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Request to participate in research projects with primiparous women

Development and validation of a tool for advising primiparous women during early labour (GebStart study)

Study information for data collection in six Swiss hospitals

Dear potential study participant

We are kindly asking you if you would be willing to participate in our research project.

Your participation is voluntary. All data collected in this project are subject to strict data protection regulations. The research project is being conducted by the Research Institute of Midwifery at ZHAW Zurich University of Applied Sciences under the lead of Prof. Dr. Susanne Grylka. If you are interested, we would be pleased to inform you about the results of the research project.

We will explain the most important points and answer your questions in a face-to-face interview. To get an idea, here are the most important points in advance. Further detailed information will then follow below.

Why are we conducting this research project?

- In early labour, meaning in the first phase of birth, first-time mothers are often unsure whether they need to go to the hospital and contact their midwife or gynaecologist. For professionals, advising at the onset of labour is usually challenging because there are no clear criteria with which to assess the needs for care.
- In our research project, we will develop a questionnaire that provides individualised, evidence-based support for advising first-time mothers in early labour. The development of this questionnaire is based on a literature search and focus group discussions with women. For including the most appropriate questions for the final Version or the questionnaire, we are testing a preliminary questionnaire with women who are having their first child.

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What do I have to do if I participate? - What happens to me if I participate?

- Form of participation: If you decide to participate, we will ask you to complete questionnaires or answer questions at several points in time, i.e., before birth, at the onset of birth, and after birth. In addition, birth data from you and from your child will be collected for the study.
- Procedure: If you attend, we will ask you to fill out a questionnaire during pregnancy. As soon as the birth starts and you call the hospital, the midwife will ask specific questions about the onset of labour symptoms and your physical and mental well-being. After having given birth, we will also ask you to fill out a questionnaire about your experience with advising and care during early labour.
- Duration: Filling out the questionnaires before and after the birth will take about 20 minutes each. At the beginning of the birth, when you call the hospital, answering questions will take about 15 minutes.

What are the associated benefits and risks?

Benefit

- If you participate in this study, you may benefit from the use of the preliminary standardised questionnaire and the decision whether or not to be admitted to the hospital will be facilitated.
- Your participation will also make an important contribution to improving advising and care for first-time mothers in early labour.

Risk and burden

- Participation in the study is not associated with any risks. Filling in the questionnaires during pregnancy and after birth will take some time. The questions that the midwives will ask you when you contact the hospital are standardised. However, the midwife will ask questions to advise you even if you do not participate in the study, so we expect only a small additional burden.

By signing at the end of the document, you confirm that you are participating voluntarily and that you understand the contents of the entire document.

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Detailed information

1. Aim and selection

We refer to our research project as a *study in* this information leaflet. If you participate in this study, you are a *study participant*.

The aim of this study is to develop a standardised questionnaire that can be used to provide more individualised advising to first-time mothers in early labour.

We are asking you because women who will give birth to their first child in the coming weeks and are planning a spontaneous birth can participate in the study.

2. General information

Pregnant women experience the onset of labour and the first phase of labour, the early labour, very differently and with different physical and emotional symptoms. Studies show that early hospitalisation is associated with increased interventions and increased caesarean section rates. However, first-time mothers often call the hospital before labour progresses because they struggle to deal with labour pain in the home environment. It is challenging for professionals to care for and advise first-time mothers in early labour. Therefore, there is an urgent need to develop a standardised questionnaire that allows for an evidence-based and individualized assessment of the physical as well as emotional state and well-being of women. This can be used to determine their care needs and support advising for or against hospital admission.

For the development of the questionnaire, we will develop a question pool based on a literature search and focus group discussion. We will show this to a group of experts and reduce the question pool to the best and most important questions, thus creating the preliminary questionnaire. These questions will be asked by midwives in six hospitals in the German-speaking part of Switzerland during one year to a total amount of about 400 women at the onset of labour. Their responses will enable us to use statistical methods to determine the most appropriate questions and to design the definitive, shortened questionnaire.

Participation in the study will last approximately two to four months, from one to eight weeks before birth to six to eight weeks after birth. If you do not participate in the study, you will not fill out questionnaires before and after birth. In this case, the midwife will also ask you questions at the onset of labour, but these are not predetermined.

We conduct this study in accordance with the laws in Switzerland. In addition, we comply with all internationally recognised guidelines. The relevant ethics committees have reviewed and approved the study. A description of this study can also be found on the website of the ZHAW (https://www.zhaw.ch/de/forschung/forschungsdatenbank/projektdetail/projektid/4220/) and the Swiss National Science Foundation (http://p3.snf.ch/project-199085).

