provision of information about the MPV during pregnancy. The obstetrician with whom the woman is being monitored is seen as the most important source of information, and this care provider could therefore play a greater role in the provision of information than is presently the case. Recent introductions of vaccinations show that vaccination coverage is difficult to predict and depends on many factors, and literature shows that the degree of acceptance of a vaccination is strongly related to the question of whether it meets the wishes of the target group (Mohammed et al., 2019). The preference of the pregnant women in this study is for administration of the MPV and provision of information about the MPV by the obstetric care provider or general practitioner, whereas these are currently done by the youth physician or nurse at the health care office. This calls for cooperation between obstetricians and the Child Health Care Centres, in order to provide optimal service to pregnant women during their pregnancy and afterwards. Also, women who do not yet have children do not yet know how to go to the health clinic. Extra attention should be paid to this aspect when providing information about vaccination.



# Chapter 4

The effect of emotion regulation strategies on decision-making about the maternal pertussis vaccination among pregnant individuals in the Netherlands: an experimental study

Published as: Petra Buursma, Charlotte Anraad, Pepijn van Empelen, Robert A.C. Ruiter & Hilde M. van Keulen (2022). The Effect of Emotion Regulation Strategies on Decision-Making about the Maternal Pertussis Vaccination among Pregnant Women in the Netherlands: an experimental study. *Patient Education and Counselling*, 2022. <https://doi.org/10.1016/j.pec.2022.11.008>

## Abstract

**Objective:** To assess whether cognitive reappraisal and acceptance are effective emotion regulation strategies to decrease the influence of negative affect on intention to accept maternal pertussis vaccination (MPV) among pregnant women in the Netherlands.

**Methods:** An experimental study with baseline and two follow-up measurements was conducted. Participants selected after baseline (N=382) were randomised into two experimental groups (cognitive reappraisal, acceptance) and a control group. The effect of the experimental manipulations on negative affect was examined with multilevel analyses. A moderation analysis was performed to examine whether the manipulations moderated the association between negative affect and intention.

**Results:** All groups showed a decrease in negative affect (all  $p$ 's < 0.001), with no differences between groups. A small decrease in the influence of negative affect on intention was found among those who used acceptance.

**Conclusion:** No additional value of the emotion regulation strategies was found compared to the control group. However, exploratory analyses showed that acceptance seemed a promising strategy to decrease the influence of negative affect on intention to accept MPV.

**Practice implications:** This study stressed the relevance for communication strategies to consider the emotions pregnant women experience during the decision-making process about the MPV.

## Introduction

Pertussis is an infectious disease caused by the bacterium *Bordetella Pertussis* and is most severe in new born infants (V. T. N. Nguyen & Simon, 2018; Nieves & Heininger, 2016). The maternal pertussis vaccination has been introduced in the national immunisation programme (NIP) of the Netherlands in 2019, in order to protect infants during their first months of life (Health Council of the Netherlands, 2015). Uptake was estimated at 70% in 2020 (van Lier et al., 2021). Informed decision making has been said to promote a robust attitude towards vaccination, leading to less vulnerability to misinformation and more stable attitudes towards vaccination (Paulussen et al., 2006). An informed decision is defined as a *decision that is based on relevant knowledge, consistent with the decision-maker's values and behaviourally implemented* (O'Conner & O'Brien-Pallas, 1989). The decision-making process of parents concerning maternal vaccinations needs to be understood in order to promote informed decision-making.

Using the Theory of Planned Behaviour (TPB) to assess the social-psychological factors influencing vaccine acceptance (Ajzen, 1991), attitude seems to be the most important predictor of intention to accept MPV (Anraad et al. et al., 2020; Lutz et al., 2018; Wilson et al., 2015; Winslade et al., 2017; Yuen & Tarrant, 2014). Studies have stressed the relevance of adding an affective component to the TPB (Conner et al., 2015; Koch, 2014; Magnan et al., 2017; Ravis et al., 2009b; Sandberg & Conner, 2008). Two studies in the Netherlands found that affective factors, such as anticipated regret and fear of vaccine uptake, are important predictors of the uptake of pertussis vaccination for pregnant women (Anraad et al. et al., 2020; Visser, Kraan, et al., 2016).

Affect and attitude influence each other in several ways. It is possible for people to simultaneously have positive and negative evaluations towards MPV. This is referred to as attitudinal ambivalence (Armitage & Conner, 2000) and has been shown to result into a weaker association between attitude and intention, while a fundamental aspect of informed decision-making is that a choice is in line with one's attitude towards the topic (Armitage & Conner, 2000; Bekker et al., 1999; Lavine et al., 1998; van Harreveld et al., 2015). Attitudinal ambivalence has been shown to result in negative affect towards decision-making (van Harreveld et al., 2015). In order to overcome this negative affect, individuals tend to seek more information to come to a consistent attitude and they become less critical to the information sources they consult (McGregor et al., 1999; Zemborain & Johar, 2007). Websites from health-authorities focus more often on providing information in numbers and facts, which usually influences cognitive attitude (Hobson-West, 2003). In contrast, vaccine-critical websites more frequently provide their information based on personal stories and emotions, which generally targets affective attitude (Betsch et al., 2010). Neg-

ative affect can lead to ignoring numbers, facts and abstaining from the weighing of pros and cons and can lead to an increase of reliance on emotions in decision-making (Lavine et al., 1998; Miller & Rollnick, 2012; Slovic et al., 2005). Therefore, it is important to take into account the affective state pregnant women experience when making the decision about MPV.

A potential strategy to address affect in communication about MPV is based on emotion regulation (ER). Numerous studies have examined ER, but research is lacking on the influence of ER in vaccine decision-making. ER refers to the experience, expression and regulation of emotions in individuals (Gross, 2013). The extended process model of emotion regulation describes three stages of ER. First of all, identification refers to being concerned with whether to regulate emotions. Secondly, selection which encompasses the question which strategy to use to regulate emotions. The last stage concerns the implementation of the ER strategy suited to the situation (Gross, 2015). Strategies can be divided into different processes of which cognitive change, a method to alter the emotional significance concerning a situation, seems to be the most effective in decreasing negative affect (Aldao et al., 2010; Gross, 2013; Webb et al., 2012). Cognitive reappraisal and acceptance are two distinct strategies based on cognitive change that could potentially be effective in decreasing negative affect around decision-making about MPV in pregnant women.

Cognitive reappraisal refers to reframing a situation that is known to induce emotional responses and works on reinterpretation of this stimulus to change its emotional impact (Gross, 2013). Previous studies have revealed that cognitive reappraisal can be successful in decreasing negative affect in various situations (Feinberg et al., 2012; Hofmann et al., 2009; Szasz et al., 2016; Troy et al., 2018; Wolgast et al., 2011). Additionally, cognitive reappraisal can result into more positive affective states, increased deliberate reasoning, and more adaptive decision-making (Feinberg et al., 2012; Szasz et al., 2016; Szekely & Miu, 2015; Webb et al., 2012).

Acceptance focusses on creating awareness on an individual's emotions without trying to alter these emotions (Gross, 2013; Hayes & Hofmann, 2017). It has also been shown that acceptance decreases negative affect in various situations (Hofmann et al., 2009; Troy et al., 2018). Furthermore, we expect that acceptance, like cognitive reappraisal, may reduce the influence of negative affect in the decision-making process and promote more deliberate reasoning. Existing findings on acceptance are inconsistent: some studies claim that acceptance is not successful in decreasing negative affect during or right after the emotional stimulus (Campbell-Sills et al., 2006; Hofmann et al., 2009; Troy et al., 2018). The same studies did report that acceptance seems to be successful in decreasing the physiological response to negative emotions, which can lead to a decrease in negative affect

over time (Campbell-Sills et al., 2006; Shallcross et al., 2015; Uusberg et al., 2016). Therefore, we hypothesize that acceptance and cognitive reappraisal could (individually) be effective ER strategies to decrease negative affect regarding the decision-making process for MPV.

The objectives of this study are to examine (1a) whether cognitive reappraisal decreases negative affect regarding MPV decision and (1b) whether it decreases the influence of negative affect on decision making about MPV, and (2a) whether acceptance decreases negative affect regarding MPV decision and (2b) whether acceptance decreases the influence of negative affect on decision making about MPV. With this we aim to inform the development of effective communication strategies to facilitate informed decision-making towards MPV.

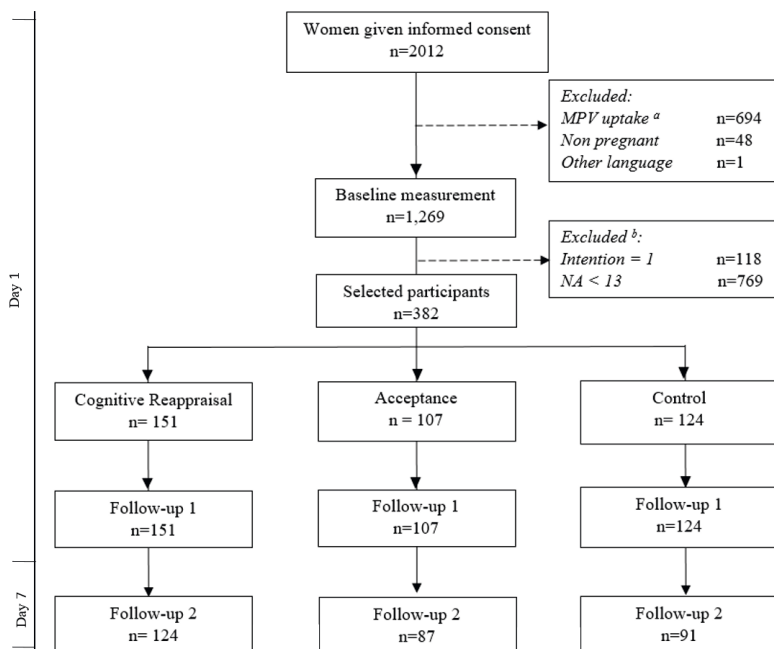
## **Methods**

### ***Study design***

An experimental study was performed online with three groups. After the participants had given informed consent, they received an online baseline questionnaire to select participants for the intervention. Participants were randomly assigned to one of the three online groups: (1) cognitive reappraisal intervention, (2) acceptance intervention and (3) control group (generic instructions). The first follow-up measurements took place immediately after exposure to the intervention or control group and the second follow-up measurements took place 7 days after the participant's baseline measurement. The flow chart of participants throughout the study is presented in Figure 1. The study was approved by the TNO institutional review board (review number 2018-050).

### ***Recruitment and procedure***

Participants were recruited through paid advertisement on social media (Facebook and Instagram) and could win a voucher worth 25 euros from an online web shop when completing participation. After seeing information for participation, participants gave consent. They were then immediately directed to the baseline survey (t0). Participants who were selected for the experiment (see criteria below), were randomised into one of the intervention groups or the control group. After the intervention, they filled out first post-test survey (t1). Seven days later, participants were invited via e-mail to respond to the second follow-up survey (t2). Participants received reminders after three and seven days if they had not filled out the survey yet. The study was conducted between April 2020, when the recruitment of participants started, and June 2020 when the final follow-up measurement was received.



**Figure 1:** Flow chart of the study. Abbreviations: n=number; MPV,=maternal pertussis vaccination; NA=negative affect. <sup>a</sup> Women who already had the MPV. <sup>b</sup> Exclusion criteria: score<13 on the Positive and Negative affect Scale, PANAS, ranging from 9–45 and score = 1 on intention scale, ranging from 1–5.

### Sample population

A total of 2012 women had given their informed consent to participate in this study. The target population of this study was pregnant women with a command of the Dutch language, who are hesitant about accepting MPV and experience negative affect concerning the decision. For baseline participation, the inclusion criteria was being less than 20 weeks pregnant, because at 22 weeks the MPV is offered. The following exclusion criteria applied to the selection of participants for the intervention study: a score<13 on negative sub-scale of the Positive and Negative affect Scale (PANAS) ranging from 9 (low negative affect) to 45 (high negative affect) and a score = 1 on intention scale, ranging from 1 (low intention) to 5 (high intention). We discussed among the authors what could be considered a minimum negative affect score based on the adjusted PANAS-scale and the answers that are needed to get a certain score. We considered that a score less than 13 did not indicate enough negative affect for it to be substantial. With a score of 13, a participant answered at least either 3 times 'a little bit', or once 'a little bit' and once 'moderately' to questions about experiencing a form of negative affect, or they filled out 'quite a bit' at least once. Only pregnant women who had indicated to have a low intention were excluded, since low



intention to vaccinate has been shown to result into a stable intention-behaviour relation regardless of the stability in intention over time (daCosta DiBonaventura & Chapman, 2005). The intention-behaviour relationship for individuals with high intention to vaccinate does depend on a stable intention over time. The participants still had to make a decision in the future and intention could still fluctuate over time. For this reason, women with a high intention were still included in this study.

### **Randomisation**

Randomisation was done using the Survalyzer software (Survalyzer BV the Netherlands, Utrecht, The Netherlands) and participants were randomised individually. Because the experiments were executed completely online and respondents were automatically randomised towards an experimental condition, blinding of researchers was not applicable.

### **Interventions**

The cognitive reappraisal group received instructions to describe how they experience the decision about MPV by trying to focus on positive aspects of MPV decision itself, for example the possibility to make the choice. The instructions for cognitive reappraisal were based on the instructions used in the study by Hofmann et al. (2009) (Hofmann et al., 2009). The acceptance group was asked to describe how they experience the decision about MPV by focusing on their emotions and trying to figure out which emotions are triggered and why. The instructions for acceptance were based on the on the instructions used in the study by Troy et al. (2018) (Troy et al., 2018). Both groups were asked to persist this ER strategy over the following week. Participants in the control group received general instructions to think about MPV decision without any specific ER instructions; this was based on a usual care principle by assuming individuals would think about the decision. In this way, the additional value of an ER strategy could be examined by comparing it to the effect of basic consideration of the decision without specific ER instructions. Instructions for all three groups are presented in English and Dutch in the Appendix.

### **Measurements**

At all three time points, measurements included negative affect towards the decision about MPV, attitude towards MPV, and intention to accept MPV. Socio-demographics were measured at baseline. Table 1 presents an overview of the construct of intention with internal consistency of the items. Final constructs presented the average of the items. Although we measured attitude towards MPV, we did not use this in the analyses due to high correlations with intention,  $r(1,267) = .918, p < 0.01$ .

**Table 1:** Reliability of intention towards MPV.

Variable	Nr of items	Reliability total participants <sup>1</sup>	Reliability selected participants <sup>2</sup>	Example question
Intention <sup>b</sup> 1= low 5 = high	2	r = .97	r = .92	Are you planning on getting the MPV? 1= definitely not to 5= definitely.

Note: Nr=number; MPV=maternal pertussis vaccination. <sup>1</sup>Total participants represent all participants who completed baseline measurements. <sup>2</sup>Selected participants represent all participants who were included following the inclusion criteria and randomised into one of the three groups. <sup>3</sup>Reliability was estimated with Cronbach's alpha. <sup>4</sup>Reliability was estimated with Pearson's correlation coefficient.

Negative affect towards the MPV decision was measured by the negative affect scale in the 10-item PANAS scale. This scale has been proven to be a reliable and valid method to measure negative affect (Watson et al., 1988). One of the items ('ashamed') used in this scale was not considered relevant for MPV and was excluded. In this study, the negative affect scale therefore consisted of 9 items measured with a 5-point Likert scale: 'when I think about making the decision on MPV vaccination, I feel: 'scared', 'afraid', 'upset', 'distressed', 'nervous', 'jittery', 'guilty', 'irritable' and 'hostile' (1= not at all, 5= very much). The final construct of negative affect was based on a sum score of the answers from the nine statements (ranging from 9, no negative affect to 45, the most negative affect).

Socio-demographic variables consisted of age, country of birth and highest completed level of education. Educational level was classified into three categories (Pot, van Keulen, et al., 2017). Additionally, number of weeks pregnant and number of children were asked.

Manipulation tests were done according to previous studies (Rood et al., 2012; Wolgast et al., 2011). Participants in the cognitive reappraisal or acceptance group received questions about whether they tried to adhere to the instructions and whether they succeeded. These questions were asked according to a 5-point Likert scale (1=disagree, 5= agree). Manipulation questions were asked during the first and second follow-up.

