Patient information letter PregSpark study

PregSpark: research for more knowledge of and experiences with pregnancy, childbirth and breastfeeding with Parkinson's disease.

Nijmegen, 25 April 2024

Deas Ms.,

Thank you for your interest in participating in the PregSpark study. By means of this questionnaire study we want to gain more knowledge of and experiences with pregnancy, childbirth and breastfeeding with Parkinson's disease. The study is conducted from the Center of Expertise for Parkinson's and Movement Disorders, Department of Neurology, of the Radboudumc Nijmegen. It is important that you read this information letter carefully before you decide to participate.

If you still have questions after reading this information letter, please feel free to contact one of the researchers:
info@my.pregspark.com

Participation in the study is completely voluntary. If you want to participate after reading the information letter, we ask that you sign the consent form online (see Appendix A).

We thank you for your interest.

Kind regards,

Dr. Bart Post, neurologist and movement disorders specialist;
Dr. Annelien Oosterbaan, senior physician-researcher, former gynecologist, diagnosed with Parkinson's disease;
Drs. Willanka Kapelle, physician-researcher PhD candidate in neurology.

1. What is the purpose of PregSpark?

In about 5-10 percent of all people with Parkinson's disease (PD), the first symptoms occur below the age of 50 years, which is referred to as early onset Parkinson's disease (EOPD). EOPD affects people in the prime of their lives and causes unique challenges and concerns regarding their employment, relationship, sexual activity, young children at home or the desire for a family. On top of this, women deal with questions related to menstruation, pregnancy and breastfeeding. Pregnancy during PD is rare, however due to increasing maternal age, PD being the fastest growing brain disease and earlier recognition of PD it is expected to become more and more common (also in young people).

In recent years, very little research has been done on pregnancy with PD. As a result, little is known about what impact pregnancy has on PD or what impact PD has on pregnancy. Knowledge about the long-term effects and infant safety of PD medication use during pregnancy and breastfeeding is scarce. Women get the advice not to breastfeed, simply because the effects are unclear and safety cannot be guaranteed. Still, many mothers have the desire to breastfeed, and since mother milk is known to be the best nutrition for the newborn child, more data is needed on infant outcome in mothers with PD who use PD medication. Hopefully, this will lead to more mothers being able to safely breastfeed in the future.

Because of this lack of knowledge, healthcare providers are less able to provide proper guidance prior to and during pregnancy. This leaves women with PD with uncertainty during a vulnerable life phase. With the development of "PregSpark", an international online registry for pregnancy in PD, we will be able to collect data through online surveys throughout and after pregnancy. The collected data will allow the development of guidelines and management protocols concerning, pregnancy, delivery and breastfeeding in women with PD and provide them with information they need to be able to make an informed decision regarding (future) pregnancies.

2. What does the study involve?

Women from all over the world can register online through the website www.pregspark.com to participate in the study. This allows us to include as many women as possible in the study and obtain as much information as possible. The registration is international, so the questionnaires are in English. Therefore, English reading and writing skills are required for participation.

As a participant you will receive at least five to a maximum of eight questionnaires over a period of approximately 2.5 years (during pregnancy up to 24 months after delivery). The number of questionnaires you will receive depends on the timing of participation relative to your pregnancy. For example, if you would participate from the beginning of pregnancy (the 1st trimester) you will first receive Q1 followed by Q2 to Q8 (spread over the period of 2.5 years). If you would participate from, for example the 3rd trimester, you will first receive Q1 followed by Q4 to Q8 (spread over the remaining period of about 2 years). So, after inclusion, you will always be asked to fill in a questionnaire to acquire baseline data related to your current pregnancy, both pregnancy and PD history, lifestyle, employment and demographics (Q1). Up to eight weeks postpartum you can register and participate in the study.

