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Development and validation of a tool for advising primiparous women during early labour: study protocol for the GebStart Study

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ABSTRACT

Introduction Pregnant women experience early labour with different physical and emotional symptoms. Early admission to hospital has been found to be associated with increased intervention and caesarean section rates. However, primiparous women often contact the hospital before labour progresses because they encounter difficulties coping with symptoms of onset of labour on their own. An evidence-based instrument for assessing the individual needs to advise primiparous women during early labour is currently missing. The study aims to develop and validate a tool to inform the joint decision for or against hospital admission.

Methods and analysis A scale development and validation study will be conducted including following steps: (1) Generation of a pool with 99 items based on a scoping review and focus group discussions with primiparous women, (2) Assessment of content and face validity by an expert panel and item reduction to 32 items, (3) Multicentre data collection in six study sites in Switzerland, with application of the preliminary tool and the validation items with a target sample size of approximately n=400 women and (4), item reduction using exploratory factor analysis, factor loading and item-to-item correlation. Internal consistency of the tool will be assessed using Cronbach's alpha and convergent validity computing correlations of items of the tool with the German versions of the Childbirth Self-Efficacy Inventory and the Cambridge-Worry Scale. Analyses will be performed using Stata V.17.

Ethics and dissemination Ethical approval was obtained by the Ethics Committees Zurich and Northwestern and Central Switzerland (BASEC-Nr. 2021-00687). Results will be disseminated at the final study conference, at national and international congresses and by peer reviewed and not peer-reviewed articles in scientific and professional journals. Approved and anonymised data will be shared. The dissemination of the findings will have a contributable impact on clinical practice, scientific discussions and future research.

Trial registration number DRKS00025572, SNCTP000004555.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The development of the tool was based on an extensive scoping review and on focus group discussions with women.
⇒ Content validity of the preliminary tool was evaluated qualitatively and quantitatively in an international expert panel.
⇒ The multicentre data collection is conducted in six study sites.
⇒ In this study, it is only possible to develop the German version of the tool, however, it may be translated into further languages at later time.
⇒ Approximately one-quarter of recruited participants may no longer meet the inclusion criteria at the time of birth because of unplanned caesarean section before onset of labour or labour induction.

INTRODUCTION

The experience of early labour care is often unsatisfactory for parturients and also challenging for health professionals.[1 2] However, women's ability to cope with early labour is crucial for labour and birth outcomes.[3 4] New pathways in care respecting the individual needs of women during early labour are urgently needed.[2 4 5]

Early labour, also called latent phase, is the first phase of the labour process and along with the subsequent active phase of cervical dilatation constitutes the first stage of labour.[6 7] A relevant heterogeneity of the definition of onset of labour was found in the literature[8] and can also be observed in clinical practice.[1 9] Current research suggests that the transition between early labour and the active phase of labour is less distinct and later than previously assumed.[10 11] Consequently, the definition of physiological labour progress needs to be reconsidered to prevent unnecessary intrapartal interventions and caesarean sections.[10]

Pregnant women recognise onset of labour and the physiological early labour process in a variety of ways.[12 13] In addition to recurrent and non-recurrent pain, they also experience

watery fluid, blood-stained loss, gastrointestinal symptoms, altered sleep patterns and emotional upheaval.[12 14] These symptoms may last for a short time but sometimes also hours or days, and the duration between the recognition of different symptoms of onset of labour and full cervical dilatation varies according to the symptoms.[12 14]

Managing early labour is a widely discussed topic internationally and challenging for women, their labour companions and health professionals.[1 2 4 5] Midwives often function as gatekeepers to delay hospital admission and trying to protect women from unnecessary interventions but thereby might not meet women's needs.[15 16] Some women and their partners have difficulties coping with labour pain at home.[1 17–19] Reasons might be a long lasting early labour or anxiety.[3 20] A Swiss study showed that women with increased anxiety scores experienced stronger pain during early labour.[20] Approximately 18%–30% of women request care during early labour because they struggle with the unfamiliar emotions and sensations.[2 3 19 21 22] However, women with hospital admission prior to contractions leading to labour progression, especially those with a longer lasting early labour, were more likely to have caesarean sections and intrapartal interventions, generating higher costs of care.[3 22–27] Furthermore, there is evidence that primiparous women who stay in hospital during early labour have an increased risk of adverse outcomes such as amnionitis and having a neonate with an Apgar score below 7 at 5 min compared with those returning or staying at home.[19 28] On the other hand, staying or returning home was found to be associated with ambivalent feelings, and women in early labour often complain of not being understood by midwives and doctors.[1 17 18 29] Consequently, it is estimated that for approximately a quarter of women, delaying hospital admission might not be the optimal care strategy.[27]