### **Sample size calculation**

The calculation of the sample size was based on the main research objectives (1a and 2a): to examine the effect of cognitive reappraisal and acceptance on negative affect towards MPV. The sample size calculation was based on the three groups with random assignment, three measurements, an Intraclass Correlation Coefficient of 0.20, and a medium effect size (Cohen's  $d=0.5$ ) for the interaction effect of intervention and time with a statistical power of 0.80. Medium effect size refers to a difference of 2.5 between the groups on the

negative affect scale (9–45) with an expected standard deviation of 4.5. Based on these characteristics, a total sample size of 381 participants was needed (127 per group).

### **Analyses**

Statistical analyses were done using IBM SPSS version 25.0. Descriptive statistics were used to describe the characteristics of the sample population and are presented as means  $\pm$  SD or n (%). Randomisation check and dropout analyses were done using socio-demographics and social-psychological factors. The analyses were done in four steps:

First, we investigated the association between negative affect and intention to accept MPV using a linear regression model. All baseline participants were included in this analysis, and only data from the baseline measurement was included.

Second, to examine the effect of the intervention (cognitive reappraisal or acceptance) on negative affect over the different time points, a multilevel regression analysis with intervention as independent variable, negative affect as dependent variable and time as interaction with intervention was performed. Data from participants that met the selection criteria were used for this analysis and will be referred to as selected participants (n=382).

Third, we investigated if being in an intervention group versus control group moderates the effect of negative affect on intention, because we expect that acceptance and cognitive reappraisal can reduce the effect of emotions in the decision about MPV. To analyse this, we created dummy codes for the intervention group (the reference group was the control group) and we added the interaction of negative affect with group (cognitive reappraisal, acceptance or the control group) to a linear multiple regression model of negative affect (independent variable) and intention (dependent variable).

Fourth, in an exploratory analysis we analysed the answers that participants gave in the intervention and coded them to see whether they used acceptance, cognitive reappraisal strategy or neither. First, two researchers (PB and CA) identified existing codes in 10% of the data and grouped them. Then, they identified themes, and discussed these until consensus was reached. Then, one researcher (CA) identified whether participants showed one, or two or more codes of cognitive reappraisal or acceptance in their answers. In order to examine the inter-rater reliability (IRR), the other researcher (PB) did the same with a sample (n=45) of the written answers. The IRR was calculated in two different manners. First, by calculating the agreement between the two coders based on the codes given to the answers per ER strategy separately (IRR = 82.22%). Second, by calculating the agreement based on the codes given to the answers for the ER strategies combined (IRR = 64.44%). Further, we repeated the moderation analysis (step 3), but used coded

answers instead of group assignment in the interaction terms. The coding resulted two scores per participant, representing the number of acceptance codes in their answer (0 to 3) and the number of cognitive reappraisal codes in their answer (0 to 3). We did this to check which ER strategy participants actually applied based on coded answers compared to what they were instructed to do in the groups they were assigned to, and the influence of these used strategies on the effect of negative affect on intention.

## Results

### *Baseline characteristics*

Table 2 presents the socio-demographic background and social psychological factors of the total sample and of selected participants. A randomisation check showed no significant differences between the cognitive reappraisal, acceptance and control group on socio-demographics and socio-psychological factors.

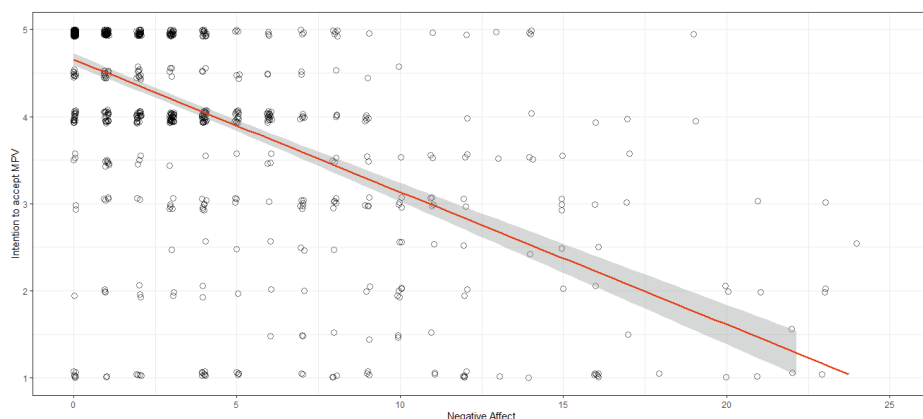
**Table 2:** Socio-demographics and social psychological factors of the sample. Abbreviations: M = mean; SD = standard deviation; n = number.

<i>Socio-demographics</i>	Total (n=1269) M ± SD or n (%)	Selected (n=382) M ± SD or n (%)
Age	30.9 ± 4.2	30.9 ± 4.4
Weeks pregnant	19.7 ± 6.1	19.0 ± 6.3
Previous children		
Yes	626 (49.3%)	219(57.3%)
No	643(50.7%)	163(42.7%)
Education		
Low	45 (3.5%)	11 (2.9%)
Intermediate	458 (36.1%)	149 (39.0%)
High	766 (60.4%)	222 (58.1%)
Country of birth		
Netherlands	1231 (97.0%)	368 (96,3%)
Other	38 (3.0%)	14 (3.7%)
<i>Social psychological factors</i>		
Intention	4.2 ± 1.3	4.0 ± 1.0
Negative Affect	12.2 ± 5.2	15.4 ± 4.8

Dropout analyses showed that participants who responded to the follow-up (n=302) were on average older and higher educated compared to participants who did not respond (n=80) (Age: M=31.1, SD=4.1; M=29.9, SD=5.3, respectively;  $t(380)=2.26$ ,  $p=0.024$ ; education:  $X^2(2, N=382)=7.71$ ,  $p<0.021$ ). Additionally, participants who responded to the follow-up had on average less negative affect at baseline compared to participants who did not respond (M=14.5, SD=1.3; M=15.6, SD=1.3, respectively;  $t(380)=-2.14$ ,  $p=0.033$ ). This difference was not found for negative affect at the first follow-up.

### **Association between negative affect and intention**

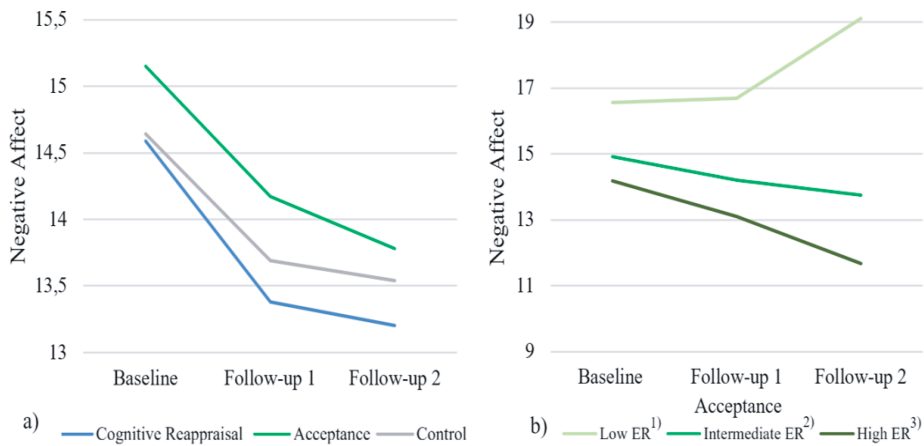
A linear regression model showed that higher levels of negative affect was associated with a lower intention to accept MPV (intercept=4.63, SE=0.03,  $\beta=-0.14$ ,  $B=-0.57$ ,  $p<0.001$ ; see Figure 2).



**Figure 2.** The association between negative affect and intention to accept MPV at baseline (n=1,269). Under low levels of negative affect, intention to accept MPV is higher than under higher levels of affect (intercept=4.63, SE=0.03,  $w\beta=-0.14$ ,  $B=-0.57$ ,  $p<0.001$ ). Dots in the graph are jittered to avoid overlap.

### **Intervention effects on negative affect**

The development of negative affect over time per intervention group is presented in Figure 3 and Table 3. All three groups showed a significant decrease in negative affect between baseline and the follow-up moments (all  $p<0.001$ , see Table 3). No significant differences were found between the groups in change in negative affect from baseline to the first and second follow-up.



**Figure 3.** Development of negative affect over time for the cognitive reappraisal, acceptance and control group. Follow-up 1=right after the exposure for the intervention or control group. Follow-up 2=one week after exposure for the intervention or control group.

**Table 3:** Development of negative effect for Cognitive reappraisal, Acceptance and Control group.

	Cognitive Reappraisal		Acceptance		Control	
	M	95% CI	M	95% CI	M	95% CI
NA						
Baseline	14.59	[13.93 – 15.27]	15.15	[14.34 – 16.01]	14.64	[13.92 – 15.41]
Follow-up 1	13.38**	[12.78 – 14.01]	14.17**	[13.41 – 14.95]	13.69**	[13.01 – 14.40]
Follow-up 2	13.20**	[12.52 – 13.90]	13.78**	[12.95 – 14.66]	13.54**	[12.78 – 14.37]

Note. NA = negative affect; M = mean; 95%CI = 95% confidence interval; ER = emotion regulation. \*Significantly different compared to baseline,  $p < 0.05$ . \*\*significantly different compared to baseline,  $p < 0.001$

### **Moderation of the relation between negative affect and intention**

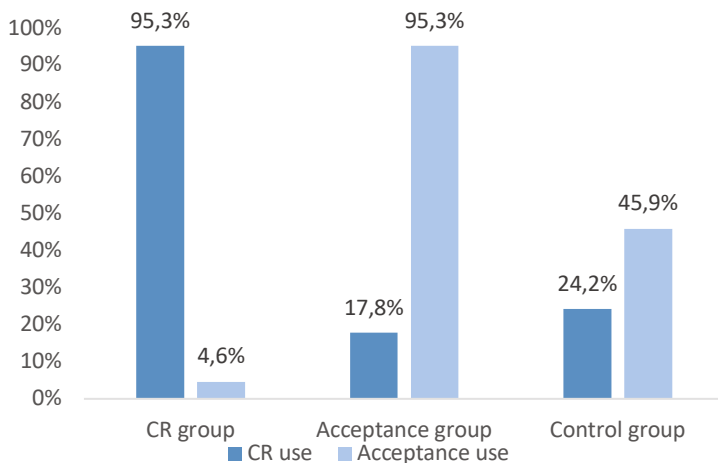
We found no moderation effect of the cognitive reappraisal intervention or the acceptance intervention on the relation between negative affect and intention. See Table 4 for the results of the moderation analysis.

**Table 4.** Moderation analyses of negative affect on the intention towards maternal pertussis vaccination among the different intervention groups.

	B	Standard error	95% interval	
			Lower bound	Upper bound
Intercept	4.025	0.085	3.858	4.191
Negative affect	-0.041	0.009	-0.058	-0.024
Cognitive reappraisal group	-0.100	0.114	-0.325	0.125
Acceptance group	0.012	0.124	-0.233	0.257
Interaction negative affect x cognitive reappraisal	0.004	0.011	-0.017	0.026
Interaction negative affect x acceptance	0.019	0.011	-0.002	0.041

### **Actual use of ER strategies based on coding of written answers**

The majority of participants in both the cognitive reappraisal group and the acceptance group indicated that they were able to follow the instructions (60,1%, 71,8% respectively). However, we also examined the written answers of the participants in all groups to identify which strategies were actually used. Based on the written answers, we identified three themes indicating that cognitive reappraisal was used. These were advantages of having the opportunity to get MPV for cognitive reappraisal within participants' answers: (1) the protection/safety that MPV provides, (2) having MPV freely available at choice, and (3) the baby can skip one vaccination with MPV. Themes indicating use of acceptance were more difficult to identify, because participants did not write down explicitly whether they had accepted negative feelings or aspects of MPV. We therefore decided to code answers based on the expression of any concerns or perceived negative aspects of MPV, because this indicates the first step of acceptance: awareness of the negative aspects or feelings. Four themes were identified: negative feelings towards MPV such as feelings of fear, unease, uncertainty or anticipated regret (1), unmet information needs (2), concerns about potential harm of MPV (3), and concerns about MPV because of the COVID-pandemic (4). Figure 4 shows the actual use of ER strategies within each group. First, the majority of the participants used the instructed ER strategy (95,3% in both the cognitive reappraisal and acceptance group), and as such our manipulations had worked. However, we also saw that in the control condition emotional regulation were used spontaneously. In the cognitive reappraisal group, 4,6% used acceptance as ER strategy either in combination with cognitive reappraisal or exclusively. In the acceptance group, 17,8% used cognitive reappraisal as ER strategy. In the control group, acceptance (45,9%) was used more than cognitive reappraisal (24,2%), but not all participants used either (13.9%) of the strategies, and some used both (8.0%).



**Figure 4.** Actual use of Cognitive reappraisal and Acceptance in the intervention and control groups. Abbreviations: CR, cognitive reappraisal.

We explored whether the actual use of these strategies based on coded answers moderated the relationship between negative affect and intention to accept MPV. We found that among participants who actually used acceptance according to our coding, the association between negative affect and intention to accept MPV was slightly weaker at follow-up (95% CI 0.008-0.032) compared to among those who did not use acceptance. The results of the moderation analysis are shown in Table 5.

**Table 5.** Moderation analyses of actual use of cognitive reappraisal and acceptance on the association between negative affect and intention. Abbreviations: CR, cognitive reappraisal.

	B	Standard error	95% interval	
			Lower bound	Upper bound
Intercept	3.987	0.048	3.893	4.081
Negative affect	-0.038	0.004	-0.047	-0.029
Actual use of CR	0.061	0.072	-0.080	0.202
Actual use of Acceptance	-0.013	0.080	-0.171	0.144
Interaction negative affect x actual use of CR	0.011	0.007	-0.002	0.025
Interaction negative affect x actual use of acceptance	0.020	0.006	0.008	0.032



## **Discussion**

This study examined whether cognitive reappraisal and acceptance interventions can be successful methods to decrease negative affect or the influence of negative affect on intention during the decision-making process of MPV among pregnant women in the Netherlands.

Negative affect was found to be negatively associated with intention to receive MPV. This is an important finding, not least because of its implications for decision making about MPV, but also because the role of negative affect in the context of vaccination decisions has still not completely been unravelled and is often described as an intuition or a general feeling (Tomljenovic et al., 2020). This study found that negative affect can be captured with an adjusted PANAS scale, and to our knowledge, this study is the first that quantitatively showed that more negative affect is associated with lower intention to accept MPV. We further found that negative affect decreased over time in the cognitive reappraisal, acceptance and the control group. However, no additional effect of the strategies on negative affect compared to the control group was found. A possible explanation for the decrease in negative affect over time is social desirability bias or common method variance. Negative affect is potentially a construct that is particularly prone to such biases, and social desirability could be higher among those who experience negative affect (Wall, 2014). Although we tried to design the surveys and interventions in such a way that participants felt the least pressure possible for providing socially desirable answers, for example by pointing out that there are no right or wrong answers, the decrease in negative affect could be partly due to the measurement design. We expect the effect to be small, because common method variance is found to cause biases in the data, but only minor bias in statistical analyses (Wall et al., 2022).

No moderation effect of the interventions on the association between negative affect and intention was found. However, despite not finding a difference between intervention groups, the exploratory analysis of the written answers suggests that acceptance may decrease the influence of negative affect on intention to accept MPV. This indicates that acceptance might be an interesting strategy to further explore in the context of MPV. We have described in the introduction that both cognitive reappraisal and acceptance are based on a cognitive change method, which tries to alter the emotional significance to a situation. Even though both methods are compatible with cognitive behavioural therapy, their mechanisms work differently. Cognitive reappraisal is based on an antecedent-focused strategy, whereas acceptance is based on a response-focused strategy. Antecedent-focused strategies occur before the emotional response has fully occurred and try to alter or reframe a situation. Response-focused ER strategies occur after the emotional re-

sponse have been initiated, but try to alter the emotional experience. Acceptance tries to do this by avoiding counterproductive response-focuses strategies, such as suppression or avoidance (Hofmann & Asmundson, 2008). This could potentially explain the difference in effect by cognitive reappraisal and acceptance.

