

BMJ Open 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will be disseminated at the final study conference, at national and international congresses and by peer reviewed and not peer-reviewed articles in scientific and professional journals.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.

INTRODUCTION

The experience of early labour care is often unsatisfactory for parturients

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.

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 literature⁸ 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 intrapartum 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 intrapartum 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 intrapartum 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 labour¹⁴ 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 cases³⁷ 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, intrapartum 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 DeVellis³⁶ 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 Survey⁴² 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 data⁴⁴ 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 Guirardello⁵³ 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 intrapartum 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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