Participant Information for Participation in Medical-Scientific Research

Title: PregnaDigit EU

Introduction

Dear Madam,

With this information letter, we would like to ask you if you would like to participate in medical-scientific research. Participation is voluntary. You are receiving this letter because your physician has proposed to start tele-home monitoring with you as part of the PregnaDigit study.
In this document, you will read about the nature of the research, what it means for you, and what the benefits and drawbacks are. It contains a lot of information. Please read through the information and decide whether you would like to participate. If you wish to participate, you can fill out the form found in Appendix 3.

Ask your questions

You can make your decision based on the information provided in this letter. Additionally, we recommend that you do the following:
- Ask questions to the researcher who provides you with this information.
- Discuss this research with your partner, family or friends.

1. General information

The UMC Utrecht, location Wilhelmina KinderZiekenhuis (WKZ), in Utrecht, The Netherlands has set up this research. We will refer to the WKZ as the “sponsor” throughout this document. Researchers, who may include doctors, midwives, nurses and research students, will conduct the research in various hospitals across Europe. For this study, approximately 400 patients from different hospitals are needed.

2. What is the purpose of the research?

The primary aim of this research is to implement tele-home monitoring during pregnancy, both nationally and internationally.

3. What participation involves

During your pregnancy, we will ask you to complete questionnaires at a maximum of two points in time: a few weeks after starting the home measurements and a few weeks after delivery. These questions will concern your opinion about tele-home monitoring. Additionally, we will ask questions about the care provided. These questionnaires will be sent to you via email. You can answer the questions on your computer. This will take approximately 10 minutes each time.

If you wish to participate, we will also ask for your consent to use data from your medical records for the research. The purpose to this is to investigate the effects of PregnaDigit on care, such as the number of visits to outpatient clinics, hospital admissions during pregnancy, and the course of pregnancy and delivery.

4. What are the advantages and disadvantages of participating in the research?

There is no direct benefit to you. However, the advantage of participating in this research is that your involvement can contribute to greater knowledge about tele-home monitoring during pregnancy. A disadvantage of your participation in the research is that you will spend extra time completing the questionnaires.

Do you not want to participate?
You decide whether or not to take part in the research. If you choose not to participate, you will not receive any questionnaires, and we will not use your data for research. You will then receive standard care.

5. When does the research stop?

The researcher will inform you if there is new information about the research that is important for you. The researcher will then ask whether you wish to continue participating.

The research will stop for you in the following situations:

- All scheduled research activities are complete.
- The end of the entire study has been reached.
- You wish to withdraw from the research. You may do this at any time. Please notify the researcher immediately; you do not need to provide a reason for stopping. The data collected up to that point will be used for the research.

6. What do we do with your data?

For this research, your personal data will be collected, used, and stored. This includes information such as your name, your date of birth, email address, and health data. The collection, use, and storage of your data are necessary to answer the research questions and to publish the results. In reports and publications regarding the research, the data will not be traceable back to you. We adhere to the General Data Protection Regulation (GDPR) when

processing your data. What this means for you can be found in Appendix 2. We ask for your consent to use your data.

7. Will you receive compensation for participating in the research?

You will not receive any reimbursement for participating in this research.

8. Do you have questions?

Do you have questions or a complaint? You can discuss this with the doctor who is treating you or contact your local research team, for contact details see appendix 1. If you prefer not to do this, you can contact the complaint mediators, for contact details see appendix 1.

9. How do you give consent for the research?

You can first take your time to think about this research. Then, you will tell the researcher whether you understand the information and whether you want to participate or not. If you wish to participate, you fill out the consent form included with this information letter. Both you and the researcher will receive a signed copy of this consent form.

Thank you for your time.