Another potential explanation for the findings is that the control group also received instructions to think about the decision. This was done to create a standard care control group, assuming individuals generally think about the decision. However, previous studies have shown that pregnant women do not always consciously deliberate vaccination decisions (Lehmann et al., 2017; Romijnders et al., 2019). Therefore, only the instruction to consider making the choice and leaving the women to adapt their own natural ER strategy during this elaboration could already be successful in decreasing negative affect. The written answers revealed that many participants in the control group indeed also used cognitive reappraisal or acceptance. This potentially made it more difficult to find the differences between the three groups. Finally, there is also a possibility that regression toward the mean contributed to the decrease in negative affect, as we selected the participants with the most negative affect for the intervention study and negative affect can fluctuate.

Our findings contradict with previous studies on cognitive reappraisal and acceptance in different contexts. Several explanations could clarify this difference. Most of the studies exposed participants to a video to induce specific negative emotions. Usually these studies compare the effect of cognitive reappraisal or acceptance instructions to a control group in which participants did not receive any instructions (Campbell-Sills et al., 2006; Feinberg et al., 2012; Hofmann et al., 2009; Shallcross et al., 2015; Szasz et al., 2016; Troy et al., 2018; Uusberg et al., 2016; Wolgast et al., 2011).

### ***Methodological considerations***

This study has the following limitations. The use of social media for recruiting participants leads to selection bias. For example, higher educated women who were born in the Netherlands were overrepresented in this study compared to the general population of the Netherlands. Therefore, more research about ER strategies among more diverse groups is needed, preferably not only in an online context. Nevertheless, social media seemed a suitable method to reach our target group, since (prospective) parents are regularly found to be active on social media and pregnant individuals who are uncertain about their choice about MPV tend to seek information on the internet (Clarke, 2020).

A limitation of the interventions was that they were online, and in the form of written instructions. Despite our efforts to design the intervention instructions based on existing

studies (Hofmann et al., 2009; Troy et al., 2018) and our efforts to ensure that participants correctly understood and applied the ER strategies, we were not able to completely assess the extent to which the strategies were implemented. Therefore, the lack of effect found of the interventions on negative affect in this study cannot completely be extrapolated to other ways in which people can be encouraged to use acceptance or cognitive reappraisal. This means that in other forms, for example with the guidance of a professional or via video instructions, these strategies could still be worthwhile to investigate.

When using the PANAS-scale to measure negative affect about the MPV decision, we argued that it is unlikely for pregnant individuals to feel shame about having the opportunity to choose about MPV, and we decided to exclude this item from the scale in our study. However, in hindsight, we can imagine that shame could have played a role, for example because of a participants' opinion about MPV that they feel shame about. This is a limitation of the study, because participants could have been experiencing slightly more negative affect than we measured.

This study was performed during early days of the COVID-19 pandemic in the spring of 2019. Some women reported negative affect due to the COVID-19 pandemic and concerns with regard to risks of infection, for example of having to go to a location to get MPV. This illustrates that the negative affect experienced by women when making the choice about MPV was sometimes based on considerations women would not have to think about when the world was not facing a pandemic. This could mean that the underlying reasons for some of the experienced negative affect would not be present in times without a pandemic.

### **Conclusion**

This study showed that negative affect is negatively associated with intention to accept the MPV. This stresses the relevance of addressing the emotions pregnant women experience when making the decision about the MPV in communication about the MPV. The study showed no effect of online, written instructions to apply cognitive reappraisal or acceptance to decrease negative affect or decrease the influence of negative affect on intention compared to the control group. Exploratory analyses showed that participants who actually used acceptance as ER strategy according to coding of the participants' answers may have had a weaker influence of negative affect on intention to accept MPV compared to pregnant women who did not use acceptance. This might suggest that acceptance could be a promising strategy to further explore. However, more studies on the effect of acceptance and cognitive reappraisal on the influence of negative affect are needed.

**Practical implications**

Negative affect is negatively associated with intention to accept MPV. Therefore, it is important for communication strategies to focus on the emotions pregnant women experience when making a decision about MPV, rather than solely focusing on information provision. Care providers can accomplish this by actively checking whether pregnant women experience negative affect regarding making the decision for MPV and encouraging them to make an informed and deliberate decision. Acceptance could potentially be a successful ER strategy that could facilitate this. Future research should examine whether acceptance is an effective ER strategy and how to effectively implement this.





# Chapter 5

The systematic development of an online tailored decision aid and a Centering-based group antenatal care intervention to promote informed decision making regarding maternal pertussis vaccination

EMBARGOED

Authors: Charlotte Anraad, Pepijn van Empelen, Robert A. C. Ruiter, Marlies Rijnders, Katja van Groessen, Hilde M. van Keulen. *Submitted for publication.*





# Chapter 6

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

EMBARGOED

Authors: Charlotte Anraad, Pepijn van Empelen, Robert A.C. Ruiter, Hilde van Keulen.  
*Submitted for publication.*



# Chapter 7

Use of an online tailored decision aid to promote informed decision making about maternal pertussis vaccination: Process evaluation of a randomised controlled trial

EMBARGOED

Authors: Charlotte Anraad, Pepijn van Empelen, Robert A.C. Ruiter, Hilde van Keulen.  
*Submitted for publication.*



# Chapter 8

Promoting informed decision-making about maternal pertussis vaccination in Centering Pregnancy group-antenatal care: a feasibility study.

EMBARGOED

Authors: Charlotte Anraad, Pepijn van Empelen, Robert A.C. Ruiter, Marlies Rijnders, Katja van Groessen, Jeroen Pronk, Hilde van Keulen. *Submitted for publication.*



# Chapter 9

General discussion





This thesis had three complementary aims: (1) to gain a deeper understanding of the needs of pregnant individuals in decision making about Maternal Pertussis Vaccination (MPV), (2) to systematically develop and pre-test two interventions promoting MPV uptake and informed decision-making about MPV, and (3) to experimentally test the interventions for effects on informed decision making and evaluate use and acceptability of the interventions among pregnant individuals. Intervention Mapping (IM) was used as the framework for designing our interventions. In this chapter, we summarize and reflect on the results of the needs assessment (**Chapters 2 and 3**), the systematic design of the interventions (**Chapters 4 and 5**) and the findings of the intervention testing (**Chapters 6, 7 and 8**). This is followed by discussing the strengths and weaknesses of the research presented in this thesis. The chapter concludes with recommendations for practice and for future research.

## Assessing needs for decision making

The needs assessment was focused on aim one: gaining a deeper understanding of the needs of pregnant individuals in decision making about MPV. In **Chapter 2** we investigated factors associated with the intention to accept MPV. We conducted a cross-sectional survey among women who were pregnant, women who had had a child in the previous two years, and those who had a child-wish and were of fertile age. Because MPV was not introduced in the Netherlands at the time, MPV uptake could not be measured so we measured intention to get MPV instead. According to the Theory of Planned Behaviour and more recently, the Reasoned Action Approach, intention is the most proximal determinant of behaviour (Ajzen, 1991; Fishbein & Ajzen, 2010), and although there is a gap between intention and behaviour, intention has been found a good predictor of future behaviour (Webb & Sheeran, 2006). In line with the Theory of Planned Behaviour, intention to accept MPV was explained by attitude towards the vaccination in our study, and attitude is in turn informed by specific beliefs and perceived social norms. In addition, the belief that it is a moral responsibility to get vaccinated (moral norm) was associated with attitude, as was the belief that MPV was safe and effective and the belief that the participant's

partner (if applicable) and obstetric care provider (usually a midwife or gynaecologist) approved of MPV (injunctive norms). Perceived risk of a baby getting whooping cough and the perceived severity of whooping cough for babies were also significantly associated. The belief that most people got MPV during pregnancy (descriptive norm) was related to a higher intention to get MPV oneself. In addition, emotions like fear of MPV and of the baby getting whooping cough and anticipated regret of getting MPV were associated with intention to get MPV.

An important finding that was not found in other studies was that pregnant women had a lower intention and attitude towards MPV than those who were not pregnant. A reason could be that affective factors about MPV play a bigger role when the decision has to be made compared to when the decision is not of direct imminence (Loewenstein, 2005). When the decision needs to be made, unanticipated intuitive feelings of wanting to protect the unborn child may influence the decision. Furthermore, we found that the relationship between MPV determinants and MPV intention was moderated by decisional certainty; attitude, beliefs, social norms and risk perceptions had lower predictive value under low decisional certainty. This finding suggests a challenge for studies promoting vaccination uptake because it indicates that we are less able to predict choices among those in doubt. And it is especially those people in doubt whose choices we most need to understand to be able to support them with informed decision-making. The determinants of MPV intention still have predictive value for those in doubt and are important to consider in intervention development, but there might be additional (affective) factors at play.

The findings in **Chapter 2** confirmed studies about maternal vaccination (either flu-vaccinations or MPV) done in other high-income countries (Wilson et al., 2015). The findings also provide support the application theories like the Theory of Planned Behaviour and its most recent adaptation, the Reasoned Action Approach, and the Health Belief Model (Ajzen, 1991; Fishbein & Ajzen, 2010; Janz & Becker, 1984) as theoretical frameworks that can help in gaining a good understanding of the determinants of behaviour. With a high explained variance of the regression model to explain MPV intention (79%) and attitude (76%) we identified a highly relevant set of factors that play a role in the decision about MPV, giving us crucial knowledge for selecting target variables for the interventions we developed later in the project. However, there is still unexplained variance in the models, and there is a difference between pregnant and non-pregnant women that is inexplicable from our measured variables. This implies that the theories underlying the study, in the context of vaccination behaviour, could benefit from taking additional factors such as affect into account. We will go further into the potential role of affect below.

Specific factors may hinder people to turn their positive intention into behaviour. A recent WHO report emphasised that creating a facilitating environment and thereby lowering barriers is one of the most important ways to promote vaccination programmes (World Health Organisation, 2020). Interventions aiming to increase uptake of vaccinations seem most effective when they focus on lowering the barrier to getting the vaccination, such as providing it at a convenient location, free of charge, at a convenient moment for the recipient (Lytras et al., 2016). To learn about these barriers to MPV uptake, we thought it was essential to understand the wishes and needs of the target group with regard to getting MPV and being informed about MPV. **Chapter 3** reports the needs for decision support, communication about and organisation of MPV. Apart from getting insights into the topics that participants wanted to be informed about and the preferred channel for the information, the most notable result was from whom they wanted to receive information from about MPV and where they preferred to get the MPV. Participants showed a strong preference for the obstetric care provider for both the counselling and administering of MPV. However, currently both tasks are assigned to the Youth Health Services (in Dutch: Jeugdgezondheidszorg). This means that there is a discrepancy between the preferences of pregnant individuals and the way the MPV is currently organised, potentially leading to sub-optimal uptake of MPV. The discrepancy can be bridged partially or completely by assigning these tasks to obstetric care providers. This could be a promising method to increase MPV uptake, given the potential of interventions that reduce barriers to vaccination uptake (Lytras et al., 2016). If the obstetric care provider gives the MPV, this means pregnant individuals do not need to make a separate appointment or go to another location to ask questions about MPV and to get MPV.

In addition to the survey studies, we ran a qualitative focus-group study that is described in the needs-assessment paragraph of the intervention design described in **Chapter 5**. The aim of this study was to get more insight into the decision-making process about MPV, and to test preferences for interventions. Some findings were in line with the findings from the survey studies, including the wish to receive information from a healthcare provider giving the vaccine. In addition to determinants from the survey study, this qualitative study provided insight into other stages of the decision-making process, such as how information is collected by pregnant women. Aside from searching for information online and asking their obstetric care provider, participants indicated asking other (formerly) pregnant women about their experience with MPV. The partner was not considered a valuable source of information, but their support was valued. When in doubt, the default decision was to not get MPV. We noticed strong differences between focus-group participants who had had a recommendation from their obstetric care provider to get MPV and participants whose obstetric care provider had not given a recommendation or did not have a strong opinion about MPV. The latter were more confused and hesitant about MPV.

Summarizing these three empirical studies we learned that the need for information about MPV among pregnant women in the Netherlands is high. Unlike with childhood vaccinations, where uptake is high despite many people making uninformed decisions (Lehmann et al., 2017), the default decision when uncertain was to refuse MPV, although it should be noted that this was during a time when MPV was not yet in the national immunisation programme. It shows that decision making about vaccination during pregnancy is different from decisions about childhood vaccinations, possibly because the vaccination during pregnancy is still relatively new, and possibly because people are extra cautious during pregnancy. This shows that studies about the acceptance of a specific type of vaccination are not always generalizable to other vaccinations, stressing the need for replication of studies and testing of determinants found in different contexts. The needs assessment showed that affect plays a potentially pivotal role in decision making among those in doubt, and yet not many interventions promoting vaccination uptake focus on affect (Betsch et al., 2010). We know specific emotions such as fear of the vaccination or of the disease are of influence. However, targeting fear is generally not considered a fruitful strategy in health interventions (Ruiter et al., 2014). It is not completely clear how affect and emotions can best be addressed in decision making interventions about vaccinations, especially in online interventions. Partly it is challenging because the exact ways in which (negative) affect influences MPV decision making are still unclear. Illustrative of this was the focus-group study in which participants indicated that getting MPV just did not 'feel good', but they were unable to specify that feeling. Negative affect is likely to be related to beliefs and concerns about safety of vaccinations, but factually communicating about safety may not be enough to help address negative affect. The helpfulness of factual information depends on trust in the source of that information (Corona Gedragsunit, 2021). The obstetric care provider can possibly play a role in supporting those experiencing negative affect, given that pregnant individuals have high trust in them.

The needs assessment gave us insights into what factors influence the intention to accept MPV, and what barriers may prevent someone from turning that intention into getting the MPV. We used this information in the next section of the thesis, where we systematically developed two interventions aiming to achieve higher MPV intentions and uptake of MPV. Some information is still lacking, e.g., how exactly we can address negative affect about vaccination decision making, and what definitive factors are for those experiencing low levels of decisional certainty. In hindsight, a longitudinal study among pregnant individuals in doubt about vaccination would have been a valuable addition to the needs assessment. This could have helped us to investigate the role of negative affect and other factors at different moments during the decision-making process, and what eventually caused the difference between a decision to refuse or accept MPV.

## Intervention development

### *Intervention Mapping and systematic design*

This part of the thesis addresses aim two: systematically developing and pre-testing two interventions promoting MPV uptake and informed decision-making about MPV. We developed an online decision aid and a Centering Pregnancy (CP) intervention (**Chapter 5**). We used Intervention Mapping to develop the interventions, aiming to increase MPV uptake by promoting informed decision-making about MPV (Bartholomew Eldredge et al., 2016). Intervention Mapping typically contains three perspectives that are applied during the intervention development process: participatory planning, use of empirical research and theory, and an ecological and systems approach for understanding and changing health problems (Bartholomew Eldredge et al., 2016; Fernandez et al., 2019). We applied participatory planning by extensively involving the target group in the intervention development using pre-tests. With regard to the use of theory and empirical research, we identified relevant and changeable determinants from the empirical studies reported in **Chapters 2, 3 and 5**, which were informed by a thorough reading of the empirical literature on determinants of vaccine uptake and underlying theories of behaviour. The ecological and systems approach was challenging to apply to its full potential in the context of MPV. We took into account the personal and interpersonal levels by looking at how the decision is made and the potential roles of others in that process. However, the organisational level, i.e., how people had to make an appointment to get MPV and where to get MPV was not completely in our control because MPV is organised based on national guidelines. Because of this, we were not able to take away some of the potential barriers that exist on the organisational level completely, although we tried to facilitate participants in making an appointment.

However, a part of the decision making about MPV takes place on the personal and interpersonal levels. We chose to focus on informed decision-making as a vehicle for MPV uptake. There were several reasons for this. First, we expected MPV uptake to be higher among those who make an informed decision. This relationship was confirmed in our study (**Chapter 6**). Second, pregnant individuals prefer to make an informed decision (**Chapter 5**). Third, from an ethical viewpoint, informed decision-making while also lowering barriers to uptake are favoured methods of increasing uptake over methods that have a higher level of manipulation and thereby decrease freedom of choice and autonomy, such as rewarding vaccinated people with exclusive benefits. This is especially the case for a vaccination like MPV where the aim is to protect the individual rather than to achieve herd-immunity (Field & Caplan, 2008; Marckmann, 2008).

