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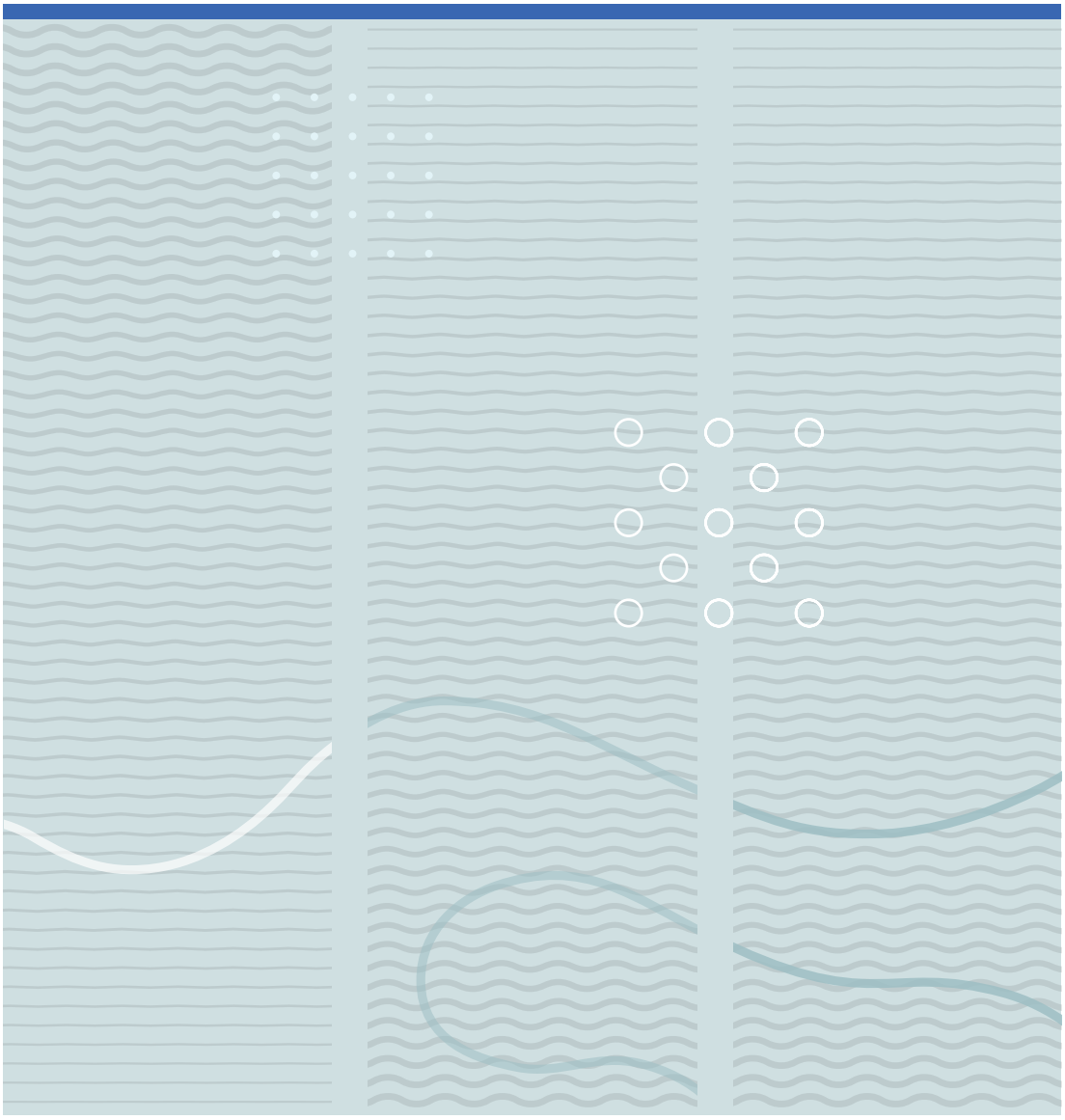
Enid Myhre

Development and testing of an online educational intervention in early labour care



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Development and testing of an online educational intervention in early labour care

A PhD dissertation in
Person-centred Health Care

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Abstract

Background: Early labour is a challenging situation for many women, and reports of dissatisfaction with care provided during early labour prior to hospital admission have been made. A mismatch between the woman's perceived need to be cared for, and midwives wanting to prevent unnecessary hospital admission may cause conflicts in early labour. Easy access to relevant and reliable information could be a way of supporting and strengthening women at home and create a common ground of understanding. Digital media offers many advantages, allowing for up-to-date information to be presented in a comprehensible way. Previous research has examined different types of interventions in relation to the experiences of early labour. However, few have developed an online educational intervention in early labour care and evaluated how it affects early labour experience.

