Information letter regarding research not subject to the WMO, including consent form

(Model version 5, 18 July 2025)

Information on participation in research

V-CHECK Study

Midwifery Counselling and Education in Cervical (HPV) Cancer Screening

1. Introduction

Dear Madam,

You are receiving this information letter because you have not yet participated, or have not fully participated, in the cervical cancer screening programme. In this information letter, we are asking you if you would like to take part in a research study. Participation is voluntary. Here you can read what the study involves, what it means for you, and what the benefits and risks are. Would you like to read through the information and decide whether you wish to take part? If you wish to take part, please complete a digital consent form together with your midwife. An example of the questions asked in this consent form can be found in Appendix B. If you do not wish to take part in this study, you will receive the care that your midwife always provides.

At present, there is no standard information provided by midwives regarding the cervical cancer screening programme. This study aims to determine whether information provided by midwives about the cervical cancer screening programme is beneficial. It will also clarify what women know about human papillomavirus (HPV) and cervical cancer, and how women feel about the screening programme. Furthermore, this study provides information on why women do or do not participate in the cervical cancer screening programme.

Are you interested?
- Please read this information leaflet carefully.

Would you like to take part?
- Please complete the digital consent form with your midwife.

Ask your questions
All information about the study is contained in this letter. You can ask questions of the midwife who is providing you with this information. You can also contact the researchers. You will find the contact details in Appendix A.

2. General information

The study has been set up by Erasmus MC.

The study is being conducted by midwives in twenty midwifery practices across the Netherlands.

ZonMw reimburses (part of) the costs of the study.

The Erasmus MC Non-WMO Review Committee has granted approval for the conduct of this study in twenty midwifery practices and at Erasmus MC.

3. What is the aim of the study?

We want to investigate whether an information session led by midwives helps pregnant women to make a more informed decision about whether they wish to participate in the cervical cancer screening programme (after pregnancy). Women aged between 30 and 60 are invited to take part in the cervical cancer screening programme. Detecting the condition early can prevent cervical cancer. Cervical cancer is caused by a long-term infection with a virus: the human papillomavirus (HPV). We know that many women do not take part in the cervical cancer screening programme and believe that personalised information could improve this.

The V-CHECK study examines the impact of information provided by midwives on the choices of women who have not previously participated in the screening programme. It also looks at the barriers to midwives providing information and how feasible it is for midwives to do so. Furthermore, a computer model is being used to assess the effect and costs on a large scale (‘population level’). In addition, the test results and any treatment for (pre-cancerous stages of) cervical cancer are being investigated among women who participate following the information session.

4. How does the study work and what does this mean for you?

During a check-up at the start of your pregnancy, your midwife will ask whether you have taken part in the cervical screening programme. If you have not, you can take part in this study.

You will receive a questionnaire during your pregnancy (around 14–18 weeks) and after you have given birth (8–10 weeks).

After you have completed the first questionnaire, your midwife will provide you with a detailed explanation (‘counselling’) about the screening programme and how and when it is still possible to take part. The explanation will cover HPV, the purpose of screening, the importance of taking part and the possible consequences of not taking part. The midwife will help you find the right information and, if necessary, apply for an HPV self-test with instructions.

You do not need to attend for additional check-ups. However, taking part in the screening programme does require extra time for the counselling session and for completing the digital questionnaires. Each questionnaire will take you a maximum of 15 minutes. The counselling session also lasts approximately 15 minutes.

If you take part in the V-CHECK study, this means that we will collect and use your data. You can read about what data this involves and how we collect, use and protect it in sections 7 and 8.

We are also looking for participants for a focus group as part of the study. Your midwife will provide you with further information. You can still take part in the study even if you do not wish to join a focus group.

5. What are the advantages and disadvantages of taking part in the study?

The benefit of taking part in this study is that you will be (even) better informed about the cervical cancer screening programme, enabling you to make a well-informed decision about whether or not to take part in the screening programme. Your participation also contributes to a better understanding of the benefits of information provided by midwives about the cervical cancer screening programme.

Participation in the study will not affect your current pregnancy. In addition to the information session, participants will receive the usual treatment and check-ups for their pregnancy.

One disadvantage of taking part may be that you are now thinking about something you had not previously considered. You may feel anxious when thinking about the cervical cancer screening programme. Another disadvantage of taking part is the time it takes to read this letter and complete the questionnaires.

6. If you do not wish to participate or wish to withdraw from the study

Participation in the study is entirely voluntary. You should only sign the digital consent form if you wish to take part. An example of this form can be found in Appendix B. Your midwife will go through the steps with you.
You can withdraw from the study at any time. We ask you to inform the researchers or your midwife as soon as possible. You do not need to give *a reason* for withdrawing. The data collected up to that point will still be used for the study.

7. What data do we collect?

Existing data
Your midwife records general data, such as your date of birth, address details, ethnic background and level of education. This data is also collected for this study.

New data
Your midwife will ask whether you have taken part in the cervical cancer screening programme. In this study, we ask about your knowledge and views on the cervical cancer screening programme.

May we request your details from other parties?
For this study, we wish to request your data from PALGA, Perined and Statistics Netherlands (CBS).

PALGA: Results from the population screening programme in the Netherlands are digitally archived in the National Automated Pathological-Anatomical Archive (PALGA). We wish to request this data for two rounds of the population screening programme.

Perined is the organisation in the Netherlands where information on all pregnancies and births is recorded by midwives, GPs, gynaecologists and paediatricians.