We chose to target informed decision making using an online decision aid, because it suits the online information-seeking behaviour of the target group, and counterbalances misinformation about vaccinations present online. In addition, the CP intervention also targets informed decision making, but it is more suitable for a wide range of sociodemographic groups, especially low-literate groups, than an online intervention (Krebs et al., 2010; Pot, Paulussen, et al., 2017). Furthermore, decision aids are not meant to replace counselling with a healthcare professional (*IPDAS Voting Document*, 2005), and the needs assessment emphasised that the role of the obstetric care provider in MPV decision making is important. We proceeded to design these interventions systematically with IM.

Using a systematic design for the development of the interventions had several advantages. First, it allowed us to select methods of behaviour change that suited the determinants of the behaviour that was targeted, giving the interventions a greater chance of success. Second, it allowed us to ensure that the interventions met the needs and wishes of the target group, giving them a greater chance of being used as well. Third, describing systematic intervention design ensures that active components of interventions can be identified. Describing the behaviour change methods and their applications in the intervention provides the opportunity to compare interventions on a theoretical level (G.-J. Y. Peters et al., 2015).

Based on the fact that systematic design is theory-based and user-centred, it is to be expected that systematically designed interventions are more effective than interventions that are not systematically designed. Indeed, studies have found that interventions that are theory-based are more effective than non-theory based interventions (O’Cathain et al., 2019; L. W. Peters et al., 2009).

Once an intervention has been developed, its theoretical blueprint can inform and speed up the development of similar interventions, winning back the initial extra time and resources spent on the process. In addition, it is even more expensive to develop an intervention that does not meet the needs of the target group or is ineffective due to a lack of theoretical groundwork or poor implementation or evaluation.

### **User-Centred Design**

We used the user-centred design approach (Kristensson et al., 2008) to make sure the interventions fit the needs and wishes of the target group. Involving members of the target group in the development of an intervention is a crucial part of the IM protocol (Bartholomew Eldredge et al., 2016). Not including the target group in the development of an intervention risks missing key requirements for reach, effectiveness, use and acceptability and yet user-engagement in intervention development is often overlooked or under-re-

ported (Willoughby & Furberg, 2015). We applied user-centred design using focus-groups, an online experiment (described in **Chapter 4**) and extensive pre-testing of the decision aid (described in **Chapter 5**). The CP intervention was developed by and with midwives who had extensive experience with CP. Furthermore, using input from participants during the group sessions is a characteristic feature of CP methodology. No two CP sessions are the same, because it is constantly being attuned to the group's needs by the facilitator.

Part of the pre-testing process for the decision aid was an online experiment that focused on how to address affect with regard to MPV (**Chapter 4**). The experiment confirmed that negative affect is inversely associated with intention to accept MPV, showing the importance of finding suitable strategies to address affect in the decision making of pregnant individuals. In this experiment we investigated whether using a cognitive re-appraisal or acceptance emotion regulation strategy in the context of online information could support pregnant individuals in decision making about MPV. We found that negative affect decreased over time in all conditions, including the control condition. We found a small indication that use of the acceptance strategy could moderate the relationship between negative affect and MPV intention. The influence of negative affect on intention to accept MPV was slightly lower among individuals who used acceptance as emotion regulation strategy. Because the effect of acceptance was very small, we chose not to incorporate acceptance in the decision aid. More research is needed to confirm the usefulness of acceptance as emotion regulation strategy in informed decision making. However, given the importance of affect found in the needs assessment, confirmed in this study by a strong association between negative affect and intention to accept MPV, we made sure that in the interventions there was attention to experienced negative affect, for example by asking participants about potential worries about MPV, and including hesitant people experiencing negative affect in the testimonials about choosing about MPV.

Although quantitatively pre-testing potential intervention components is ideal to optimize effectiveness, it is not feasible to do this with all components. However we used co-creation strategies with the target audience, and interventions are more likely to be effective when they meet the needs of the target group (Bartholomew Eldredge et al., 2016). So, we used smaller sample, qualitative pre-tests to iteratively test intervention prototypes (described in **Chapter 5**). In the first qualitative pre-test of the decision aid in a focus-group setting, we proposed using questions about MPV in the decision aid that participants needed to answer before seeing relevant information or being directed to the intervention component that best suited their needs. In this way, we meant to deploy extensive tailoring of information content, seeing how tailored messages show consistently more positive effects compared to non-tailored messages (Krebs et al., 2010; Smit et al., 2015). Providing task support or guidance through the intervention, for example in the form of

tailoring, and at the same time keeping the intervention workload low and giving users freedom of choice on how to use the intervention is a balancing act. Some participants indicated that answering questions before being able to use the decision aid created a threshold for further use of the decision aid. Therefore, we decided on an approach with more freedom of choice on how to move through the intervention, and we made answering the questions optional. This may have slightly decreased the effectiveness of the intervention, but a higher workload of an intervention is known to cause non-usage attrition, especially among low-literate users (Eysenbach, 2005). To make the intervention as accessible as possible but at the cost of a higher level of content-tailoring, we offered all users the same information initially, with options to answer questions or choose a larger amount of information later on. However, it would have been valuable to quantitatively test whether a more tailored design does indeed lower user engagement, as it is also possible that like with tunnelling elements, it only decreases the perception of efficiency while it increased engagement (Crutzen et al., 2012).

The pre-tests with potential users led to many adjustments and some rigorous changes to the intervention, showing the importance of doing extensive pre-tests at several moments in the intervention development. In each pre-test it turned out that some aspects of the intervention were unclear, which had gone unnoticed by the researchers. Especially based on tests with low-literate users, unforeseen challenges for users came up that led to valuable changes in the decision aid.

### **Low-literate users**

There is a clear link between low literacy and health: low literacy contributes to health inequalities (Moon et al., 2015; Wilson, 2003). In the Netherlands alone, there are an estimated 1.9 million people with poor reading skills (*Aanpak van Laaggeletterdheid. Report on Behalf of the Dutch Parliament*, 2016). Many decision aids do not meet the needs of low-literate people (van Balken et al., 2021). Online interventions can be made suitable for low-literate users by using inclusive design, and there have been calls for health-literacy screening tools for online interventions (Kim & Xie, 2017). We explicitly intended to make the intervention suitable for low literate users and performed one pre-test exclusively among low-literate participants. Among other things, this led to the development of a video on the homepage that explained the use of the decision aid. We altered videos and text and included the possibility to have text read out, to meet different information-mode needs, as this improves the processing of the information (M. H. Nguyen et al., 2018). Texts were adapted to be suitable for low-literate users, without losing appeal to high-literate users. In our study, the pre-test with low-literate users in the intervention development showed that low-literate users use a decision aid differently from other users, emphasizing the importance of adapting online interventions specifically to the needs of low-literate



users (Reinwand et al., 2015). Furthermore, this was possible without compromising the extent to which the intervention meets the needs of other users.

## Evaluation of the interventions

The evaluations of the interventions addressed aim three: testing the interventions to see if they are effective in increasing MPV uptake, its determinants, and promoting informed decision making about MPV, and to assess their reach, use and acceptability. We first conducted effect and process evaluations of the decision aid. We intended to do the same for the CP intervention but due to the COVID-19 pandemic and its associated social distancing measures, group care was not possible for a long period of time. When group care started up again, a large-scale study was not possible within the timeframe of the current project, so we performed a feasibility study.

### *Online decision aid*

The effect evaluation of the decision aid (**Chapter 6**) used a broad scope, measuring not just MPV uptake and informed decision-making, but also determinants of uptake that were targeted in the intervention. Contrary to our expectations, we found no significant effect on MPV uptake with only a 1.3% difference in uptake between the intervention and control group. A first explanation for this is that MPV uptake was much higher in our sample (91%) than in the general population (estimated 70%)(van Lier et al., 2021), so there was less room for improvement than expected. With a sample powered to find a 10% difference in MPV uptake, we could not statistically prove the difference of 1.3% in uptake between the intervention and control group. Albeit small, such differences are relevant on a population level, and therefore it would be worthwhile investigating this further. The selective sample could be due to selection bias; people who are more positive about vaccination and have more trust in academic research are more likely to participate in studies about vaccination decisions. This kind of selection bias is difficult to avoid and very common in intervention studies about vaccine hesitancy (Sadaf et al., 2013). Because we needed informed consent for retrieving vaccination status from the national register, we had to inform participants beforehand about the topic of the study. Future studies that do not require retrieving vaccination status could consider not including the topic of the study in the information for participants or could consider asking for permission at a later point in the study.

Another possible explanation for the lack of a significant effect on uptake is the relatively short amount of time averagely spent on the decision aid by participants; this was just over 4 minutes. This could mean that a potential effect on MPV uptake is not visible in

our data because of a lack of exposure to the intervention. Increasing the use of the intervention is essential to increase its effects, an opportunity for improvement of the intervention lies in its capacity to maintain user engagement. A potential way to do this would be to experiment with using more ‘tunnelling’ elements, i.e., elements that guide the user through the intervention. Although it is counterintuitive because participants in our user-test indicated that a lack of freedom of choice within the intervention would lower their use of the intervention, it may in reality increase use (Crutzen et al., 2012). Potentially most so among those who would most benefit from the decision aid, because it is likely that those in doubt will engage longer with the intervention. Another way in which the use of the decision aid could be improved is by combining it with or integrating it in an interaction with a healthcare professional (Jarrett et al., 2015). For example, the decision aid contains a conversation preparation that can be used to prepare a conversation about doubts about MPV with a healthcare professional. Both reach and use of the intervention could be improved if a pregnant individual was encouraged to use the decision aid to prepare questions about MPV, if needed. In this manner, it can also be combined with the CP intervention. It would be worthwhile to test these strategies and their effects on reach, use, and uptake of MPV.

It is not uncommon for a decision aid about vaccination to have effects on determinants of vaccination uptake and decision making, but inconclusive effects on uptake itself, according to a meta-analysis (Vujovich-Dunn et al., 2021). It could indicate that decision aids increase the robustness and informedness of decisions among those who would have otherwise also chosen to vaccinate, i.e. leading to more deliberated decisions (Peretti-Watel et al., 2015).

Positive intervention effects were found on informed decision-making, specifically on knowledge, and decisional certainty. Seeing no significant increase in MPV uptake, but observing an increase in informed decision making indicates that people moved from passive conformism to enlightened conformism according to the classification of vaccination decisions by Peretti-Watel et al. (Peretti-Watel et al., 2015). This is a positive result, because people who make deliberated, conscious decisions about vaccination are less vulnerable to misinformation because they tend to have more stable attitudes and beliefs about vaccinations (Paulussen et al., 2006). The increase in informed decision-making about MPV is beneficial not only for acceptance of vaccinations during pregnancy, but also for childhood vaccinations, because decision making about vaccination during pregnancy is a predictive factor for vaccination decisions for the child (Danchin et al., 2018). We found a dose-response relationship between use of the intervention and informed decision-making. This means that when the intervention was used more, based on the number of clicks, time spent on the intervention or number of components visited, in-

formed decision-making was higher. Again, this stressed the need for increasing use of the intervention to maximize its effects.

The process evaluation of the decision aid (**Chapter 7**) showed that the intervention was used by most participants who were offered the intervention (80%). Use was higher among those who were recruited via midwifery practices than those recruited via social media. A higher commitment to the study among those recruited in a clinic is not unexpected, because the recommendation to participate in a study from a midwife or other trusted healthcare professional can help engagement (*Primary Care Physicians' Attitudes and Beliefs about Cancer Clinical Trials - Carma L Bylund, Elisa S Weiss, Margo Michaels, Shilpa Patel, Thomas A D'Agostino, Emily B Peterson, Maria Christina Binz-Scharf, Natasha Blakeney, M Diane McKee, 2017, n.d.*).

It has been argued that decision aids are mainly beneficial for hesitant groups (Vujo-vich-Dunn et al., 2021). We found that effects of the decision aid on IDM were present across different levels of decisional certainty and intention towards MPV at baseline, but there was an additional effect on (more positive) affect among those with low decisional certainty. So, the decision aid was useful for the participants that were not hesitant too, but there was an additional benefit for hesitant participants. In the subjective evaluation of our decision aid (**Chapter 7**), evaluations with regard to the amount of information and text and whether the decision aid helped in the decision varied, meaning that some groups evaluated this positively and others indicated that the decision aid did not help them in their decision. Overall, participants evaluated the intervention positively on relevance, usability and reliability.

### **Centering Pregnancy**

During the pandemic, when covid-regulation measures were relaxed, some CP groups tried to start up again or resorted to online group sessions within the boundaries the existing measures. However, due to the changing of measures and limited possibilities because of the measures, and safety-concerns for pregnant individuals, these groups were not consistently taking place. After the lock-down of the fall and winter of 2021-2022, groups started to meet in person again, and we set up a study to investigate whether the CP session about MPV was being implemented as intended, and to see to what extent the session met the needs of the participants. Unfortunately, we were unable to assess effectiveness of the intervention with regard to MPV uptake and informed decision-making with sufficient power to draw conclusions, due to the small sample size and lack of control condition.

In most CP groups, the session was implemented as intended, including detecting the groups' needs, an interactive form of providing information, and time and space to deliberate on the decision. CP facilitators and participants were positive about the intervention, and although most participants were already positive about MPV, they indicated finding it useful to have a full overview of the information, or have their memory refreshed. It seemed that lower-educated participants valued the intervention more highly, indicating it was more relevant for their decision about MPV. CP facilitators were reluctant to ask participants about their personal views on MPV to avoid heated discussions about vaccinations, but participants preferred to have time during the sessions to exchange thoughts and experiences with other participants.

This study showed that group care is a feasible and promising method for promoting informed decision making about MPV. The polarisation of the vaccination debate in society may make healthcare professionals wary of discussing vaccination openly in a group, but the experiences in our study were that it did not lead to problematic discussions. The importance of open conversations between healthcare professionals and people deciding about vaccinations cannot be overstated. Although the final decision about whether or not to get vaccinated is up to the individual, the decision-making process can be shared with a trained healthcare worker. Shared decision making is an effective strategy to increase vaccination uptake (Scalia et al., 2022), especially when done with a trusted healthcare professional such as in the case of MPV, the obstetric care provider.

## **Strengths and weaknesses**

In this section, we will discuss the strengths and limitations of the needs assessment, intervention development, and intervention evaluation.

The first strength of this thesis is that for the needs assessment and intervention development, we used a mixture of qualitative and quantitative methods. While qualitative methods allowed us to dive deeper into the decision making about MPV than the quantitative methods, the latter was more effective in testing to what extent determinants of decision making were present across a larger population sample. Combining qualitative and quantitative methods has been recommended for investigating targets for behaviour change (Steckler et al., 1992), and provides a more complete understanding of the behaviour that one aims to change.

Another strong point is the use of IM and user-centred design as leads for the development of the decision aid. Using these frameworks ensured that the intervention met the

needs of the target group. Pretesting is crucial to ensure that the design results in an appealing, understandable intervention that can be implemented (Bartholomew Eldredge et al., 2016). Although the sample sizes of qualitative pretesting were small, the sample was diverse and included low-literate users. This is another strength, because by doing this the intervention development met an important criterium for inclusive design. We thus had confidence that the decision aid matched the preferences of a wide variety of pregnant individuals in our target group. The fact that the CP intervention and the decision aid can be used separately or complementary adds to the inclusivity of the interventions, because the CP intervention is especially suitable for those with low literacy.