In case of an eventful pregnancy for example due to a miscarriage, termination of pregnancy or stillbirth, you will be asked if you are willing to answer some final questions (Q9). Q9 includes questions regarding date of pregnancy ending, cause of pregnancy ending, prenatal examination/screening and its outcomes. Afterwards your participation in PregSpark ends, due to the complicated pregnancy course. See Figure 1: "study flow PregSpark" for the eight moments participants receive the questionnaires. See Table 1: "list of questionnaires" for an overview of the different questionnaires with its topics and duration.

Every questionnaire contains various open and closed questions. The open questions invite you to describe your experiences by using their own expressions, which is useful for collecting more in-depth insights. Some questions are mandatory and others are non-mandatory. The time it will take you to fill in each questionnaire depends on whether you decide to answer all non-mandatory questions as well. The average duration per questionnaire will therefore vary between 30 to 60 minutes. The questions in the different questionnaires allow assessment of your clinical, providing crucial information of understanding pregnancy in PD.

Different questions and questionnaires keep coming back to discover the changes over time, for example, to enable comparison of the severity of PD symptoms at different time points in pregnancy and after delivery. Other topics and questions are more trimester specific or related to delivery or pregnancy outcome.

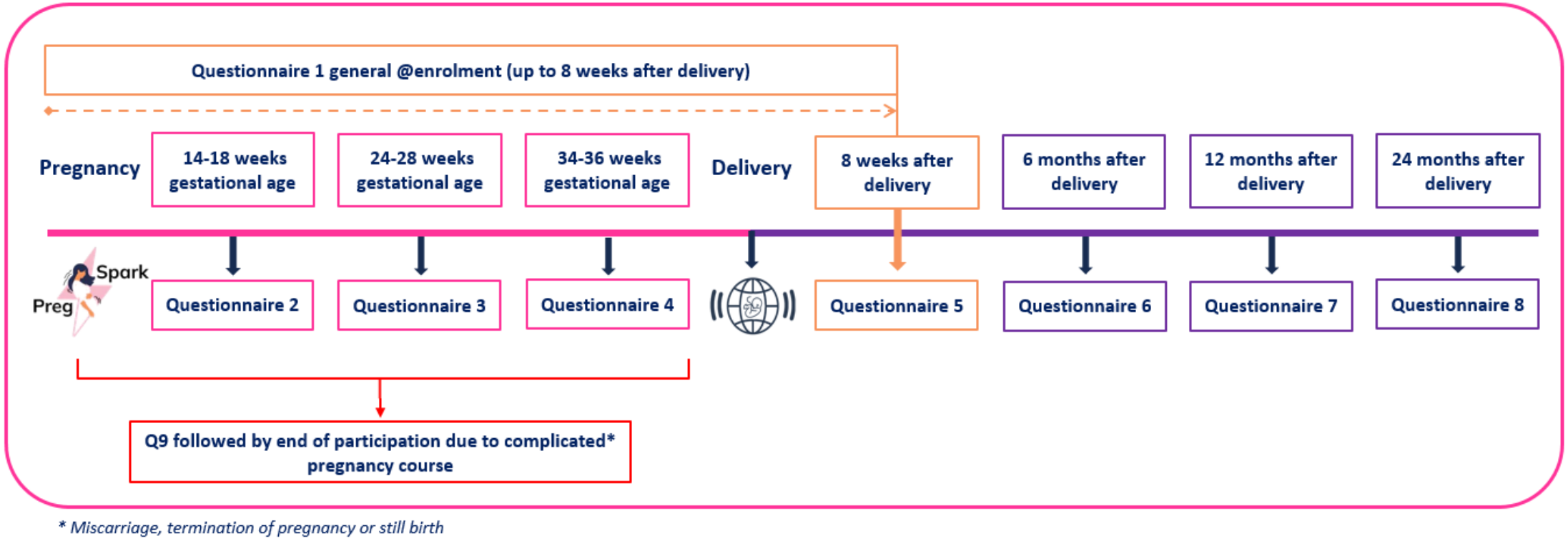

Figure 1: study flow PregSpark

Table 1: list of questionnaires

Questionnaire:	**Topics:**	**Duration:**
Q1 – at enrolment (Every participant, regardless of the time of inclusion, will receive Q1)	1) Time to pregnancy 2) Pregnancy history 3) Parkinson's history 4) Medical history 5) Vitamin supplement use 6) Lifestyle 7) Working conditions 8) Demographics	20 min (only mandatory questions) 50 min (all questions)
Q2 – First trimester, week 14 to 18 of pregnancy	1) Early pregnancy 2) Pregnancy general 3) Medication use 4) General health and major life events 5) Various aspects of Parkinson's symptoms 6) Performance of activities of daily living 7) Disease acceptance 8) Self-report scale to assess dimensions of anxiety	30 min (only mandatory questions) 60 min (all questions)
Q3 – Trimester 2, week 24-28 of pregnancy	1) Second trimester of pregnancy 2) Pregnancy general 3) Medication use 4) General health and major life events 5) Various aspects of Parkinson's symptoms 6) Performance of activities of daily living 7) Disease acceptance 8) Self-report scale to assess dimensions of anxiety	30 min (only mandatory questions) 60 min (all questions)