3. Procedure

If you decide to participate in the study, the following procedure is planned:

- The hospital's study midwife will send you the link for the online questionnaire with questions about yourself and your health as well as confidence and concerns about the birth after you have consented to the study. You should complete this before giving birth at a time of your choice.

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- When you contact the hospital at the onset of labour, the midwife will ask you standardised questions on the phone or at the personal check-up appointment. These are intended to support the decision whether or not you should already go to the hospital.
- Immediately having given birth, the study midwife will enter birth information about you and your child into the data collection tool.
- Approximately six weeks after birth, the study midwife will again send you a link to an online questionnaire about your experience of care during early labour, which you can complete within one to two weeks at a time of your choosing.

We may have to exclude you from the study prematurely. This may happen if an unplanned induction of labour or caesarean section would be necessary, or if the birth is already very advanced at the time of contact with the hospital. Your continued medical care is guaranteed at all times.

4. Benefit
If you participate in this study, you may benefit from the use of the preliminary standardised questionnaire and the decision whether or not to go to the hospital will be facilitated. However, there may also be no benefit of participation. Yet, the results of this study may be important for other first-time mothers with labour onset.

5. Voluntariness and duties
You are participating voluntarily. If you do not want to participate in this study or later withdraw your participation, you do not have to justify this. Your medical care is guaranteed regardless of your decision.

If you participate in this study, you will be asked to complete the questionnaires during pregnancy and after birth, and to answer the questions when contacting the hospital at the onset of labour.

6. Risks and burdens
Participation in the study is not associated with any risks. Filling in the questionnaires during pregnancy and after birth will take some time. The questions that the midwives will ask you when you contact the hospital are predetermined. However, the midwife would ask questions to be able to advise you even without participating in the study, so we expect only a small additional burden.

7. Alternatives
Participation in the study is associated with opportunities and low burdens. If you do not want to participate in the study, you do not have to fill in questionnaires before and after giving birth. The conversation with the midwife at the first contact with the hospital at the onset of labour will not be guided by standardised questions and the decision whether you enter the hospital or not could be made more randomly. Your study midwife will advise you on this during the conversation.

8. Results
The study leads to objective final results of the whole study. It will lead to the determination of the most appropriate questions for the definitive, standardised questionnaire. It will also give indications whether the application of the questionnaire could lead to more physiological births. If you wish, the principal investigator of this study can send you a summary of the results after the interviews have been analysed.

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9. Confidentiality of data and samples

9.1. Data processing of encryption

For this study, data about you and your health will be collected and processed. During data collection, your data will be encrypted. Encryption means that all reference data that could identify you (name, date of birth, etc.) are deleted and replaced by a code. People who do not have access to this key list cannot draw any conclusions about your person. The key list is kept on the study centre server in a separate, secured folder. Only very few professionals will see your unencrypted data, and only to perform tasks related to the study. These individuals are bound by confidentiality. You as a participating person have the right to see your data.

9.2. Data protection and sample protection

All data protection specifications are strictly adhered to. It is possible that your data must be transmitted in encrypted form, for example for a publication, and may be made available to other researchers.

9.3. Data protection for further usage

Your data might be important for answering other questions at a later point in time and could be reused. For this purpose, the same standards must be used as for this study.
For this further usage, we ask you to sign another consent form at the very end of this document. This second consent is independent of your participation in this study.

9.4. Inspection rights during inspections

This study may be reviewed by the responsible ethics committee. The study management must then disclose your data for such inspections. Everyone must maintain absolute confidentiality.

10. Resignation

You can withdraw from the study at any time. In this case, however, the data collected up to that point will still be analysed in encrypted form. The key allocation will be destroyed so that the data and samples can no longer be referred to your person. That is primarily for data protection purposes.

11. Compensation

If you participate in this study, you will not be compensated. There are no costs to you or your health insurance company for participating.

12. Liability

The ZHAW (with the principal investigator Prof. Dr. Susanne Grylka), which initiated the study and is responsible for its implementation, is liable for the study. The requirements and the procedures for this are regulated by law. The ZHAW has taken out insurance for research projects with Zurich Insurance and registered this study there.

13. Funding

The study is funded by the Swiss National Science Foundation.