Aside from making sure that the decision aid met the needs of the target group, we also made efforts to maximize its potential for implementation. Many decision aids, even when found effective, are never implemented in routine care (Herrmann et al., 2016). To make it possible to implement the decision aid, during several iterations of the decision aid, we asked for advice from our advisory board including all relevant stakeholders, including the provider of the National Immunisation Programme (National Institute for Public Health and the Environment, RIVM), the Royal Dutch Organisation of Midwives (KNOV), the organisation training for Centering Pregnancy (CenteringZorg) the overarching organisation of direct providers of the MPV to pregnant women (Dutch Youth Health Centre), physicians from preventive Youth Health Services responsible for administering child and maternal vaccinations, and the Netherlands Patients Federation. By doing this, especially by involving the RIVM as communication coordinator about vaccinations and the potential future owner of the decision aid upon implementation, we increased chances of successful implementation upon evaluation. Also, because the decision aid is an online intervention, it can reach a large group at low costs. In the Netherlands, internet use is high at over 90% of the total population (*Individuals Using the Internet (% of Population) - Netherlands / Data*, n.d.). Furthermore, the CP intervention is already continuing to be used by those CP facilitators that received the training, and the training can easily be included in the overarching CP training programme.

Throughout the studies, with the exception of the pre-testing of the interventions, high educated women were overrepresented in our samples. Although we dealt with this by looking at differences between high and low educated participants in the samples, and where possible, correcting for differences, it is a weakness of this thesis. A more representative sample, including more low educated participants, would have allowed us to get a better overview of the heterogeneity of this group with regard to decision making about MPV. Our online recruited samples were selective in the sense that MPV intention and attitude were high, as was MPV uptake, compared to the general population. This kind of selection bias is not uncommon in studies about vaccination uptake (Bradley et al., 2021),

but it is a problem because interventions are most needed among those in doubt and holding ambivalent beliefs about vaccinations. Our RCT results are still generalizable to a large group of the population, but effects may differ slightly among those more hesitant about MPV, and those lower educated.

The intervention evaluation was a challenge due to the COVID-19 pandemic. Initially, we had planned an RCT with a two-by-two design, to test both interventions separately and combined. However, the CP intervention could not take place when the pandemic hit, and social-distancing measures came into place. We then decided to run the trial with two groups, a control group and a group receiving the online decision aid. Recruitment was planned to take place completely via midwifery clinics. This did not work out as planned, with pandemic-related measures of online consultations, fewer consultations, and an increased workload of healthcare professionals working at the clinics, leading to slower recruitment via the clinics than planned. Aside from making efforts to speed up recruitment via the clinics and including more clinics, we had to resort to online recruitment via social media, probably leading to a higher-educated sample. Overall, strengths of our RCT were the randomised and longitudinal design, as well as including a largely objective measure of MPV uptake.

Another strength is the fact that on top of the effect evaluation, we did a process evaluation. This provided insight into whether the intervention was implemented as intended such as who used the intervention and which parts of it were used. The process evaluation included a subjective evaluation of the decision aid, providing insights into how it can be optimised.

During the COVID-19 pandemic, CP facilitators' efforts to find alternative ways to deliver CP care have been tireless and creative. Some groups resorted to online sessions. In our feasibility study, we included both online and in-person sessions about MPV, and we conducted interviews on top of surveys among participants and CP facilitators. Although this type of study, with a small sample, cannot provide us with conclusions about effectiveness and this is a weakness in the thesis, it provided a more in-depth view of how the CP session was received by different participants and CP facilitators than we could have achieved with survey data. This gave us insights into how to tweak the intervention to the needs of the participants and simultaneously how to facilitate CP midwives in doing so.

## **Recommendations for practice**

First, we strongly recommend that the decision aid is implemented and made available on a national scale. The decision aid positively contributed to informed decision making

about MPV, and effects were stronger among participants who used the decision aid more thoroughly. In addition, the decision aid met the needs of pregnant individuals for informed decision making, and they were very positive about the usability, understandability, and usefulness of the decision aid. To maximize successful dissemination of the intervention and reach among low-educated groups, obstetric care providers could provide the decision aid to pregnant individuals who want to read information about MPV. Furthermore, a link to the decision aid could be included in the invitation to get the vaccination that is currently being disseminated by obstetric care providers.

We also recommend that the CP intervention is implemented in its current form. Both participants and midwives evaluated the intervention positively and said it contributed to informed decision making. We recommend CenteringZorg to continue providing training for midwives to implement the intervention. Because with our study we were unable to assess the effects on MPV uptake, MPV uptake should be monitored in CP groups upon implementation.

Following the conclusions from the needs assessment, we recommend that future interventions target beliefs about safety, decisional certainty, social norms, and beliefs about the effectiveness of MPV because these factors are closely associated with MPV uptake. The participants in our studies positively evaluated the decisional balance and two-sided information about MPV in the decision aid, as well as the active learning elements in the CP intervention. In addition, participants indicated wanting to learn from others' experiences with MPV during CP sessions. Therefore, we recommend these methods to target the above determinants of MPV uptake. Interventions should also involve actively checking whether a person experiences decisional conflict and/or negative affect about MPV, and if so, what the cause of that conflict or affect is, because we found that negative affect negatively influenced the intention to get MPV. It is important for healthcare providers to be aware of common misperceptions so they can actively check whether they are present. If so, they need to correct them. We found that common misperceptions are that MPV is not a combination vaccine, and that MPV is unsafe. Because there is a heterogeneity in needs among those choosing about MPV, interventions could choose to focus only on hesitant groups by specifically involving hesitant individuals in the development process.

In the needs assessment we further found that there is a difference between pregnant women versus women who are not yet pregnant in their attitudes towards MPV, with pregnant women having more negative attitudes. Clear explanations for this are lacking, but it indicates that decision making about MPV differs in different stages of pre-pregnancy and pregnancy. Therefore, we recommend not to limit communication about MPV to the pregnancy period. A broader audience can be made aware of MPV to create more robust

attitudes (Petty & Cacioppo, 1986), and to spread awareness about the idea of vaccination during pregnancy in general.

We found that pregnant women who want to talk to a healthcare professional about MPV, want to do this with their obstetric care provider. They also prefer to receive the vaccine from their obstetric care provider. Currently, both tasks are done by the Youth Health Services. In addition, obstetric care providers in our feasibility study (**Chapter 8**) indicated that they often counsel about MPV regardless that it is not their task officially, because they receive questions about it and want to fulfil the information need of their pregnant clients. However, this leaves less time for other topics during consultations, or extra time has to be used for which the obstetric care provider is not compensated. We recommend that both counselling and vaccination should officially be assigned to the obstetric care provider. Not only does this match the preferences of the target group, it also decreases the barrier to accept MPV to not have to make a separate appointment with a new healthcare professional, thereby more effectively addressing the intention-behaviour gap. This was confirmed by a study in the UK that found that uptake increased when obstetric care providers received reminders about MPV and gave MPV instead of the GP, so pregnant clients did not have to make a separate appointment (Skirrow et al., 2021).

Another way to address the intention-behaviour gap within the current situation of Youth Health Services providing MPV is making it easier to make an appointment. Currently, making an appointment to get MPV is organised differently per region, with options including having to call via telephone or having to navigate an online planning system. Based on feedback in our usability test with low-literate users we recommend that all regions include at least an option to make an appointment via telephone. This is crucial in order to make the MPV more inclusive. Ideally, appointments can be made online and by telephone.

We recommend that interventions aimed at informed decision-making and uptake of vaccines are designed using systematic development and user-engagement. This optimizes the chances of success of the intervention, and provides transparency about that methods were used, aiding the identification of effective strategies and causal mechanisms (Gardner et al., 2010; Webb et al., 2010). Design blueprints can be re-used or partly re-used for the design of interventions with similar goals. For example, the design blueprint described in this thesis can be used for the design of other interventions aimed at vaccine-uptake. Such a strategy should include the necessary adjustments and pre-testing to ensure suitability for the new target-group. For example, the blueprint for the decision aid described in this thesis has been used to create a decision aid for COVID-19 vaccinations and a decision aid for the HPV vaccination for children aged ten. This is further described in the impact paragraph. Other possibilities for extending the decision aid blueprint could



be other childhood and flu vaccinations. In addition, it could be extended to other decisions during pregnancy, such as screening decisions.

Nowadays, with digital tools at hand such as text-to-speech converters, decision aids have the chance to help low-literate users, and they should be considered in the design of interventions. We recommend actively involving low-literate users in all stages of the intervention development to promote inclusiveness of interventions.

We recommend that in view of the evaluation of strategies to improve uptake, the MPV vaccination registration is improved, meaning that all MPV administrations are registered. In our study about the effects of the intervention, we found significant discrepancies between self-reported uptake and registered uptake. Because Youth Health Services do not have a complete record of who is pregnant, only those who get MPV can be registered. However, there are also large gaps in data between those who reported having had MPV and those registered to have had MPV. A better view of vaccination uptake will help the evaluation of interventions.

## Recommendations for research

Although we know a lot about cognitive factors influencing MPV decisions, there is still a knowledge gap about the exact ways in which affect influences vaccination decisions. We investigated the effects of online written instructions for cognitive reappraisal and acceptance strategies on the influence of negative affect. More research is needed to make conclusions about the effectiveness of these strategies, and more strategies to address affect should be investigated. This could be done by focusing on hesitant groups, but also by looking at how affect about vaccinations changes over time in the decision-making process, what causes these changes, and what possible entry points for intervention are. A longitudinal study among those experiencing doubt about vaccinations could examine this. This provides further insight into the differences between pregnant and non-pregnant women in their attitudes and intentions towards MPV, explaining different affective and cognitive states before, during and after the decision-making process. This then provides leads for intervention development, such as when interventions can best be used in the decision-making process and how negative affect should be approached.

We also recommend needs assessment studies to take into account decisional certainty as a potential moderator of other determinants. Because we were less able to predict decisions under low certainty, we were potentially missing information about exactly who is in doubt about vaccinations, and some of the potential reasons for their doubt.

Measuring informed decision-making poses challenges. The scale we used, with continuous scores for informedness (knowledge) and consistency between attitude about MPV and behaviour (uptake of MPV), was rigorous in classifying decisions to not vaccinate as uninformed due to low levels of consistency between behaviour and attitude about MPV. Although we avoided using cut-off values in the measure as much as possible, creating a measure of consistency requires the use of one or more cut-off values. For example, the middle of the scale can be used, or the mean or median of the scale. Informed decision-making is a complex process and capturing it in a single output is arbitrary. Based on our findings we support the recommendations by Ghanouni and colleagues (Ghanouni et al., 2016) to describe informed decision-making in terms of informedness and consistency separately. In hindsight, we would have liked to include a measure of deliberation in the informed decision making-scale, as suggested by Elwyn & Miron-Shatz (2009), Lewis et al. (2016) and M. van den Berg et al., (2006). This would have given us additional insight exactly how the interventions contributed to decision quality, and whether decisions have become more deliberate, and thus less prone to future regret or instability, as well as more informed (Elwyn & Miron-Shatz, 2009).

We recommend studies about online interventions to look at how we can optimize reach of low-literate people and other people with low socio-economic status. We have ways to make interventions accessible to those groups, but adequate reach is still lacking. Effective strategies to promote online interventions among these groups are urgently needed. We recommend looking at how the potential of online interventions can be unlocked in vulnerable groups by combining the initial use of an intervention with an in-person interaction such as consultations with a healthcare professional. Human support increases engagement with health-apps (Balaskas et al., 2021).

### **General conclusion**

The thesis contributed to knowledge on how to support pregnant individuals in their decision making about MPV. It described how pregnant individuals make the decision about MPV and what their needs and preferences are (**Chapters 2 and 3**). It provided an initial exploration of how negative affect can be managed in vaccination decisions (**Chapter 4**). It described the systematic development of two interventions promoting informed decision-making about MPV (**Chapter 5**). We used Intervention Mapping and user-centred design to develop an online decision aid and a CP intervention that show promising results for informed decision making. Although the results about effects on uptake of MPV were inconclusive, the decision aid was effective in increasing informed decision-making and was evaluated positively by the participants (**Chapters 6 and 7**). The CP intervention showed to be a feasible and promising intervention (**Chapter 8**) and is especially suitable for vulnerable groups. It met the needs of both CP participants and

facilitators. Both interventions can be used separately or complementary. We recommend the implementation of the decision aid into standard communication about MPV, and the further investigation of the effects of discussing MPV in CP group care settings.



References

Impact paragraph

English Summary

Nederlandse samenvatting

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Curriculum Vitae

Publication list

Appendices



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## **Impact paragraph**

Vaccination is a proven effective strategy to prevent infectious diseases. Most countries have extensive childhood vaccination programmes to prevent infectious diseases from spreading, and to protect children against illness. Vaccinations are further recommended to protect oneself when travelling to places where certain infectious diseases are present and in specific populations and contexts. Most recently, vaccinations have helped us prevent illness and deaths caused by the COVID-19 pandemic. Vaccination is voluntary, and not everyone finds deciding about vaccinations easy. There is a lot of contradicting information and misinformation present online, and not everyone has faith in governments and national health institutes providing the vaccinations. This leads to sub-optimal reach of vaccination programmes. Therefore, there is a need for adequate information, counselling, and easy access to vaccinations.

This thesis is about how we can support people with their informed decision making about vaccination and increase uptake of vaccinations, specifically in the uptake of Maternal Pertussis Vaccination (MPV). This is a vaccination offered to pregnant individuals at 22 weeks of pregnancy, to protect new-born babies against pertussis, commonly known as whooping cough. From 2005 until 2014, 1,711 cases of pertussis were reported in Dutch infants (Health Council of the Netherlands, 2015c). Of these cases 1,279 were five months of age or younger with 1,020 being admitted to hospital and five mortalities. Based on these numbers, it was decided that MPV should be offered to all pregnant individuals. As of December 2019, MPV is offered by the Youth Health Services in the Netherlands. The aim of this thesis was to understand how pregnant individuals decide about MPV, and to develop and test programmes to promote informed decision making.

We identified needs around decision making about MPV and found that in addition to existing information, interactive online information could be a valuable addition. However, this is not suitable for all groups, especially people with low literacy or people who simply prefer not to use online information. Therefore, we developed two interventions: an online decision aid and a Centering Pregnancy group-care session about MPV. In the online decision aid, people could interactively learn about MPV, and weigh the pros and cons of MPV. The second intervention is based on Centering Pregnancy group-based antenatal care, meaning that individual consultations with an obstetric care provider are replaced with group sessions with 8-12 participants. We developed a training for group-care facilitators and a manual for the session about MPV, that can be used in one of the CP sessions during pregnancy. The session was offered to pregnant individuals between 16 and 18 weeks of pregnancy. Both interventions were developed with the input of the target group and relevant stakeholders.

We evaluated the decision aid and found that it increases how sure people felt about their decision and how informed their decision was. It also increased several factors associated with MPV uptake such as the perceived risk that the participant's baby gets whooping cough. Participants experienced the decision aid overall positively. However, the decision aid did not contribute to a significant increase in MPV uptake, although vaccination rates were higher than average for the studied sample. This needs further exploration in future research. Because a large-scale study with a CP group-care intervention was impossible during the COVID-19 pandemic, we conducted a smaller feasibility study. Interviews with both participants and facilitators of CP indicated that the session met their needs. Those who said that they had not yet decided about MPV before the session, indicated that the session helped them in their decision.

### **Scientific relevance**

This thesis contributes to the field of research on vaccine acceptance and hesitancy. Our finding that the commonly found determinants of MPV uptake have less predictive value under low certainty has consequences for how we study vaccination behaviour and calls for studies specifically among those experiencing low certainty. Additionally, we provided a lead for research about affect regarding vaccinations and emphasised its importance in vaccination behaviour. We also described implications of different ways of measuring informed decision making, providing recommendations for how to measure this in vaccination behavioural research. Furthermore, we hope that this thesis contributes to more use of systematic and user-centred needs assessments and design methods for interventions.

The early studies in this thesis have been published in scientific journals and the rest of the studies have been submitted for publication. Results have also been presented at national and international conferences. We chose conferences both in the field of vaccines and vaccination uptake and health psychology because the studies are relevant for both fields.