The **Central Bureau of Statistics (CBS)** is an independent statistical agency with a statutory duty to collect and publish reliable data on Dutch society.

We only request data that is relevant to this study. We ask for your consent to request your data.

8. What do we do with your data?

Why do we collect, use and store your data?
We collect, use and store your data in order to answer the questions in this survey. We intend to publish the results of the survey.

How do we protect your privacy?
To protect your privacy, we assign a code to your data. We apply only this code to all your data. The data that directly identifies you will then no longer be used. The code key is kept in a secure location at the midwifery practice. Only members of the research team know which code has been assigned to you. Whenever we process or share your data, we will only use that code. In reports and publications about the study, no one will be able to identify you.

How long do we keep your data?
We will keep your data for 10 years after the study has ended at the midwifery practice and at Erasmus MC.

Can we use your data for other scientific research?

After this study has ended, your data may still be of interest for other scientific research in the field of public health screening. The data may be shared with researchers from other organisations. In that case, we will only share coded data, never your name. You can indicate on the consent form whether you agree to this. If you do not give your consent, you can still take part in this study.

Can you withdraw your consent for the use of your data?
You can withdraw your consent for the use of your data at any time. This applies to the use of your data in this study and in other scientific research. If you withdraw your consent, the researchers may still use the data already collected.

May we contact you again after this study for a follow-up study?
Once this study has finished, we may conduct a follow-up study. We would then like to contact you to ask if you would like to take part again. On the consent form, you can indicate whether you give us permission to contact you again.

Would you like to know more about your privacy?
Would you like to know more about your rights regarding the processing of personal data? Please visit
https://www.autoriteitpersoonsgegevens.nl/nl/over-privacy/persoonsgegevens.
If you have any questions or complaints regarding your privacy, we recommend that you discuss these with the research team first. You can also contact the Data Protection Officer at Erasmus MC. Alternatively, you can submit a complaint to the Dutch Data Protection Authority.

Where can you find more information about the study?
Your midwife can answer questions about the V-CHECK study. You can also contact the Erasmus MC researchers by email for further information atV-CHECK@erasmusmc.nl .
You can find more information about the study on the following website(s): www.v-checkstudie.nl

9. Will you receive compensation for taking part?

There is no cost to you as a participant in this study. Therefore, there is no payment for taking part.

10. Do you have any questions?

If you have any questions about this study, please contact the research team.
You will find the contact details in Appendix A.

Kind regards,

The research team

Appendix A: Contact details

This information letter is used by all participating midwifery practices.

If you have any questions about this study, please contact the midwifery practice where you are receiving care.

You can use the contact details you received from your own practice at the start of your care pathway. If necessary, the practice can forward your question to the research team.

You can also contact the Erasmus MC researchers directly by email at V-CHECK@erasmusmc.nl.

Principal Investigator, Erasmus MC:
Drs. Ralf van de Laar, Department of Gynaecological Oncology

Principal investigator at Erasmus MC:
MSc. Marjolein Lansbergen-Mensink, Department of Gynaecological Oncology & Public Health, Erasmus MC.

Complaints:
If you are dissatisfied with the research or treatment, you can contact the independent complaints service/complaints officer at Erasmus MC.
A digital complaints form is available on the Erasmus MC website at https://www.erasmusmc.nl/nl-nl/patientenzorg/klachtenopvang-en-klachtenbemiddeling
Once completed, the form will be sent automatically to the complaints officer.
If you are unable to complete the digital complaints form, you can also send your complaint by post to: Erasmus MC, Complaints Office (GK-745), Freepost 55, 3000 WB Rotterdam.
Please state your name, patient number (if applicable), the name of the study and your contact details in the letter. Once the letter has been received, the complaints officer will contact you.

The institution's Data Protection Officer:
Further information about your data protection rights or general questions regarding the processing of your personal data can be found in the Erasmus MC privacy statement at https://www.erasmusmc.nl/nl-nl/pages/privacyverklaring.
If you have any further questions regarding the protection of your data, or if you suspect that your data protection rights have been infringed, please contact the Erasmus MC Data Protection Officer (functionaris.gegevensbescherming@erasmusmc.nl) or the Dutch Data Protection Authority.

Appendix B: Sample Participant Consent Form

Consent for this study is provided via a digital signature. Your midwife will guide you through the steps.

Electronic Informed Consent V-CHECK Study

Midwifery Counselling and Education in Cervical (HPV) Cancer Screening

If you cannot or do not wish to answer 'yes' to the questions below, you cannot take part in the study. In that case, we thank you for your time and you may close this page.

- I have read the information leaflet. I was also able to ask questions. My questions have been answered satisfactorily. I had enough time to decide whether to take part.
- I understand that participation is voluntary. I also understand that I can decide at any time not to participate or to withdraw from the study. I do not need to give a reason for doing so.
- I give my consent for the collection and use of my (medical) data in the manner and for the purposes set out in the information letter.
- I give my consent for my data to be retained for a further 10 years after this study within the midwifery practice and Erasmus MC.
- I give my consent to the members of the research team to request my data from PALGA, Perined and the CBS, as mentioned in the information letter, for up to 10 years after my current participation in the population-based study

The questions below are optional fields and you may participate in the study regardless of what you enter here.

- I give my consent for my data to be stored for use in other scientific research, as stated in the information letter.
- I give my consent to be asked, after this study, whether I wish to take part in a follow-up study.

The participant enters:
Surname
First initial
Date of birth
Email address

You will receive a copy of this consent form at your email address, along with the digital patient information leaflet.

The midwife will complete:
Name
Practice name
Email address