Early labour interventions aiming at delaying hospital admission and decreasing intrapartal intervention rates are challenging.[30] Previous studies have investigated support at home during early labour, early assessment, one-to-one structured care, telephone triage prior to hospital admission, and an algorithm to diagnose active labour or structured care during early labour with varying results.[4 31–35] The authors of a Cochrane review including five trials and investigating assessment and support during early labour found no clear impact of these interventions on caesarean section and instrumental birth rates.[4] However, they found some evidence for lower use of epidural analgesia and increased maternal satisfaction with care in cases of early labour intervention.

It is recognised that more evidence and new pathways for the assessment and care during early labour are needed.[2 4] One of the major challenges for care during early labour was found to be the individual woman's needs.[5] Postponing hospital admission might be appropriate for some women but be very stressful for others.[16 26] In previous studies, assessment during early labour did not take into consideration the different symptoms of the onset of labour[14] and the potential to use this information to assess how far the process of early labour might have progressed. Additionally, no previous study has considered a combination of physical and emotional aspects for assessing individual needs of support leading to advice about the best place to stay during early labour. An evidence-based instrument for assessing the individual needs for support to inform the decision for or against hospital admission is currently missing.

The aims of this study are to develop and validate a tool to provide evidence-based and structured advice to primiparous women during early labour. The specific objectives are: (1) The development of an evidence-based tool, (2) The assessment of validity (content and construct validity) and reliability (internal consistency) of this instrument, (3) The assessment of women's, midwives' and doctors' satisfaction with the use of the instrument and (4) The investigation of the potential for using the tool to improve perinatal outcomes.

METHODS AND ANALYSIS

Study design, setting and project structure

The planned study consists of the development and the validation of a tool in the German speaking area of Switzerland. The project lasts 3 years from 1 May 2021 to 30 April 2024. The multicentre data collection applying the preliminary version of the tool takes place in six hospitals in the German part of Switzerland from March 2022 to June 2023.

Scale development is a complex process which needs a multistep approach for the generation and reduction of items leading to the final version of the tool.[36] An overview of the study process is presented in box 1.

Sampling and recruitment

The multicentre data are conducted in the target population which fulfils the following inclusion criteria: women who are pregnant with their first child, expecting a singleton in cephalic presentation, do not plan an elective caesarean section or a labour induction, are ≥18 years old and have sufficient oral and written German language knowledge. The study focuses on primiparous women because early admission to the hospital during early labour and adverse outcomes were found to be more frequent compared with multiparous women.[3 19 28]

Sample size estimation was primarily based on the required sample sizes for exploratory factor analysis. It is common practice for an acceptable sample size for factor analysis to have at least 300 cases[37] and that ten cases per factor helps reduce computational problems.[38] It was planned that the preliminary tool should include 30–40 items leading to n=400 participants for factor analysis. This sample size will also be sufficient for the proportional odds modelling needed to define the cut-off-points to inform the decision for or against hospital admission. Approximately a quarter of the recruited women will not be admitted to hospital with spontaneous onset of labour or during early labour, meaning that labour might

Box 1 Work steps in the different study phases

Development phase

1. Generating an initial item pool with 99 items by
   - Scoping review about symptoms of onset of labour and their relation to care and support needs.
   - Focus group discussions with primiparous women who have experienced early labour (four semi-structured interviews with n=18 participants, content analysis).
2. Designing the preliminary tool with 32 items
   - Workshop with national and international experts and assessment of content and face validity by an expert panel.
   - Item reduction to 32 items, determination of the format of measurement and the preliminary cut-off points to inform the decision for or against hospital admission.

Data collection phase

1. Training midwives and doctors.
2. Baseline data collection.
3. Multicentre data collection in six sites with 400 women women:
   - Preliminary tool with 32 items.
   - German versions of CBSEI [39 45] and the CWS. [40 46]
   - Perinatal outcomes (mode of birth, intrapartal interventions, labour duration, postnatal quality of life.[50 51]
   - Satisfaction of women and health professionals with the tool.