### **Societal relevance**

Our target group of pregnant individuals has been involved in the design of the interventions. By examining their information needs and preferences as well as their preferred mode of delivery of information, we were able to draw conclusions that can be used in practice immediately. For example, we now know which topics future communication should focus on, and which (sub-)topics are of less interest. This helps the development of communication materials providing pregnant individuals with information about MPV in the Netherlands. These results have been presented at an innovation session at the Dutch Youth Health Centre (NCJ) to healthcare professionals working in Youth Health Services. In addition, upon learning about the discrepancy between the needs of pregnant



women to be informed about MPV and to receive MPV by their obstetric care provider and the current practice of these tasks being performed by the Youth Health Services, we published an article in a Dutch scientific journal for health professionals to raise attention for this. Although in practice it may be a logistic challenge to have MPV delivered by obstetric care providers, it is easier to officially place the task of counselling about MPV with them, given that they do most of the counselling in practice.

When designing the interventions, we involved an advisory committee. The committee consisted of representatives of the RIVM (National Institute for Public Health and the Environment), holder of the National Immunisation Programme and responsible for communication about vaccinations in the Netherlands; the Royal Dutch Organisation of Midwives (KNOV) advocating for the interests of midwives in the Netherlands; the organisation training for Centering Pregnancy (foundation CenteringZorg); the overarching organisation of direct providers of the MPV to pregnant individuals (Dutch Youth Health Centre, NCJ), physicians from preventive Youth Health Services, responsible for administering child and maternal vaccinations; and, finally, the Netherlands Patients Federation. The RIVM was involved from the start of the project as co-applicant. Their early involvement helped us to align the design of the decision aid with their implementation context and their needs and requirements for future ownership, to maximise the chance of successful implementation. This means that they can imbed the decision aid in their information provision and disseminate it among the target group. Additionally, they can imbed information about new vaccinations during pregnancy (e.g., flu vaccination, expected to be offered in 2023) in the decision aid. The foundation CenteringZorg is a potential co-owner of the decision aid and was the implementation partner for the CP intervention. The CP intervention was developed in collaboration with CenteringZorg and was implemented through training of CP facilitators. Not only are the CP facilitators who took part in the study still using the MPV session in their CP practice, but the training is also imbedded in the CP facilitator training programme

The target group of pregnant individuals in the Netherlands can benefit from the implemented CP intervention and the decision aid that is ready to be implemented. The decision aid has been shown to promote informed decision-making about MPV and decrease perceived uncertainty about the decision. Informed decision-making can lead to more stable vaccination opinions and can lead to higher uptake of MPV. With MPV being the first vaccination in a series of parental vaccination decisions, informed decision making about MPV can also help uptake of childhood vaccinations.

The CP intervention was perceived positively by participants in our study, and most participants who had not yet made the decision indicated that the session about MPV helped

them. The existing information does not include interactive online information or group-care. Our interventions add this, to help optimise informed decision-making and MPV uptake. Once developed, they are relatively easy and cheap to use. The interventions can be disseminated through obstetric care providers into the current context of the information provided by the RIVM and within existing CP care. Since recruitment via the obstetric care provider increased the use of the decision aid in our study, we believe that obstetric care providers can play an important role in disseminating the decision aid, either in combination with the CP intervention or in individual consultations. The decision aid can also be disseminated by adding a link or QR-code to the invitation to get MPV handed out by obstetric care providers.

Furthermore, the systematic design of the decision aid has already led to the development and implementation of two other vaccination decision aids: one for COVID-19 vaccinations ([www.coronavaccinatie-keuzehulp.nl](http://www.coronavaccinatie-keuzehulp.nl)) and one for Human Papilloma Virus (HPV) vaccination for adolescents and children ([www.hpvkeuzehulp.nl](http://www.hpvkeuzehulp.nl)). With the existing intervention blueprint, these decision aids could be developed very quickly. Relevant stakeholders (e.g., the Ministry of Health and the RIVM) were involved, texts and videos were adapted, and user tests were done with the target group to see where the decision aid needed adjustments.

### **Conclusion**

We have contributed to knowledge about decision making about vaccination during pregnancy. We developed two interventions that have shown their ability to assist pregnant individuals decide about MPV: a decision aid and CP group-care intervention. The decision aid can be made accessible to the general population to help pregnant individuals in the Netherlands choose about MPV. The CP intervention can be offered to all pregnant individuals in CP groups. These interventions have the potential to help make vaccination decisions more robust, leading to a higher uptake of MPV and other vaccinations.

## English Summary

Pertussis, commonly known as whooping cough, is a worldwide health concern for babies. Newborns who are not vaccinated yet are particularly vulnerable to it; infection can lead to hospitalisation, brain damage, or even death. In the Netherlands, pertussis is also prevalent, causing babies to get infected every year. Therefore, maternal pertussis vaccination (MPV) was introduced in the National Immunisation Programme in 2019. MPV consists of one injection given to a pregnant individual at 22 weeks of pregnancy. Maternal immunisation is passed on to the baby, giving them protection against pertussis from birth. However, uptake of MPV had room for improvement with 70% of pregnant individuals choosing to get MPV in 2020. Therefore, this thesis focused on decision making about MPV by pregnant individuals.

This thesis had three complementary aims: (1) to gain a deeper understanding of the needs of pregnant individuals in decision making about Maternal Pertussis Vaccination (MPV), (2) to systematically develop and pre-test two interventions promoting MPV uptake and informed decision-making about MPV, and (3) to experimentally test the interventions for effects on MPV uptake, level of informed decision making, use and acceptability of the interventions. To reach these aims, we used the Intervention Mapping (IM) protocol. IM provides a framework for the systematic, evidence-based development of interventions, and consists of 6 steps: (1) a needs assessment; (2) specification of change objectives; (3) selection of theory-based intervention methods and practical applications; (4) production of the intervention programme; (5) planning of programme implementation; and (6) a process and effect evaluation. The needs assessment is reported in **Chapters 2 and 3**. **Chapters 4 and 5** describe the intervention development. **Chapters 6, 7 and 8** describe the effect and process evaluations of the interventions.

**Chapter 2** describes a survey study about the determinants of the intention to accept MPV among pregnant individuals in the Netherlands. Our findings confirmed studies from other countries: main determinants associated with intention to accept MPV were attitude about MPV, beliefs about safety of MPV, moral norms, the belief about the effectiveness of MPV, injunctive norm (the belief that most pregnant individuals will get MPV), anticipated regret of vaccinating, and decisional certainty. In our sample, decisional certainty was further found to be moderating the relationship between attitude about MPV and intention to accept MPV, meaning that we were less able to explain intention under low decisional certainty than under high decisional certainty. Furthermore, average intention and attitude regarding MPV was lower among pregnant individuals compared to the non-pregnant individuals in our sample, indicating that affective factors may also

play a role. These results were the groundwork for the development of the interventions to promote informed decision making about MPV described in chapter 5.

**Chapter 3** provided insight into the preferences and information needs of pregnant individuals regarding MPV. This survey study showed that pregnant individuals want to receive information about side-effects for themselves and the baby, the effectiveness of the vaccine, and the risk for babies to get pertussis with or without a vaccination. They, by order of preference, wanted to receive information about the vaccine from their midwife, their gynaecologist or their general practitioner (GP). Participants preferred to be informed ahead of getting the vaccine, at the beginning of pregnancy or at 20 weeks of pregnancy. Participants indicated that they would prefer to receive the vaccine from their obstetric care provider or their GP. There is a discrepancy between the preferences of pregnant individuals and the way MPV injections are organised, because MPV is currently administered at the Youth Health Services (JGZ).

**Chapter 4** describes an exploration on how to address negative affect about MPV. With literature on effective strategies to address negative affect in decision making about vaccinations lacking, we designed an experiment to test emotion regulation strategies in MPV decision making. Participants were requested to apply cognitive reappraisal or acceptance strategies when experiencing negative affect. We found that negative affect was inversely associated with intention to accept MPV. Over time, negative affect decreased in all groups, including the control group. Although we did not find effects of the emotion regulation strategies on negative affect directly, the acceptance strategy appeared to decrease the influence of negative affect on intention to accept MPV. This study emphasised the importance of considering emotions and affective states in communication about vaccinations, and the acceptance strategy is worth researching further.

**Chapter 5** describes the design of the two interventions using IM. We focused on promoting informed decision making (IDM) as a vehicle to increase uptake of MPV. The information from the needs assessment was integrated into a theoretical framework, in which determinants were linked to theory-based methods of behavioural change. These methods were then developed into practical applications. We created an online tailored decision aid (DA), applying user-centred design to develop and test the intervention with pregnant individuals, including people with low literacy, in four iterations. Participants evaluated prototypes of the intervention positively on relevance and usability. In addition, a Centering Pregnancy (CP) intervention was developed with midwives. CP is group-based antenatal care, where individual consultations are replaced with 2-hour group sessions with 8-12 participants. Our intervention consisted of a CP session, led by a midwife, in which MPV was discussed.

**Chapter 6** describes the effect-evaluation of the online DA. The aim of this evaluation was to study the effects of the DA on MPV uptake, IDM and determinants of MPV compared to usual care (no DA). We recruited participants via midwifery clinics and social media for a randomised controlled trial. 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 and its component knowledge about MPV. We also found an increase in decisional certainty, perceived susceptibility and severity of pertussis, and positive affect about MPV. Among participants in the intervention condition, 79.0% used the DA at least once. There was an association between level of use of the intervention and MPV uptake, indicating that increasing the use of the intervention could be beneficial for its effects on MPV uptake.

**Chapter 7** describes the process evaluation of the online DA. To interpret the results from the effects evaluation and to identify ways in which the decision aid can be improved, we looked at how the DA was used by participants in the intervention group and studied the acceptability of the DA. Participants evaluated the DA positively, reflecting the user-centred design approach. Reach of the DA was adequate, with 79% of the participants visiting the DA. However, use of the DA left room for improvement, with only 4.25 minutes spent on the DA on average.

**Chapter 8** shows the results of a feasibility study of the CP intervention. We were not able to conduct a large-scale trial due to the COVID-19 pandemic, hence we studied the CP intervention in a smaller setting once pandemic-related regulations were relaxed. Interviews and surveys showed that the CP intervention was implemented as intended in almost all groups. Participants were positive about the interactive CP-methods used to discuss MPV, and most participants preferred hearing from other participants about their experiences with MPV and opinions of MPV. Participants and facilitators evaluated the intervention as positive and relevant, although the intervention was time-consuming, and some participants had already made the decision about MPV. However, those who had not yet decided indicated that the session was helpful for the decision.

In the general discussion in **Chapter 9**, we summarised the results from the studies, and described recommendations and implications for future research and practice. We emphasised that attention for affect and emotions in research and communication about vaccination decisions are essential. We recommend future interventions to be developed systematically and with user-centred design. Although IM is a time-consuming process, the systematic development of the DA has already served as a blueprint for two other decision aids (i.e., for COVID-19 vaccinations and for HPV-vaccinations). It is important to ensure reach and use of the interventions among vulnerable groups such low-literate

people. Obstetric care providers can play an essential role in promoting the DA. Furthermore, we recommend that both the CP intervention and the DA are implemented on a national scale, given their potential to increase IDM and uptake of MPV.

## Nederlandse samenvatting

Kinkhoest is over de hele wereld een gezondheidsprobleem voor baby's. Pasgeboren baby's die nog niet gevaccineerd zijn, zijn er bijzonder kwetsbaar voor. Besmetting kan ziekenhuisopname, hersenbeschadiging of zelfs overlijden tot gevolg hebben. Ook in Nederland komt kinkhoest veel voor, waardoor jaarlijks baby's besmet raken. Daarom is in 2019 de maternale kinkhoestvaccinatie (MKV) ingevoerd in het Rijksvaccinatieprogramma. MKV bestaat uit één injectie die bij 22 weken zwangerschap wordt toegediend. De maternale antistoffen worden doorgegeven aan de baby, waardoor die vanaf de geboorte beschermd is. In 2020 besloot een sub-optimale 70% van de zwangeren om de MKV te nemen. Daarom richtte dit proefschrift zich op de besluitvorming van zwangeren over de MKV.

Het proefschrift had drie complementaire doelstellingen: (1) een beter begrip krijgen van de behoeften van zwangere personen bij de besluitvorming MKV, (2) het systematisch ontwikkelen en testen van twee interventies ter bevordering van acceptatie van MKV en geïnformeerde besluitvorming over MKV, en (3) het experimenteel testen van de interventies op effecten op de MKV-vaccinatiegraad, geïnformeerde besluitvorming, gebruik van de interventies en de subjectieve evaluatie van de interventies van zwangeren. Om deze doelen te bereiken, gebruikten wij het Intervention Mapping (IM) protocol. IM biedt een kader voor de systematische, evidence-based ontwikkeling van interventies, en bestaat uit 6 stappen: (1) een analyse van het probleem; (2) matrix van veranderdoelen; (3) selectie van op theorie gebaseerde interventiemethoden en praktische toepassingen; (4) programmaontwikkeling; (5) planning van de programma-implementatie; en (6) een proces- en effectevaluatie. De probleemanalyse is beschreven in de **Hoofdstukken 2 en 3**. De **Hoofdstukken 4 en 5** beschrijven de ontwikkeling van de interventie. De **Hoofdstukken 6, 7 en 8** beschrijven de effect- en procesevaluatie van de interventies.

**Hoofdstuk 2** beschrijft een onderzoek naar de determinanten van de intentie om MKV te nemen onder zwangeren in Nederland. Onze bevindingen bevestigden resultaten van onderzoek uit andere landen: de belangrijkste determinanten waren attitude t.o.v. MKV, de overtuiging dat MKV veilig is, morele normen m.b.t. vaccineren, de overtuiging over de effectiviteit van MKV, injunctieve norm (de inschatting dat de meeste zwangeren MKV zullen nemen), geanticipeerde spijt van vaccineren, en zekerheid over de beslissing. In deze studie bleek een lage zekerheid over de beslissing verder de relatie tussen attitude t.o.v. MKV en intentie om MKV te nemen te matigen. Bovendien was de gemiddelde intentie en attitude t.o.v. MKV lager bij zwangeren dan bij niet-zwangeren in onze steekproef, wat erop wijst dat affectieve factoren ook een rol kunnen spelen. Deze resultaten vormden de basis voor de ontwikkeling van de in hoofdstuk 5 beschreven interventies om de geïnformeerde besluitvorming rondom MKV te bevorderen.

**Hoofdstuk 3** gaf inzicht in de voorkeuren en informatiebehoeften van zwangeren met betrekking tot MKV. Uit dit onderzoek bleek dat zwangere individuen informatie willen ontvangen over bijwerkingen voor henzelf en de baby, de effectiviteit van het vaccin en het risico voor baby's om kinkhoest te krijgen met of zonder vaccinatie. Zij ontvangen bij voorkeur informatie over het vaccin van hun verloskundige, gevolgd door hun gynaecoloog of huisarts, en worden het liefst geïnformeerd aan het begin van de zwangerschap, en uiterlijk bij 20 weken zwangerschap. De deelnemers gaven aan dat zij het vaccin het liefst van hun verloskundige zorgverlener of hun huisarts zouden krijgen. De voorkeuren van zwangeren en de huidige manier waarop MKV is georganiseerd komen niet overeen, omdat MKV momenteel wordt toegediend bij de Jeugdgezondheidszorg (JGZ).

**Hoofdstuk 4** is een verkenning van mogelijke manieren om met negatief affect, dat wil zeggen een negatief gevoel, t.o.v. MKV om te gaan. Bij gebrek aan literatuur over effectieve strategieën hebben we een experiment ontwikkeld om emotieregulatiestrategieën bij MKV-besluitvorming te testen. Deelnemers werden gevraagd om cognitieve herwaarderings- of acceptatiestrategieën toe te passen bij het ervaren van negatief affect. Negatief affect was negatief geassocieerd met de intentie om MKV te aanvaarden. Na verloop van tijd nam negatief affect in alle groepen af, ook in de controlegroep. Hoewel we geen direct effect vonden van de emotieregulatiestrategieën op negatief affect, bleek de acceptatiestrategie de invloed van negatief affect op de intentie om MKV te accepteren te verminderen. Deze studie liet het belang van het overwegen van emoties en affect in communicatie over vaccinaties zien, en de acceptatiestrategie is verder onderzocht waard.

