Information for participation in medical research

RISE UP study

Official title: Risk and resilience factors of unintended pregnancies

Introduction

Dear reader,

With this information sheet, we would like to ask you to take part in a scientific study. Participation is voluntary. You have received this letter because you are or were pregnant and live in The Hague or because you are (ex-) partner of someone who is or was pregnant and lives in The Hague.

You can read about the study in this information sheet, what it means for you, and what the pros and cons are. It is a lot of information. Can you please read the information and decide if you want to take part? If you want to take part, you can fill in the online consent form at https://forms.lumc.nl/lumc2/rise-up-toestemming or on paper in Appendix B (participant), C (as parent/guardian of the participant), or D (as representative of the participant).

Ask your questions

You can take your decision based on the information in this information sheet. There is also a video with English subtitles in which the researcher explains the most important information in this sheet, you can find it on www.riseupstudie.nl. We also suggest that you do this:

- Ask questions to the person giving you this information.
- Talk to you partner, family or friends about this study.
- Ask questions to the independent expert, Prof. Dr. Thomas van den Akker (his contact details can be found in Appendix A).
- Read the information on www.rijksoverheid.nl/mensenonderzoek.

1. General information

The Leiden University Medical Centre (LUMC) has set up this study. Researchers and representatives of researchers conduct the study in several health care institutions.

This study needs at least 500 participants.

The Medical Ethics Review Committee Leiden Den Haag Delft has assessed this study.

2. What is the purpose of the study?

In this study, we want to map pregnancies in The Hague and see how we can best support pregnant people in The Hague. We are curious to find out how many pregnancies in The Hague are unintended and which factors play a role. An unintended pregnancy is of course not always an unwanted pregnancy, but it may be challenging. We are also interested in the effect of the pregnancy on the pregnant person and their (ex-)partner and child (when they decide to carry the pregnancy to term).

3. What is the background of the study?

In the Netherlands, around 2 in 10 pregnancies are unintended. Midwives think that in The Hague, almost half of all pregnancies are unintended. Compared to the average in the Netherlands, The Hague sees large differences in outcomes around pregnancy and birth. We want to find out if this has to with a higher prevalence of unintended pregnancies.

It is important that we do this study, because we can find out in which situations a pregnancy is more often unintended. And what effect this has in the 2 years after pregnancy on the pregnancy person and their partner and, if carried to term, child. That is why it is important to gather knowledge about all pregnancies in The Hague, from unintended to intended. With the results of this study, we can find ways to better support people who are experiencing an unintended pregnancy.

4. What happens during the study?

How long will the study take?

Are you taking part in the study? Then we ask you to fill out a survey once at the start of the study and we ask your consent to look at information about you and your health until 2 years after the end of the pregnancy.

Step 1: are you eligible to take part?

First, we want to know if you are eligible to take part. You can take part if you:

- Speak Dutch, Turkish, Arabic, Mandarin, Polish, Bulgarian or English, and;
- Live in The Hague and are pregnant or terminated a pregnancy no longer than 3 months ago, or;
- Are (ex-)partner of someone who lives in The Hague and is pregnant or terminated a pregnancy no longer than 3 months ago.

Step 2: the study

You receive 1 survey. You can fill out the survey online. You can also fill it out on paper and send it to us for free in a self-addressed envelope. The questions are about your personal characteristics, your lifestyle, the pregnancy, social support and events you experienced in your life. We are also curious how you are doing, if you have any worries, and how you deal with challenges. It will take you about 25 minutes to fill out this survey.

There are many people who find it challenging to fill out a survey. If this is the case for you, you can make an appointment with the researcher to do it together. If you want to have this conversation in a different language than Dutch or English, we will make sure that a translator is present.

Some information is hard or even impossible to collect from the answers to our questions. For example, because it will make the survey very long and complex. CBS (Centraal Bureau voor Statistiek or Statistics Netherlands) has additional information that we can use. For example, about your health, household, and the pregnancy outcomes. If you have a baby, we will – with your consent – also see information about your child's health, for example the birth weight. We will use the information from now until 2 years after the end of the pregnancy. In collaboration with CBS, we can combine this information with your answers to our survey. This is done in highly secured computer systems. In the informed consent form you indicate if you consent to this.