Analysis and finalisation phase

1. Analyses:
   - Factor analyses for item reduction to 15–20 items.
   - Validity and reliability of the instrument.
   - Proportional odds model for determination of the cut-off points to inform the decision for or against hospital admission
2. Designing final instrument with 15–20 items.
3. Dissemination (final conference, publications) and implementation.

CBSEI, Childbirth-Self-Efficacy Inventory; CWS, Cambridge-Worry Scale.

be medically induced, the admission could occur with cervical dilatation >6 cm or before onset of labour with a medical indication for an unplanned c-section. The target sample size to be enrolled in the study is therefore approximately n=550 participants so that n=400 women with complete data should be available for the analyses. Previous studies showed that observations in spontaneous birth, respectively, c-section rates required sample sizes of more than 800 women per group to detect a 20% relative risk reduction.[33] The sample size of the planned study might not be sufficient to achieve significant results in change of risk ratios for spontaneous birth and interventions but could indicate if a reduction would be possible in larger samples.

Recruitment takes place during pregnancy. Contact opportunities with pregnant women from the study sites differ, however in all sites, women are registered by their care provider 4–8 weeks before the estimated date of birth, providing contact details of the women. Further contact options are medical records, antenatal classes, acupuncture appointments, midwifery prenatal assessment, antenatal care by obstetricians or midwives in the hospital, or prenatal contact in the labour ward. All available opportunities are used to have access to the majority of primiparous women giving birth during the study period. Recruitment planning was done individually for each site and is tested and amended during a 2-month pilot phase. Recruitment seems feasible during the envisaged data collection time. A total of over 13 000 women will give birth during 1 year of data collection in the six study sites. Taking into consideration the inclusion and exclusion criteria, the study population will include approximately 2300 eligible women. It seems highly feasible that the target sample size of n=550 participants can be recruited.

Primary and secondary outcomes

The primary outcome of the study are the validity and the reliability of the tool. Secondary outcomes for mothers are perinatal outcomes such as mode of birth, interventions during childbirth, perineal injuries, breast feeding, hospital stay, postnatal quality of life, satisfaction with the application of the tool, satisfaction with the care received. For infants, following secondary outcomes are assessed: birth weight, Apgar score, umbilical cord pH, admission to neonatal intensive care. Secondary outcomes for health professionals are satisfaction with the application of the tool.

Development of the preliminary tool

The guidelines of scale development by DeVellis[36] was followed. The initial item pool with 99 items was generated through the results of a scoping review and focus group discussions. The literature research was conducted on the databases Pubmed, Medline, Midirs, PsycINFO and CINAHL and its protocol was registered on Open Science framework. The review investigated physical and emotional symptoms of onset of labour and their relation to care and women's needs during early labour.[12 39–41] A total of 91 articles were included in the data extraction of which the results will be published separately. Additionally, four focus group discussions were conducted with n=18 first-time mothers within 6 months after having given birth. Women were asked how they had experienced onset of labour and the support during the latent phase and what needs they did have. Results of the focus group discussions will also be published elsewhere.

Content and face validity of the item pool was evaluated qualitatively and quantitatively by a maternity care expert panel (midwives, researchers and mothers) to first improve and then reduce the initial item pool and achieve the preliminary version of the instrument.[36] First, important themes, the structure, response options and cut-off points of the tool were discussed in a workshop with n=16 international experts from Switzerland, Germany, Sweden, Norway, the UK and the USA. Consequently, the item pool was amended, and it was decided, that results of the tool should lead to three categories of advises, for or against hospital admission and an additional middle category keeping in contact/proposing a check-up. A German speaking panel with n=8 experts from Switzerland, Germany and Austria evaluated the relevance and clarity of the proposed 99 initial items on four-point Likert Scales ranging from not relevant at all

to very relevant, respectively, not clear at all to very clear. Additionally, suggestions could be written for each item. A maximum of eight points could be given per item. The selection of the items for the preliminary instrument was done based on the sums of allocated points and the frequencies of experts allocating ≥7 points. After reducing the items and amending the remaining ones according to the comments of the experts, the drafted preliminary tool was administered to n=4 midwives for face validity and further revised. These midwives also evaluated the preliminary subdivision of the scores to inform the decision for or against hospital admission, respectively, keeping in contact/proposing a check-up. This first proposition for possible cut-off-points was necessary to enable the application of the preliminary instrument. Pretesting the tool in the target population takes place during the 2-month pilot phase of the multicentre data collection.