**Hoofdstuk 5** beschrijft de opzet van de twee interventies met IM. We richtten ons op het bevorderen van geïnformeerde besluitvorming als middel om het gebruik van MKV te vergroten. De informatie uit het behoeftenonderzoek werd geïntegreerd in een theoretisch kader, waarin determinanten werden gekoppeld aan op theorie gebaseerde methodes voor gedragsverandering. Deze methodes werden vervolgens uitgewerkt tot praktische toepassingen. We maakten een online keuzehulp op maat en pasten gebruikersgericht ontwerp toe om de interventie in vier iteraties te testen met zwangeren en laaggeletterden. De deelnemers beoordeelden de prototypes van de interventie positief op relevantie en bruikbaarheid. Daarnaast werd samen met verloskundigen een Centering Pregnancy (CP)-interventie ontwikkeld. CP is prenatale groepszorg, waarbij individuele consulten worden vervangen door 2 uur durende groepsessies met 8-12 deelnemers. Deze interventie bestond uit een CP-sessie waarin MKV werd besproken.

**Hoofdstuk 6** beschrijft de effectevaluatie van de online keuzehulp. Het doel van deze evaluatie was om de effecten van de keuzehulp op (MKV) vaccinatie-status, geïnformeerde besluitvorming en determinanten van MKV te bestuderen in vergelijking met gebruikelijke



zorg (zonder keuzehulp). We werven deelnemers via verloskundigenklinieken en sociale media voor een gerandomiseerde gecontroleerde trial. In onze steekproef was het aantal deelnemers dat MKV had geaccepteerd hoog (92,3%). Er werd geen significant effect van de keuzehulp op de vaccinatie-status gevonden in vergelijking met de controleconditie. Wel zorgde de keuzehulp voor een grotere mate van geïnformeerde besluitvorming en, als onderdeel daarvan, meer kennis over MKV. We vonden ook een toename in zekerheid over de beslissing, ingeschatte kans dat een baby kinkhoest krijgt en ernst van kinkhoest, en (een meer) positief affect over MKV. Van de deelnemers in de interventieconditie gebruikte 79,0% de keuzehulp minstens één keer. Er was een verband tussen de mate van gebruik van de keuzehulp en het gebruik van MKV, dat erop wijst dat een groter gebruik van de interventie gunstig zou kunnen zijn voor de effecten ervan op positieve MKV-vaccinatiestatus.

**Hoofdstuk 7** beschrijft de procesevaluatie van de online keuzehulp. Om de resultaten van de effectbeoordeling te kunnen interpreteren en na te gaan hoe de keuzehulp kan worden verbeterd, hebben we gekeken naar het gebruik van de keuzehulp door deelnemers in de interventiegroep, en de aanvaardbaarheid van de keuzehulp bestudeerd. De deelnemers evalueerden de keuzehulp positief, wat het gebruikersgerichte ontwerp weerspiegelt. Het bereik van de keuzehulp was voldoende: 79% van de deelnemers bezocht de keuzehulp. De mate van gebruik van de keuzehulp was echter voor verbetering vatbaar: gemiddeld werd slechts 4,25 minuten aan de keuzehulp besteedt.

**Hoofdstuk 8** toont de resultaten van een haalbaarheidsstudie van de CP-interventie. Omdat we vanwege de COVID-19-pandemie geen grootschalige proef konden uitvoeren, hebben we de CP-interventie in een kleinere setting bestudeerd zodra de pandemiegerelateerde regelgeving was versoepeld. Uit interviews en enquêtes bleek dat de CP-interventie in bijna alle groepen werd toegepast zoals bedoeld. Deelnemers waren positief over de interactieve CP-methoden die werden gebruikt om MKV te bespreken, en de meeste deelnemers hoorden graag van andere deelnemers over hun ervaringen met MKV en meningen over MKV. Deelnemers en begeleiders beoordeelden de interventie als positief en relevant, ondanks dat de interventie veel tijd in beslag nam en sommige deelnemers de beslissing over MKV al hadden genomen. Degenen die nog niet hadden besloten gaven echter aan dat de sessie nuttig was voor de beslissing.

In de algemene discussie in **Hoofdstuk 9** vatten we de resultaten van de studies samen, en beschrijven we aanbevelingen en implicaties voor toekomstig onderzoek en praktijk. Wij benadrukten dat aandacht voor affect en emoties in onderzoek en communicatie over vaccinatiebeslissingen essentieel is. Wij bevelen aan om toekomstige interventies systematisch en met een gebruikersgericht ontwerp te ontwikkelen. Hoewel IM een tijd-

roevend proces is, heeft de systematische ontwikkeling van de keuzehulp al gediend als blauwdruk voor twee andere online keuzehulpen (namelijk voor COVID-19-vaccinaties en voor HPV-vaccinaties). Het is belangrijk om extra te investeren in het bereik en het gebruik van de interventies onder kwetsbare groepen zoals laaggeletterden. Verloskundigen kunnen een essentiële rol spelen bij de bevordering van de keuzehulp. Daarnaast bevelen wij aan dat zowel de CP-interventie als de keuzehulp op nationale schaal worden ingevoerd, gezien hun potentie om geïnformeerde besluitvorming en het gebruik van MKV te vergroten.

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## **Curriculum Vitae**

Charlotte Anraad was born in Utrecht in 1993. She finished her BSc in Health Sciences at VU University Amsterdam in 2015, during which she focused on biomedical and health interventions. After an extracurricular minor in journalism at the Hogeschool Utrecht, she started her MSc at Maastricht University. In 2016, she finished the program 'Healthcare Policy, Innovation and Management', with a thesis focusing on Health Economics in the domain of smoking cessation interventions at Brunel University in London, hosted by prof. S. Pokhrel.

She then worked as a research funding advisor at the Erasmus Medical Centre in Rotterdam. There, she advised about personal grants and funding international cooperation in research. Inspired by the research projects at Erasmus MC and by working on her master thesis publication, she decided to pursue a PhD. In 2018, she started her PhD project at the department of Work and Social Psychology at Maastricht University, seconded at TNO Child Health in Leiden. Under the supervision of prof. Rob Ruiter, dr. Hilde van Keulen, dr. Pepijn van Empelen and dr. Theo Paulussen, she started her project about decision making about maternal pertussis vaccination (MPV) in pregnant women in the Netherlands. Her project was funded by ZonMW. At TNO, Charlotte was involved in the staff association, organizing several events. During the COVID-19 pandemic, she contributed to a project about behavioural compliance to COVID-19 measures. During the final phase of her PhD, Charlotte spent some time at Konstanz University, hosted by prof. Britta Renner. At Maastricht University, she contributed to teaching in the Intervention Mapping Summer School programme.





## Publication list

### *Included in this thesis*

**Anraad, C.**, Lehmann, B. A., Visser, O., van Empelen, P., Paulussen, T. G. W., Ruiter, R. A. C., Kamp, L., van der Maas, N. A. T., Barug, D., Ruijs, W. L. M., de Melker, H. E., Mollema, L., & van Keulen, H. M. (2020). Social-psychological determinants of maternal pertussis vaccination acceptance during pregnancy among women in the Netherlands. *Vaccine*, 38(40), 6254–6266. <https://doi.org/10.1016/j.vaccine.2020.07.047>

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**Anraad, C.**, van Empelen, P., Ruiter, R. A. C., Rijnders, M., van Groessen, K., & van Keulen, H. M. (2021). The systematic development of an online tailored decision aid and a Centering-based Group Antenatal Care intervention to promote informed decision making regarding maternal pertussis vaccination. *Submitted*.

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**Anraad, C.**, van Empelen, P., Ruiter, R. A. C., & van Keulen, H. M. (2022). Process evaluation of an online tailored decision aid to promote informed decision making about maternal pertussis vaccination in the Netherlands. *Submitted*.

**Anraad, C.**, van Empelen, P., Ruiter, R. A. C., Pronk, J., Rijnders, M., van Groessen, K., & van Keulen, H. M. (2022) Counselling about maternal pertussis vaccination in Group-Antenatal Care: a feasibility study. *Submitted*.

### **Other publications**

**Anraad, C.**, Cheung, K., Hiligsmann, M., Coyle, K., Coyle, D., Owen, L., West, R., de Vries, H., Evers, S. M., & Pokhrel, S. (2018). Assessment of cost-effective changes to the current and potential provision of smoking cessation services: An analysis based on the EQUIPTMOD. *Addiction* (Abingdon, England), 113 (Suppl Suppl 1), 96–105. <https://doi.org/10.1111/add.14093>

Sanftenberg, L., Kuehne, F., **Anraad, C.**, Jung-Sievers, C., Dreischulte, T., & Gensichen, J. (2021). Assessing the impact of shared decision making processes on influenza vaccination rates in adult patients in outpatient care: A systematic review and meta-analysis. *Vaccine*, 39(2), 185–196. <https://doi.org/10.1016/j.vaccine.2020.12.014>

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### **Conference contributions**

*Oral presentations:*

**C. Anraad.** Waarom vaccineren zwangere vrouwen (niet)? *Landelijk JGZ Innovatieatelier, Utrecht, 25 September 2019*

**C. Anraad,** P. van Empelen, R. Ruiters, L. Mollema, H. van Keulen. Social-psychological determinants of maternal pertussis vaccination acceptance among pregnant and non-pregnant women in the Netherlands. *13<sup>th</sup> Vaccine Congress, Bangkok, 15-18 September 2019.*

**C. Anraad,** P. van Empelen, R. Ruiters, L. Mollema, H. van Keulen. What factors play a role among pregnant women in the decision for maternal pertussis vaccination? 10<sup>th</sup> conference of the Association for Researchers in Psychology and Health (online conference).

**C. Anraad,** P. van Empelen, R. Ruiters, M. Rijnders, K. van Groessen, H. van Keulen. Developing an online decision-aid and CenteringPregnancy intervention promoting informed decision making about maternal pertussis vaccination. 35<sup>th</sup> Annual Conference of the European Health Psychology Society, 23 -27 August 2021 (online conference).

**C. Anraad,** P. van Empelen, R. Ruiters, H. van Keulen. Effects and acceptability of an online decision aid (DA) about maternal pertussis vaccination (MPV). 36<sup>th</sup> Annual Conference of the European Health Psychology Society, 23 -27 August 2022, Bratislava, Slovakia.



# Appendices



## Appendix Chapter 2

**Table 7.** Moderated regression analyses with Intention as dependent variable with decisional certainty as moderator (n=611).

Step	Variable entered	unstandardised beta		R <sup>2</sup>	Model F	ΔR <sup>2</sup>	ΔF
		Step 1	Step 2				
1.	Attitude MPV	0.78***	0.636***	.73	818.10***		
	Decisional certainty	0.145***	<-0.01				
2.	Attitude MPV x decisional certainty		0.252*	.73	551.60***	<.01	5.77*
	1. Attitude about vaccines in general Decisional certainty	0.49*** 0.40***	-0.08 -0.49***	.47	268.34***		
2.	Attitude about vaccines in general x decisional certainty		1.17***	.52	222.29***	.06	69.62***
	1. Belief safety Decisional certainty	0.72*** 0.12***	0.38*** -0.20**	.61	485.88***		
2.	Belief safety x decisional certainty		0.58***	.63	343.72***	.01	23.48***
	1. Outcome expectancies Decisional certainty	0.55*** -0.34***	0.07 -0.48**	.51	323.38***		
2.	Outcome expectancies x decisional certainty		1.07***	.55	244.39***	.03	42.39***
	1. Effectiveness MPV against pertussis Decisional certainty	0.63*** 0.29***	.17** -0.16*	.59	444.04***		
2.	Effectiveness MPV against pertussis x decisional certainty		0.76***	.63	314.59***	.04	60.34***
	1. Moral Norm Decisional certainty	0.67*** 0.21***	0.23*** -0.16**	.60	461.25***		
2.	Moral Norm x decisional certainty		0.70***	.64	354.06***	.03	56.10***
	1. Injunctive Norm Decisional certainty	0.53*** 0.28***	0.15 -0.17	.47	271.64***		

**Table 7. (Continued)**

Step	Variable entered	unstandardised beta		R <sup>2</sup>	Model F	ΔR <sup>2</sup>	ΔF
		Step 1	Step 2				
2.	Injunctive Norm x decisional certainty		0.71***	.49	197.96***	.02	27.20***
1.	Descriptive Norm	0.29***	0.12	.31	137.38***		
	Decisional certainty	0.39***	-0.19				
2.	Descriptive Norm x decisional certainty		0.31*	.31	93.62***	.01	4.51*
1.	Risk perception pertussis child when not vaccinating	0.22***	-0.09	.28	120.38***		
	Decisional certainty	0.47***	0.32***				
2.	Risk perception pertussis child x decisional certainty		0.37**	.29	85.20***	.01	10.88**
1.	Risk perception side eff. mother	-0.39***	.13	.38	190.49***		
	Decisional certainty	0.42***	0.62***				
2.	Risk perception side eff. mother x decisional certainty		-0.57***	.43	155.04***	.05	52.12***
1.	Risk perception side eff. child	0.41***	0.13	.40	199.99***		
	Decisional certainty		0.61***				
2.	Risk perception side eff. child x decisional certainty		-0.59***	.45	168.47***	.06	64.00***
1.	Trust	0.53***	0.05	.49	297.46***		
	Decisional certainty	0.35***	-0.30**				
2.	Trust x decisional certainty		0.92***	.54	239.65***	.05	63.18***
1.	Fear vaccine	-0.36***	-0.02	.32	145.35***		
	Decisional certainty	0.28***	0.55***				
2.	Fear vaccine x decisional certainty		-0.33***	.34	107.73***	.02	22.30***
1.	Fear disease	0.36***	-0.18*	.36	173.47***		
	Decisional certainty	0.46***	-0.13				
2.	Fear disease x decisional certainty		0.86***	.41	142.76***	.05	52.16***

Note. \*p<.05. \*\*p<.01. \*\*\*p<.001.



**Appendix chapter 4–** Instructions for Cognitive reappraisal, Acceptance and Control group in English and Dutch

***Cognitive reappraisal intervention (English)***

You have indicated at the previous questions that you feel uncomfortable when thinking about making the decision about the maternal pertussis vaccination. It is normal that people can be worried about making the decision sometimes.

We are asking you to think about the decision about the maternal pertussis vaccination again, but try to think about it in a more positive light. For example, think about the positive aspect that there is a possibility to make the choice about the vaccination yourself and about the good things that could result from it. In other words, try to think about making the decision as positively as possible.

Write down the positive thoughts that arise. It does not matter how much you know about the vaccination or what opinion you have about the vaccination. Try to think about the positive aspects of the choice when you are worried about making the decision in the upcoming period.

***Acceptance intervention (English)***

You have indicated at the previous questions that you feel uncomfortable when thinking about making the decision about the maternal pertussis vaccination. It is normal that people can be worried about making the decision sometimes.

We are asking you to think about the decision about the maternal pertussis vaccination again, but try to think about your feelings and emotions without trying to alter them. In other words, try to accept these emotions.

Write down the feelings and emotions that you feel below. It does not matter how much you know about the vaccination or what opinion you have about the vaccination. Try to accept the emotions that arise when you are worried about making the decision in the upcoming period

***Control group (English)***

We are asking you to think about the decision about the maternal pertussis vaccination again. Write down your thoughts below.

## Appendix Chapter 5

**Table 1 of the supplementary material.** Change objectives for each performance objective, grouped per behavioural determinant.

Performance objective	Determinant	Attitude	Positive outcome expectancies
PO1 Make an informed decision about the maternal pertussis vaccination	<b>Knowledge</b>		
	Describe that whooping cough is an infectious disease caused by a bacteria.	Evaluate MPV positively by recognizing the health benefits of MPV for the mother and unborn child.	Describe the potential positive outcomes of MPV.
	Describe that the bacteria can be transmitted via droplets in the air, via coughing and sneezing, physical contact such as shaking hands or kissing.	Recognize that the benefits outweigh the disadvantages of MPV	Describe that MPV reduces the risk of whooping cough for a baby in their first months of life.
	Recognize that whooping cough is prevalent in the Netherlands.	Evaluate the communication with important others about MPV positively.	Describe that MPV reduces the severity of whooping cough in a baby once it is born.
	Describe that newborn children in their first few months of life are especially vulnerable to serious effects of whooping cough.		Describe that the risk of getting whooping cough is reduced by MPV, and that the severity of getting whooping cough is reduced by MPV.
	Describe that there is a vaccination against whooping cough during pregnancy at 22 weeks gestational age to protect a baby against pertussis.		Differentiate between facts and stories regarding the positive outcomes of MPV.
	Recognize that MPV serves the purpose to protect a child once it is born for several months until it can be vaccinated itself.		
	Recognize that currently, MPV is the most effective strategy to protect a baby for pertussis in their first months of life.		
	Recognize that the whooping cough vaccination is freely available during pregnancy.		
	Recognize that there is no evidence for a link between MPV and adverse pregnancy outcomes, pregnancy complications and side-effects in the baby once it is born.		
	Recognize that MPV cannot give the mother or the baby whooping cough.		
	Describe where one can get MPV and how to make an appointment.		