You can also choose to only fill out the survey and to not give us consent to use the information from CBS. Or to consent to this, but to not fill out the survey.

5. What agreements do we make with you?

We want the study to go well. That is why we want to make the following agreements with you:

- You fill out the survey truthfully and as completely as possible.
- You contact the researcher in these situations:
  - You no longer want to take part in the study.
  - Your telephone number, address or email address changes.

6. What are the pros and cons if you take part in the study?

Taking part in the study can have pros and cons. We will list them below. Think about this carefully and talk to other people about it.

You yourself do not benefit from taking part in this study. But if you take part, you will help the researchers to get more insight into how many pregnancies in The Hague are unintended and to improve care for people experiencing an unintended pregnancy. It is very important that we also have your answers.

Taking part in the study can have the following cons. It takes time (about 25 minutes). The questions may be confronting, and you share personal information with the researcher, for example about life events.

You do not wish to participate in the study?

It is up to you to decide if you wish to participate in the study. You do not wish to participate? Then you do not have to fill out anything and you can throw this sheet away. We would like to thank you for reading this information sheet.

7. When does the study end?

In these situations, the study will stop for you:

- The end of the whole study has been reached.
- You want to stop participating in the study yourself. You can stop at any time. Report this to the researcher immediately. You do not have to explain why you want to stop.
- One of the following authorities decides that the study should stop:
    - LUMC,
    - the government, or
    - the Medical Ethics Review Committee assessing the study

What happens if you stop participating in the study?

The researchers use the data that have been collected up to the moment that you decide to stop participating in the study. If you do not want this, you can let us know and we will remove your data and not use it in the study at all.

8. Resistance of your child or the person you represent (in case of a minor or incapacitated participant)

It may happen that your child or the person you represent resists (does not cooperate) during the study. Then, the researcher must stop their study participation immediately. It is hard to describe what resistance is exactly. Before the start of the study, we will discuss with you what we see as resistance. The researchers will comply with the Dutch Behavioural code resistance minors or mentally disabled people.

9. What happens after the study has ended?

Will you get the results of the study?

After 3 years after you took part in the study, the researcher will inform you about the most important results of the study.

10. What will be done with your data?

Are you taking part in the study? Then you also give your consent to collect, use and store your data.

What data do we store?

We store these data:

- Your name
- Your birthday
- Your postcode
- Your answers to the survey
- Your personal data and data about your health from CBS (only with your consent)

Why do we collect, use and store your data?
We collect, use and store your data to answer the questions of this study. And to be able to publish the results in a scientific journal.

How do we protect your privacy?
We will only use your answers for the study. We will **not** contact health or social care based on your answers, and we will not share your answers with them. Only if you want us to share your answers with your general practitioner and/or midwife, we will. They can use this information to provide better care for you.

To protect your privacy, we give your data a code that means nothing. Your name and other data that could directly identify you will be left out. Only with the key to the code, the data can be traced back to you. Only the researchers of this study have access to this key. When we process your data, we only use the code, we never use your name or initials. Also, in reports and articles about the study, no one will be able to know that it was about you.

A copy of your signed informed consent form will be saved in the LUMC. The researchers of this study may also be able to see your personal and health care data via CBS. In the informed consent form, you specifically choose if you want to give consent for this.

Who can see your data?
Some people can see your name and other personal information without a code. These are people checking whether the researchers are carrying out the study properly and reliably. These persons can access your data:

- An auditor who works for the LUMC.
- National and international supervisory authorities. For example, the Healthcare and Youth Inspectorate.

These people will keep your information confidential. We ask you to give permission for this access.

For how long do we store your data?
The LUMC stores your data for 15 years in secure storage.

Can we use your data and body material for other research?
Your data may also be important after this study for other scientific research about pregnancy. For this purpose, your data will be stored in secure storage for 15 years. Please indicate in the consent form whether you agree with this. Do you not want to give your consent? Then you can still take part in this study.