14. Contact person(s)

You may ask questions about study participation at any time. Also, if you have any uncertainties or emergencies that arise during or after the study, please contact:

Contact in the study centre

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Contact at Zurich University of Applied Sciences

Prof. Dr. Susanne Grylka
Deputy Head of Research Institute of Midwifery
School of Health Sciences
ZHAW Zurich University of Applied Sciences
Katharina-Sulzer-Platz 9
8401 Winterthur

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E-mail: susanne.grylka@zhaw.ch

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Declaration of consent

Written informed consent to participate in data collection in six Swiss hospitals
Please read this form carefully. Please ask if there is anything you do not understand or would like to know. Your written consent is required for participation.

BASEC number (after submission):	2021-00687
Title of the study (scientific and lay language):	*Development and validation of a tool for advising primiparous women during early labor (GebStart study).* OR in simpler terms: *Development and testing of a questionnaire for advising first-time mothers at the beginning of childbirth (GebStart study).*
Responsible institution (sponsor with address):	Prof. Dr. Susanne Grylka, Research Institute for Midwifery, School of Health Sciences, ZHAW Zurich University of Applied Sciences, Katharina-Sulzer-Platz 9, 8401 Winterthur
Place of implementation:	
Investigator at the study site: Last name and first name in block letters:	
Participant: Family name and first name in block letters: Date of birth:	

- I was informed orally and in writing by the undersigned researcher about the purpose, the procedure of the study, about possible advantages and disadvantages as well as possible risks.
- I am voluntarily participating in this study and accept the contents of the written information given to me. I have had sufficient time to make my decision.
- My questions related to the participation in this study have been answered. I will keep the written information and receive a copy of my written informed consent.
- I was informed about potential alternatives to the study and was told how to contact the hospital without participating in the study.
- I agree that my gynaecologist will be informed about my participation in the study.
- I agree that the responsible experts of the ZHAW and the responsible ethics committee may inspect my unencrypted data for testing and control purposes, but in strict compliance with confidentiality.
- I know that my health-related and personal data can only be passed on in encrypted form for research purposes for this study. The principal investigator of this study, Prof. Dr. Susanne Grylka of the ZHAW, guarantees that data protection in accordance with Swiss standards will be complied.

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- I can withdraw from the study participation at any time and without reasoning. My continued medical treatment is guaranteed regardless of study participation. The data collected up to the point of withdrawal will still be evaluated within the scope of the study.
- The ZHAW's liability insurance will cover any damages. I am informed that the ZHAW has taken out an insurance policy that covers possible damages resulting from the research project.
- I am aware that the obligations stated in the information document must be complied with. In the interest of my health, the study director may exclude me from the study at any time.

Place, date	Signature Participant

Confirmation by the study midwife: I hereby confirm that I have explained the nature, significance and scope of the study to this participant. I assure that I will fulfill all obligations in connection with this study in accordance with the law applicable in Switzerland. If, in the course of the study, I learn of any aspects that could influence the participant's willingness to take part in the study, I will inform her immediately.

Place, date	Family name and first name of the study midwife Signature

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Informed consent for further usage of data from the study in six Swiss hospitals in encrypted form

BASEC number (after submission):	2021-00687
Title of the study (scientific and lay language):	*Development and validation of a tool for advising primiparous women during early labor (GebStart study).* OR in simpler terms: *Development and testing of a questionnaire for advising first-time mothers at the beginning of childbirth (GebStart study).*
Participant: Name and first name in block letters: Date of birth:	

I give permission for my encrypted data from this study to be further used for medical and health-related research. The data will be kept encrypted on the ZHAW server and used for future, as yet undefined research projects for an indefinite period of time.

I understand that the data is encrypted and the key is kept secure.
The data can be sent to other research institutes in Switzerland for analysis if they adhere to the same standards as the ZHAW. All legal requirements for data protection are complied with.
I decide voluntarily and can withdraw this decision at any time. If I withdraw, my data will be anonymised, this means that my personal data in the key will be deleted. I only inform the responsible examiner and do not have to justify this decision.

I decide voluntarily and can revoke this decision until the destruction of the key. I only inform the study director and do not have to justify this decision.

Place, date	Signature participant

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Study midwife's acknowledgement: I hereby acknowledge that I have explained to this participant the nature, significance, and implications of further use of the data from this study.

Place, date	Family name and first name of the study midwife Signature

Grylka-Baeschlin S, *et al. BMJ Open* 2022; 12:e062869. doi: 10.1136/bmjopen-2022-062869