Development of questionnaires and data collection tools

Questionnaires and data collection tools were submitted with the ethics application. An Excel spreadsheet for the collection of baseline data of primiparous women at the study sites was designed based on data used to assess secondary outcomes. Sociodemographic parameters such as age and gravidity as well as obstetric interventions and obstetric and neonatal outcomes of women who would fulfil the eligibility criteria of the study are collected for a period of 6 months before the start of the multicentre data collection. Data are extracted from the hospital's electronic database or its birth records. Means as well as absolute and relative frequencies are calculated to be transferred to the project leader.

A REDCap database including a case report form, an antenatal and a postnatal questionnaire as well as the newly developed tool was created for the multicentre data collection. Mandatory questions will be used to minimise missing data. The case report form for study participants was designed based on the Swiss Health Survey[42] and the Statistics of independent midwives in Switzerland.[43] Sociodemographic and medical history related characteristics, labour and birth data as well as obstetric and neonatal outcomes are collected.

The antenatal questionnaire includes sociodemographic data derived from a previous Swiss study,[44] questions about pregnancy history and antenatal preparation, the German versions of the Childbirth Self-Efficacy Inventory (CBSEI)[39 45] and the Cambridge-Worry Scale (CWS).[40 46] The CBSEI[39 45] and the CWS[40 46] will be used for the validation of the newly developed tool because of items related to self-efficacy and worries. As recommended by Green *et al*[40] and done in other studies with women during early labour, items of this scale were slightly adapted to the specific situation of women who will soon be giving birth. Further questions were developed based on the existing literature about early labour experience and early labour care.[1 4 5 16 17]

The postnatal questionnaire contains questions regarding satisfaction with the application of the tool, symptoms of onset of labour,[47] experiences of early labour, the quality of early labour care provision,[48] the German version of the Salmon's items list (SIL-Ger) to assess satisfaction with labour and birth,[49] self-reported postpartum outcomes as well as the German version of the Mother-Generated Index to assess postnatal quality of life.[50 51]

For the last study phase, an online survey for midwives and obstetricians, who used the tool at the first contact with study participants was developed. The questionnaire includes sociodemographic and professional data[44] and questions to assess satisfaction and quality of care provision for parturients during early labour as well as the satisfaction with the application of the tool. These items were developed based on scientific literature by Turnbull *et al*,[52] Dorigan and Guirardello[53] and Luther *et al*.[48]

Data collection

After recruitment for the multicentre data collection, participants complete the antenatal questionnaire, which is sent via an online link after consent to the study participation is obtained. Reminders are sent if participants do not complete the questionnaires. The preliminary newly developed tool for the structured assessment is applied at the first contact with the parturient during early labour, which can either be by telephone or face to face. Midwives complete the questionnaire by asking the questions orally. Labour and birth related data are collected from medical records by the study midwife. The postnatal questionnaire is sent via an online link to participants during the early postpartum period and reminders will be sent as well. At the end of data collection, the questionnaire to assess satisfaction of midwives and obstetricians with the early labour care provision and the newly developed tool as well as its user-friendliness will be distributed in the study sites via online link. In order to ensure uniform data collection and consistent application of the tool in the study sites, study midwives as well as employed midwives and doctors were trained prior to the start of data collection. Hospital visits every month with fidelity checks to assess how the use of the instrument is performed take place during the whole data collection phase.

Data analysis

The main analyses for scale development consist of the explorative factor analysis, factor loading and item to item correlation for item reduction. Internal consistency of the scales and of subscales will be computed with Cronbach's alpha, and convergent validity will be assessed through the calculation of correlations between study items and validation items from the German versions of the CBSEI[39 45] and the CWS.[40 46] Proportional odds modelling will be applied to determine the cut-off-points of the final instrument to inform the decision for or against hospital admission, respectively, keeping in contact/proposing a check-up. Proportional odds modelling will be adjusted for possible sociodemographic as well as medical and perinatal history related confounders.