**Table 1 of the supplementary material. (Continued)**

Performance objective		Determinant				
	Negative outcome expectancies	Perceived control	Social pressure	Positive affect	Negative affect	Beliefs
PO1 Make an informed decision about the maternal pertussis vaccination	<p>Describe the potential negative outcomes of MPV.</p> <p>Recognize that after getting MPV, one might experience side effects such as a painful arm, a red injection spot, body-ache, fatigue or fever, and that some people will experience headache, nausea, vomiting, diarrhea, stomach ache and arm swelling.</p> <p>Recognize that no evidence exists of a relationship between MPV and side effects in the baby.</p> <p>Differentiate between facts and stories regarding the negative outcomes of MPV.</p>	<p>Describe feeling in control of processing information about MPV.</p> <p>Describe feeling in control of deciding to get MPV.</p> <p>Describe feeling in control of talking to others about the decision of getting MPV.</p> <p>Pregnant woman expresses confidence about talking to important others about MPV.</p>	<p>Recognize feelings of social pressure to accept or refuse the vaccine.</p> <p>Demonstrate the ability cope with feelings of social pressure to accept or refuse the vaccine.</p>	<p>Describe feeling supported concerning any concerns about MPV.</p> <p>Describe feeling reassured about any concerns and beliefs about MPV.</p> <p>Describe feeling confident to ask questions about MPV in case of doubt.</p>	<p>Describe that having doubts about MPV is normal.</p> <p>Describe not feeling stressed about any potential doubt about MPV.</p> <p>Describe having low or no feelings of fear about MPV and its possible side-effects.</p> <p>In case of feelings of fear about the vaccine and possible side-effects, recognize this and describe strategies to cope with these feelings.</p>	<p>Recognize that MPV has proven to be safe for mother and child.</p> <p>Recognize that the vaccine has proven to be effective in reducing infections with and severity of pertussis in newborn children.</p> <p>Recognize that MPV is the most effective mean to protect a newborn baby against whooping cough.</p> <p>Explain that living healthily is not an effective prevention strategy against pertussis</p> <p>Recognize that breast feeding is particularly effective against pertussis if the mother has received MPV, but not if she has not.</p> <p>Recognize that going through whooping cough is not beneficial for a baby's mental or physical health.</p>

**Table 1 of the supplementary material. (Continued)**

Performance objective	Determinant					Trust	Decisional certainty
	Risk perceptions	Moral norm	Injunctive norm	Descriptive norm			
PO1 Make an informed decision about the maternal pertussis vaccination	Acknowledge the risk of whooping cough and the severity of whooping cough of children in their first months of life.  Acknowledge the risk of side-effects of MPV, such as a painful arm, a red injection spot, body-ache, fatigue or fever.  Describe that there is a smaller risk of headache, nausea, vomiting, diarrhea, stomach ache and arm swelling.  Describe that if one has ever in had an allergic reaction to a vaccine, they should inform their MPV provider.	Describe making the choice to be vaccinated oneself, on behalf of the unborn child.  Describe feeling in control of making the choice about MPV.	Formulate an opinion about MPV  Describe the opinion of important others (e.g. partner) about MPV  Express resistance to contrasting opinions about MPV towards important others	Recognize that other pregnant women decide to receive MPV.	Express trust in the MPV to protect babies from whooping cough.  Express trust in scientific research on MPV and information based on this.  Express trust in healthcare (the JGZ and midwives and/or gynecologist and/or GP) with regards to MPV.  Recognize that the government has implemented MPV in the NIP to reduce the number and the severity of pertussis infections in newborn babies.  Recognize that MPV is implemented to reduce pertussis in babies and not to benefit the pharmaceutical industry.	Recognize that feeling uncertainty about vaccination is common.  Describe feeling sure about the decision about MPV.  Describe feeling on balance positively about the decision.	

**Table 1 of the supplementary material. (Continued)**

Performance objective	Determinant			Trust
	Knowledge	Attitude	Perceived control	
PO2 Make an appointment to get MPV	Describe how to make an appointment to get MPV.	Evaluate making the appointment to get MPV as smoothly and positively.	Describe feeling in control of making an appointment at the JGZ.	Express confidence in the answers provided by the healthcare professional when she asks questions.
	Describe what to bring to the appointment.			
	Describe what to expect of the appointment.			
PO3 Ask questions about MPV if one has any			Express confidence about talking to a healthcare professional about MPV	Express confidence about formulating questions about MPV and possibly writing them down before going to the appointment with the healthcare professional.
PO4 Go to the Youth Health Centre to get MPV	Describe where to go to get the MPV	Evaluate getting the vaccine at the JGZ positively.	Describe feeling in control of the process of getting the vaccine and going to the Youth Health Centre.	

**Table 2 of the supplementary material.** Behavioural change methods and their applications in the intervention, and the targeted determinants. All determinants were targeted in order to achieve performance objective 1, and additionally, perceived control was also used to achieve performance objective 2. Determinants are ordered from most targeted in the intervention to least targeted in the intervention.

Determinant	CP intervention		
	Online decision aid	Strategy	Methods
Knowledge	Consciousness raising (Health Belief Model, Precaution-Adoption Process Model, Trans-Theoretical Model)	Two-sided information was presented per subject, and in levels, with the possibility to click to reveal more information. Both videos and textual information was presented so participants could choose how to process information based on their preferences. Subjects were: What is the whooping cough vaccination during pregnancy? (i.e. How does the vaccination work? What is in the vaccination?) What is whooping cough? Is the vaccination safe? Are there side-effects? What do other think of the vaccination?	Active learning (Elaboration Likelihood Model, Social Cognitive Theory)
	Active learning (Elaboration Likelihood Model, Social Cognitive Theory)	Per subject, a quiz-question was available, with direct feedback.	An example of an interactive CP method is using an exercise where participants were asked to indicate if a question is true or false, after which they are given immediate feedback, or letting participants write down their questions and encouraging others to discuss the answers.
	Feedback (Theories of Learning)	Participants could do a knowledge-quiz in the 'my choice' section, where feedback was also provided	Participants were facilitated to conclude answers to questions themselves, a process during which the midwife guides the conversation by asking questions and encouraging participants to conclude answers based on the facts that were provided. Which sub-topics were further explored depended on the input of the participant s.
	Chunking (Theories of Information processing)		Discussion (Elaboration Likelihood Model)

Table 2 of (Continued)

Determinant	Online decision aid		
	Methods	Strategy	CP intervention
Attitude	<p>Feedback on benefits and barriers (decisional balance)</p>	<p>Participants were provided with a decisional balance with pros and cons of MPV, based on their concerns and values. For example they were asked if they agreed with: 'I am concerned that my baby might get whooping cough' and 'I would prefer my baby to be able to skip the first vaccination at two months of age', resulting in a visual overview of personal pros and cons of MPV. Questions could also be skipped when found irrelevant. The content of the questions was based on focus-group interviews (see step 2) and was balanced between pros and cons.</p> <p>Participants were provided with quotes from pregnant women about choosing about MPV.</p>	<p>Upon having discussed some of the facts around MPV, participants were encouraged to actively think about what that information meant for their decision about MPV. Participants were further encouraged to voice their concerns and considerations about MPV. The consequences of vaccinating versus not vaccinating were discussed, and arguments for and against the MPV could be shared. An example of a method that could be used by the midwife, is to collectively make a list of pros and cons of getting the MPV, and to individually write down those that are evaluated as most personally relevant.</p>
Outcome expectancies	<p>Consciousness raising (Health Belief Model, Precaution-Adoption Process Model, Trans-Theoretical Model)</p> <p>Belief selection (Theory of Planned Behaviour)</p> <p>Active learning (Elaboration Likelihood Model, Social Cognitive Theory)</p> <p>Feedback (Theories of Learning)</p>	<p>Participants were shown two-sided information about MPV (see above). Per subject, a quiz-question was available, with direct feedback. Participants could do a knowledge-quiz in the 'choice' section</p>	<p>The consequences of vaccinating versus not vaccinating were discussed and explored. Incorrect beliefs about safety and effectiveness of MPV were weakened, and correct beliefs about safety and effectiveness were strengthened, confirmed, or if needed, introduced.</p>

**Table 2 of (Continued)**

Determinant	Online decision aid	
	Methods	Strategy
Perceived control	Resistance to social pressure (Theory of Planned Behaviour)	Participants could practice a conversation about MPV in an automated virtual chat, where they could fill out several questions to get an overview of what they want to say, what they need, and want to ask. They were provided with an overview of their answers.
		We provided practical information about how to get the vaccine, and what to expect during the process of getting the vaccine, to remove barriers.
Social pressure	Resistance to social pressure (Theory of Planned Behaviour)	In the information, it was emphasised that MPV is a choice and that accepting it is voluntary. Participants could practice a conversation about MPV in an automated virtual chat, and they were provided with an overview of their answers.
		Through discussions in the group, participants learned from each other, and the way they handle social pressure.
Emotions	Self-affirmation (Self Affirmation Theory)	It was emphasised that it is important that participants made an informed decision that they felt positive about. There was space in the decisional balance to become aware of worries and feelings about the MPV. By addressing concerns seriously in the information, yet debunking myths firmly, we aimed to make participants feel heard.
		It was emphasised that it is important that participants made an informed decision that they felt positive about. During the session, there was time and space to express emotions, worries and concerns surrounding the MPV.
Beliefs about safety and beliefs about the effectiveness of MPV	Belief selection (Theory of Planned Behaviour)	Incorrect beliefs about safety and effectiveness of MPV were weakened, and correct beliefs about safety and effectiveness were strengthened, confirmed. This was done in the information and in the quiz-elements of the intervention.
		Incorrect beliefs about safety and effectiveness of MPV were weakened, and correct beliefs about safety and effectiveness were strengthened, confirmed, or if needed, introduced.



**Table 2 of (Continued)**

Determinant	Online decision aid		CP intervention	
	Methods	Strategy	Methods	Strategy
Risk perception Pertussis	Scenario based risk information (Precaution-Adoption Process Model)	Risk information was presented using natural frequencies (eg. 1 out of 100) to improve understandability of probabilities.	Scenario based risk information (Precaution-Adoption Process Model)  Personalise Risk (Precaution-Adoption Process Model)	Risk information was presented using natural frequencies (eg. 1 out of 100) to improve understandability of probabilities. Personal risk factors of contracting whooping cough, such as being exposed to a lot of people, were discussed.
Moral Norm	Framing (Protection Motivation Theory)	It was emphasised that taking the vaccination is something you do on behalf of your unborn child.	n/a	n/a
Injunctive Norm	Information about others approval (Theory of Planned Behaviour; Social Comparison Theory)	Participants could practice a conversation about MPV in an automated virtual chat, and they were provided with an overview of their answers.	Information about others approval (Theory of Planned Behaviour; Social Comparison Theory)  Modelling (Social-Cognitive Theory, Theories of Learning)	Participants during the session shared their thoughts on the MPV, and learned how to address these in other situations through discussing the MPV and voicing their concerns and beliefs, and seeing other participants do this as well.
Descriptive Norm	Information about others approval (Theory of Planned Behaviour; Social Comparison Theory)	Participants could read about which countries in the world already use MPV.	Information about others approval (Theory of Planned Behaviour; Social Comparison Theory)	Participants during the session shared their thoughts on MPV.
Trust in the NIP	n/a	The different parties involved in the MPV and their roles were explained in the information, as well as the rationale for the government to implement MPV in the National Immunisation Programme.	n/a	Background information about the NIP was provided, as well as the rationale for the government to implement MPV in the National Immunisation Programme.
Decisional certainty	Planning coping responses (Theories of Self-Regulation)  Decisional balance (Motivational Interviewing)	Participants were offered suggestions of what to do when uncertain, such as speak to a professional, their partner, gather more information, or weigh the pros and cons. Furthermore it was emphasised that feeling uncertainty is normal.	Planning coping responses (Theories of Self-Regulation)	Participants who were still in doubt about MPV upon the session about MPV, were encouraged to think about, express and pursue what they needed to make a decision that they felt good about, for example an individual consultation with the Youth Doctor or providing the vaccine, or a conversation with the partner.

## Appendix Chapter 6

### Drop-out analysis

**Table 1** of the supplementary material. Outcomes of the drop-out analyses, differences in average between those who did and did not complete the 20-22 weeks post-test survey. <sup>1</sup>Low and intermediate versus high educational levels were compared. \*p<.05, \*\*p<0.01, \*\*\*p<0.004 (significant after Bonferroni correction)

	Post-test at 20-22 weeks completed (n=829)	Post-test at 20-22 weeks not completed (n=407)	Chi-squared or independent samples t-test			
	Mean (SD) or percentage		Chi-squared		p-value	
<b>Recruitment channel</b>	73.5%	26.5%	8.27			<b>0.004**</b>
<b>Clinic sample</b>	64.7%	35.2%				
<b>Social media sample</b>						
Has at least one child	71.2%	28.8%	4.07			0.04
No	63.1%	36.9%				
Yes						
Country of birth	67.4%	32.6%	1.27			0.26
Netherlands	58.8%	41.2%				
Other						
<b>Highest education completed</b>	66.7%	33.3%	14.76 <sup>1</sup>			<b>&lt;.001****</b>
<b>Low</b>	57.0%	43.0%				
<b>Intermediate</b>	69.8%	30.2%				
<b>High</b>						
			t-value	Cohen's D	95% CI	p-value
Age	32.31 (3.73)	31.77 (4.35)	-2.16	0.14	-1.04,-0.05	0.03*
Religion (1-7)	2.10 (1.33)	2.08 (1.29)	-0.21	0.01	-0.17,0.14	0.83
<b>Intention to accept MPV (1-5)</b>	4.67 (0.65)	4.45 (0.96)	-4.20	0.27	-0.32,-0.12	<b>&lt;.001***</b>
<b>Attitude MPV (1-5)</b>	4.67 (0.58)	4.50 (0.80)	-3.99	0.25	-0.26,-0.09	<b>&lt;.001***</b>
<b>Beliefs safety (1-5)</b>	4.50 (0.77)	4.31 (0.90)	-3.70	0.23	-0.29,-0.09	<b>&lt;.001***</b>
<b>Beliefs effectiveness (1-5)</b>	4.62 (0.57)	4.49 (0.68)	-3.35	0.21	-0.21,-0.05	<b>&lt;.001***</b>
Perceived severity (1-5)	4.40 (0.62)	4.39 (0.66)	-0.30	0.02	-0.09,0.07	0.76
Perceived susceptibility (1-5)	2.60 (0.77)	2.70 (0.78)	1.98	0.11	<0.01,0.19	0.05
<b>Moral norm (1-5)</b>	4.36 (0.78)	4.19 (0.95)	-3.16	0.20	-0.28,-0.07	<b>0.002***</b>
Knowledge (1-5)	4.88 (1.52)	4.69 (1.55)	-2.06	0.12	-0.37,-0.01	0.04*
<b>Perceived control (1-5)</b>	4.74 (0.42)	4.54 (0.58)	-5.98	0.38	-0.26,-0.13	<b>&lt;.001***</b>
Injunctive norm (1-5)	4.14 (0.99)	4.00 (1.01)	-2.27	0.14	-0.26,-0.01	0.02*
<b>Affect (1-5)</b>	4.47 (0.71)	4.25 (0.92)	-4.25	0.27	-0.32,-0.12	<b>&lt;.001***</b>
Decisional certainty (1-5)	4.45 (0.92)	4.34 (1.01)	-1.87	0.12	-0.23,0.01	0.06*