Can you take back your consent for the use of your data?
You can take back your consent for the use of your data at any time. This applies both to the use in this study and to the use in other scientific research. But please note: if you take back your consent, and the researchers have already collected data for research, they are still allowed to use this information. Only if you also indicate that you want us to remove all your data, we will do this and we will not use your data for the study.

Do you want to know more about your privacy?

- Do you want to know more about your rights when processing personal data? Visit www.autoriteitpersoonsgegevens.nl.
- Do you have questions about your rights? Or do you have a complaint about the processing of your personal data? Please contact the person who is responsible for processing your personal data. For this study, this is the LUMC. See Appendix A for contact details and website.
- If you have any complaints about the processing of your personal data, we recommend that you first discuss them with the research team. For more information about privacy, you can read the LUMC privacy statement at the LUMC website: see Appendix A. You can also contact the Data Protection Officer of the LUMC. Or you can submit a complaint to the Dutch Data Protection Authority.

11. Will you receive compensation if you participate in the study?

Yes, you receive a gift card of €10. This is a VVV Gift Card that you can exchange at different (web)shops, restaurants, museums, and more, including: Bol.com, Amazon, Zalando, HEMA, Bruna, ICI Paris XL and Rituals. You also get compensation for any additional travel costs. You do not have to pay taxes for this compensation.

12. Are you insured during the study?

The Leiden University Medical Centre (LUMC) is insured for harm as a result of medical scientific studies. However, for this study, no harm is expected.

13. Do you have any questions?

You can ask questions about the study of researcher. Would you like to get advice from someone who is independent from the study? Then contact Prof. Dr. Thomas van den Akker. He knows a lot about the study but is not a part of this study. His contact details can be found in Appendix A.
Do you have a complaint? Discuss it with the researcher. If you prefer not to do so, go to the complaints officer of the LUMC. In Appendix A, you can find where to contact them.

14. How do you give consent for this study?

You can first think carefully about this study. Then you tell the researcher or their representative if you understand the information and if you want to take part or not. If you want to take part, fill in the consent form that you can find on https://forms.lumc.nl/lumc2/rise-up-toestemming or on paper with (a representative of) the researcher. You and the researcher will both get a signed version of this consent form.

Thank you for your time.

15. Organisations for help or support

If you need help or support, you can call the following numbers:

In need of someone who listens	De Luisterlijn	088 0767 000
Abuse	Veilig Thuis	0800 2000
Sexual abuse	Centrum Seksueel Geweld	0800 0188
Advice for young people up to 27 years	Jongeren Informatie Punt en Loket voor Jonge Moeders	070 205 35 00
Support for unintended pregnancies	Fiom Den Haag	070 205 20 05
	Siriz	0800 440 00 03

16. Appendices with this sheet

Appendix A: LUMC contact details

Appendix B: Consent form participant

Appendix C: Consent form parent or guardian

Appendix D: Consent form representative

Appendix A: LUMC contact details

Researcher:

Merel Sprenger

m.sprenger@lumc.nl

+31 6 15 67 78 34

Available Monday to Thursday from 9AM to 5PM.

Promotor:

Prof. Dr. Jessica Kiefte-de Jong

j.c.kiefte@lumc.nl

+31 71 5 26 91 11

Available Monday to Friday from 9AM to 5PM.

Independent expert:

Prof. dr. Thomas van den Akker

Gynaecologist (LUMC) and Professor Global Maternal Health (Vrije Universiteit Amsterdam)

t.h.van_den_akker@lumc.nl

+31 71 5 26 28 96

Available Monday to Friday from 9AM to 5PM.

Complaints:

In case of complaints, you contact go to the LUMC complaint officer via email: klachtenfunctionaris@lumc.nl. You can also phone the secretariat of the Directory Quality and Patient Safety (071-5264646; during office hours). They will redirect you to the complaint officer in attendance.

LUMC Privacy officer:

When you have questions about the protection of your privacy, you can contact the LUMC privacy officers via infoavg@lumc.nl.

For more information about your rights:

Contact details LUMC
Albinusdreef 2
2333 ZA Leiden
Central phone number: (071) 526 91 11
For more information about your rights, see the LUMC website:

https://www.lumc.nl/12367/Deelnemers-wetenschappelijk-onderzoek/