Descriptive statistics will be used to present information about the women's postnatal quality of life and the satisfaction of both the women and healthcare providers with the application of the tool. Changes in spontaneous birth rate and intervention rates will be calculated with risk ratios. Baseline-rates for these factors will be assessed for a 6-month period before the start of the trial and the rates of the participants will be compared with baseline data.

Patient and public involvement

Pregnant women at the onset of labour and young mothers are involved at different points in this study: the development of the instrument was based on the results of four focus group discussions especially conducted for this purpose. Additionally, pregnant women and young mothers were involved as experts participating in the workshop (n=1) and in the evaluation of content validity (n=2). Finally, the preliminary instrument is tested with n=400 pregnant women at the onset of labour during the first contact with the health professional in six study sites.

ETHICS AND DISSEMINATION

Potential participants are screened according to the inclusion and exclusion criteria for study participation eligibility. Eligible women receive oral and written study information by the study midwife in the study sites and sign a consent form (see online supplemental material). They are informed about their right to withdraw at any time during the study process without negative impact on their care. Data are pseudonymised by the study midwives and local principal investigator (PI) in the study sites and the participant identification lists are stored in sites. The whole study process respects national and cantonal ethics and data protection laws as well as the Swiss human research legislation.[54 55] Adverse effects were defined and are reported to the local PIs, the sponsor-investigator, and the Ethics Committee in accordance with the regulations. Women with adverse effects will be cared for in the study sites. The monitoring of the conduct of the study and data entry will be done by a person not involved in the study management or the study conduct. The study was classified as a clinical trial by the Ethics Committee of the Canton of Zurich and version 1.2 of the study protocol was approved by the Ethics Committees of Zurich as well as North-western and Central Switzerland (BASEC-Nr. 2021-00687). Amendments concerning adaptations of instruments and change of local PI were and will further be submitted to the Ethics Committee.

This new tool can be applied by midwives and doctors for telephone or face to face contact and will therefore be of great benefit for clinical practice. It is expected that the instrument will fill a recognised gap in early labour care provision.[2] Its application might delay hospital admission of women who are not already in need of inpatient care. On the other hand, it might prevent women who are not able to cope at home from being sent home and receive the care and empowerment they need. The tool can be applied in the whole German speaking area since it was developed with experts from Switzerland, Germany and Austria. The implementation in clinical practice is very important and should be achieved by an open access distribution. Clinicians will be invited to participate at the final conference of the study. Furthermore, the tool will be presented at national and international congresses for midwives and obstetricians and in professional journals in the whole German speaking area. Follow-up implementation studies should be planned to analyse beneficial and impending factors for the application in practice.

Early labour care is an important topic which attracts international scientific attention. Previous research did not provide sufficient evidence about the effectiveness of early labour interventions to improve maternal and neonatal outcomes and highlighted the importance of individualised care.[2 4 5 31–35] This study might indicate that individualised assessment and advice is possible if the physical and the emotional state during the early labour process as well as other aspects such as support and attitude of parturients are taken into consideration. It will therefore add valuable information to the scientific discussion about optimising early labour care. Scientific articles about the first study phase consisting in a scoping review and focus group discussions will be published to increase general knowledge about the onset of labour and early labour care. Additionally, results of the validation of the newly developed tool will be presented in peer reviewed journals and at national and international conferences to contribute to the scientific discussion about early labour and for introducing the tool to an international audience. The validated tool will be available for application in a larger population and its effectiveness to increase spontaneous birth rates and reduce intrapartal interventions should be tested in a future randomised controlled trial. Additionally, the tool can be translated on request into further languages and can therefore be of international interest. Hence, the planned study will be embedded in the current scientific discussion and provide a base for future research.

Approved and anonymised data will be shared with the final scientific publications related to the respective data. Following the FAIR data principles, FORSbase and DaSCH and maybe further repositories will be evaluated during the project as potential repositories for the publication of approved and anonymised data.

In conclusion, the dissemination of the findings will have a contributable impact on clinical practice, scientific discussions and future research.

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Logo of the study centre

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.

Logo of the study centre

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.

Logo of the study centre

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.

Logo of the study centre

- 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

Logo of the study centre

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

Tel. : +41 58 934 46 77 or +41 78 720 36 98
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