Kind regards,

Professor M. Bekker and Dr. M. Depmann

Appendices:

1. Contact details [your hospital]
2. Additional information about the processing of your data
3. Consent form participant

Appendix 1: Contact details [your hospital]

Principal Investigator:
Prof. dr. M.N. Bekker, obstetrician
Available through tel. +31 6 2571 01 16 (secretary)

Complaints:

If you are not satisfied with the examination or treatment, please contact the complaint mediators. They can be reached by phone at 088-75 562 08 or online at: https://www.umcutrecht.nl/nl/een-klacht-indienen.

Privacy

If you would like to know more about your rights regarding the processing of personal data, visit http://www.autoriteitpersoonsgegevens.nl .

If you have any questions about your rights or complaints about the processing of your data, we recommend discussing them first with the research team. You can also contact the Data Protection Officer of UMC Utrecht at privacy@umcutrecht.nl or file a complaint with the Dutch Data Protection Authority.

Field Code Changed

Appendix 2: Additional information about the processing of your data

How do we protect your privacy?
To protect our privacy, your data will be assigned a code. Your name and other information that can directly identify you will be removed. Only with the key to the code the data can be traced back to you. The key to the code will be securely stored at the local research institution. In reports and publications regarding the research, the data will not be traceable back to you.

Who can see your data?
Some people can see your name and other personal information without a code. This could include data specifically collected for this study, but also data from your medical file. These are people checking whether the investigators are carrying out the study properly and reliably. These persons can access your data:

- Members of the committee that keeps an eye on the safety of the study.
- National and international supervisory authorities, such as the Health and Youth Care inspectorate.

These people will keep your information confidential. We ask you to give permission for this access. The Health and Youth Inspectorate can access your personal information without your permission.

How long do we retain your data?
Your data must be stored for 10 years at the research site.

Can we use your data for other research?
Your data may also be important for other scientific research related to tele-home monitoring during pregnancy after this study ends. For this purpose, your data will be retained for 10 years. You can indicate on the consent form whether you agree to this. If you do not consent, you can still participate in the current research and will receive the same care.

What happens in case of unexpected discoveries?
During the research, we may accidentally find something that is important for your health. The researcher will then contact your obstetric health care provider. You will discuss what should happen next. By signing the form, you consent to informing your obstetric health care provider.

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 in this research and for use in other research. However, please note: if you withdraw your consent and the researchers have already collected data for the study, they may still use that data.

We will send your data to countries outside the European Union

In this research, we will also send your coded data to countries outside the European Union. In those countries, the privacy regulations of the European Union do not apply. However, your privacy will be protected at an equivalent level.

Do you want to know more about your privacy?

- If you have questions about rights or complaints regarding the processing of your personal data, we recommend discussing them first with the research team. You can also contact the Data Protection Officer/ Office from [your hospital] or you can file a complaint via [your hospital], for contact details see appendix 1.

Appendix 3: Consent form participant

PregnaDigit EU

- I have read the information letter. I was also able to ask questions. My questions have been adequately answered I had enough time to decide whether I want to participate.

- I understand that participation is voluntary. I also know that I can decide at any time not to participate or to withdraw from the research without providing a reason.

- I give my consent for the collection and use of my data to answer the research questions in this study.

- I understand that, for the oversight of the research, some individuals may have access to all my data. These individuals are listed in the appendix to this information letter. I give my consent for this access.

- I give my consent for the forwarding of my data in connection with this research. Data must be transferred in coded form and without my name and other personal information that can directly identify me.

- I understand that my coded data will be sent to countries outside the EU where EU privacy regulations do not apply.

- I □ **Give** consent
  □ **Do not give** consent for my personal data to be stored and used for future research in the field of home telemonitoring.

- I □ **Give** consent
  □ **Do not give** consent to be contacted again after this study for follow-up research.

- I want to participate in this study.

Name participant: ……

Signature: …… Date : __ / __ / __

I declare that I have fully informed this participant about the mentioned research.

If any information arises during this research that could influence the participant's consent, I will notify her in a timely manner.

Name researcher (or their representative):……

Signature: …… Date: __ / __ / __

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* Cross out what does not apply.

The participant receives a complete information letter, along with a copy of the signed consent form.