Q4 – Trimester 3, week 24 to 36 of pregnancy	1) Third trimester of pregnancy 2) Pregnancy general 3) Medication use 4) General health and major life events 5) Various aspects of Parkinson's symptoms 6) Performance of activities of daily living 7) Disease acceptance 8) Self-report scale to assess dimensions of anxiety	30 min (only mandatory questions) 60 min (all questions)
Q5 – 8 weeks after birth of the baby	1) Delivery 2) Maternal health 3) Infant health 4) Medication use 5) Various aspects of Parkinson's symptoms 6) Performance of activities of daily living 7) Disease acceptance 8) Self-report scale to assess dimensions of anxiety	30 min (only mandatory questions) 60 min (all questions)
Q6 – Follow-up, 6 months after birth of the baby	1) Maternal health 2) Infant health 3) Medication use 4) Various aspects of Parkinson's symptoms 5) Performance of activities of daily living 6) Disease acceptance 7) Self-report scale to assess dimensions of anxiety	20 min (only mandatory questions) 45 min (all questions)
Q7 – Follow-up, 12 months after birth of the baby	1) Maternal health 2) Infant health 3) Medication use 4) Various aspects of Parkinson's symptoms 5) Performance of activities of daily living 6) Disease acceptance 7) Self-report scale to assess dimensions of anxiety	20 min (only mandatory questions) 45 min (all questions)

Q8 – Follow-up, 24 months after birth of the baby	1) Maternal health 2) Infant health 3) Medication use 4) Various aspects of Parkinson's symptoms 5) Performance of activities of daily living 6) Disease acceptance 7) Self-report scale to assess dimensions of anxiety	20 min (only mandatory questions) 45 min (all questions)
Q9 – Eventful outcome of pregnancy (miscarriage, termination of pregnancy, still birth, or neonatal death)	1) Eventful outcome of pregnancy 2) Medication use 3) General health and major life events	10 min (only mandatory questions) 15 min (all questions)

** Latest moment of enrollment = 8 weeks postpartum.*

3. What is expected of you?

If you decide to participate in the study, we will ask you to complete the online consent form (see Appendix A). You will receive the questionnaire by email at the 5 - 8 different times, depending on the timing of participation. For completing the questionnaires, we will ask about 30-60min of your time, each questionnaire.

4. When are you eligible to participate?

You can participate in the study if you:

1) Are pregnant or up to maximum 8 weeks after you gave birth to the baby;

2) Have been diagnosed with PD by a neurologist after the age of 21 years and before 50 years,;

3) Can read and write English;

4) Have signed the online informed consent.

5. The possible advantages and disadvantages of participating in the study.

Participation in the study has no direct benefits for you. Results of the study will provide more insight and knowledge regarding pregnancies in PD. Which can be used for guidelines to improve the quality of care among young pregnant women with PD.

The disadvantage for participation is the time investment for completing the various questionnaires. An average duration of 30 – 60 minutes should be counted per questionnaire. This depends on whether you will complete only the mandatory, or both mandatory and non-mandatory questions. There are no risks associated with participating in the study.

6. Am I required to participate?

Participation in this study is completely voluntary. You may withdraw from the study at any time. Even after signed informed consent. If desired, the collected data for each questionnaire can be deleted. This can be done up to two weeks after completion of the questionnaire. This can be done by sending an email to annelien.oosterbaan@radboudumc.nl or willanka.kapelle@radboudumc.nl. Once this two-week period has passed, the already collected data will still be used for the study. If you decide to not to participate after reading this information letter or want to withdraw during the study, this will have no consequences for your further medical treatment and you do not have to give a reason for this.

7. What will we do with your data?

The data you provide for registration is stored securely on the website, with a secured https-connection. The data you enter in the various questionnaires are collected by the research team. This data will be processed and monitored in accordance with the European General Regulation Data Protection Act (GDPR).

Your privacy is ensured. Your data will be pseudonymized: data will be linked to a unique code and is stored in a code list file. Only with the key to the code can the data be traced to you. The key to the code is kept secured by the researchers. The code list file is stored in a secure Excel file on a secure server of the Radboud university medical center. Only members of the research team, the medical ethics committee and the Dutch Health Care and Youth Inspectorate can view your (medical) personal data related to the study on request. These last two check whether the research is carried out medically-ethically and reliably, but will not do anything else with the research data.

After completion of the study we are obliged to keep your data for 15 years on a secure server of the Radboudumc. The code list will be removed after 5 years.

8. Will I receive compensation for participating?

No, you will not receive any compensation.

9. Who can I contact for questions or if I have a complaint?

The research team is available throughout the study to help you or answer questions. Please contact: info@my.pregspark.com

If you have a complaint about the study, we recommend you to first contact the researchers about it. You can also contact the Radboudumc Complaint Mediation. For privacy concerns you can contact the Radboudumc Data Protection Officer (see Appendix B).

Appendix A: INFORMED CONSENT

"Thank you for registering to PregSpark, the International Registry for Pregnancy in Parkinson's disease! Participating in the PregSpark Registry means you also participate in a scientific study. On this behalf we need to save a limited amount of personal data to be able to reach you. We process your personal data with extreme confidentiality. By clicking the confirmation link, you agree to the following:

- *I have read the information on the website. I was able to ask questions. My questions have been answered satisfactorily. I have had enough time to decide whether or not to participate.*
- *I know that participation is voluntary. I also know that I can decide at any time not to participate or to stop the study. I don't have to give a reason for that.*
- *I know that I am participating in scientific research for which I am expected to complete questionnaires.*
- *My details allow me to be contacted for help with the program, but also to remind me to continue participating. I give permission for the collection and use of my data to answer the research questions in this study.*
- *I know that the people from the research team have access to my data to check the research. I give permission for inspection by these persons.*

You can now participate in the PregSpark Registry.

How to log in?

Via this link [link] you confirm your enrollment and you can log in once to create a password.

Next use your email address and password to log in.

Thank you in advance for participating, this is of great importance to the YOPD women community!

Yours sincerely,

Annelien Oosterbaan
on behalf of the PregSpark team"

Appendix B: Contact information

In case of complaints, please contact:

Radboudumc Complaint Mediation Committee

number P.O. Box 540 (home office 628)

6500 VC Nijmegen

The Netherlands

Telephone: +31 (0)24-361 3191

For more information on your rights regarding the processing of personal data, please contact:

Radboudumc Data Protection Officer

P.O. Box 9101 (home post 624)

6500 HB Nijmegen

The Netherlands

E-mail: gegevensbescherming@radboudumc.nl