Aim: The main aim of this project was to develop an online educational resource for women in early labour and test how it affected women's experience of early labour and subsequent labour characteristics. The aims of the three substudies are based on different parts of the process. Substudy 1 aimed at exploring women's experience with information, and their information needs in pre-admission early labour. The second substudy describes the development of a Norwegian website, Latens.no, and explores users' experiences with the website to increase its user-friendliness. In the third study, first-time mothers' experience of early labour and subsequent labour characteristics before and after introducing Latens.no is compared, and the underlying structure of the Swedish version of the Early Labour Experience Questionnaire for primiparous women (SWE-ELEQ-PP) in a Norwegian setting is tested.

Materials and methods: Two qualitative studies and one quantitative study were conducted to address the aims. Substudy 1 was a qualitative interview study involving five focus group interviews with sixteen first-time mothers who all had experienced staying at home during early labour. The study had an exploratory and descriptive approach, and data was analysed using systematic text condensation. Using this information, we developed a website with a multidisciplinary research team, health

personnel, users, a graphic designer, and an expert in software development working together in an iterative process. In substudy 2, the development-process was described, and the website's user-friendliness was examined. A total of eight participants verbalized their experiences in semistructured individual interviews and completed tasks on Latens.no in think-aloud interviews. Participants' feedback on the website was analysed using thematic analyses. In the third substudy, a prospective before-and-after-design was used. Pre- and post-intervention cohorts were recruited (174 pre-intervention and 178 post-intervention). The SWE-ELEQ-PP was distributed among primiparous mothers in the maternity ward at Oslo University Hospital. Data on obstetric outcomes were obtained through the medical record system 'CSAM Partus'. The relationship between cohorts and demographic characteristics were analysed using chi-square statistics and t-tests. Confirmatory factor analyses (CFA) were used to evaluate model fit, and the internal consistency of the scale was measured by Cronbach's α coefficient.

Main results: The most important theme in substudy 1 involved information. To the women, having accessible trustworthy information at the appropriate time was crucial. However, to have a positive impact in reassuring the women in early labour, information had to be accompanied by acknowledgement and support from both midwives and partners or other supporting persons. Overall, the participants in substudy 2 both confirmed the user-friendliness of the website and at the same time provided information for its improvement. In substudy 3, Latens.no did not improve early labour experience as measured by the SWE-ELEQ-PP questionnaire. When assessing the labour characteristics, however, we found that women in the post-intervention group presented at the labour ward with greater cervical dilatation than those in the pre-intervention group. Moreover, the post-intervention group received less oxytocin during labour. The number of telephone consultations increased significantly after the intervention was introduced. Despite poor fit of Question 9, the CFA of the SWE-ELEQ-PP is within an acceptable fit.

Conclusion: Findings from the first study suggest that easy access to trustworthy online information at the right time, together with acknowledgment and support from

midwives, can reassure women in early labour. In the second study we demonstrate that a multidisciplinary approach may be used to develop and test an online educational resource, and that users may provide suggestions for improvements using the think-aloud method. In the third part of this thesis, we were unable to demonstrate that the introduction of an online educational resource for women in early labour improved early labour experience. However, women who had access to Latens.no presented to the labour ward with greater cervical dilatation and received less oxytocin. The findings demonstrate that participation and use of the think-aloud method is useful in the development of online resources, and that a website may be a suitable way to convey information on early labour. However, as this is a single study, more research about women's information needs in early labour is warranted, including studies that further explore the format for information and assess the outcomes after implementation of such information. This in order to make women feel more comfortable staying at home during early labour.

Keywords: Early labour; Early labour experience; eHealth; Information needs; Latent phase; Labour characteristics; Think aloud; Usability; User-friendliness; User satisfaction; Website

Sammendrag

Bakgrunn: Mye tyder på at fødselens første fase er utfordrende for kvinner, og flere tidligere studier har rapportert misnøye med omsorgen gitt under tidlig fødsel før innleggelse på sykehuset. Et misforhold mellom kvinnens opplevde behov for omsorg og jordmødres ønske om å unngå unødvendig tidlig innleggelse på sykehuset, kan føre til at fødselens første fase oppleves som konfliktfylt. Enkel tilgang til relevant og pålitelig informasjon kan være en måte å støtte og styrke kvinnene, og samtidig gi et grunnlag for felles forståelse. Digitale medier gir mange fordeler, og oppdatert informasjon kan presenteres på en tilgjengelig og forståelig måte. Tidligere forskning har undersøkt effekten av ulike typer intervensjoner på opplevelsen av fødselens første fase. Det finnes imidlertid få studier som rapporterer om å ha utviklet en digital intervensjon, med påfølgende testing av effekt på opplevelse av fødselens første fase og fødselskarakteristikker.

Formål: Hovedmålet med prosjektet var å utvikle en nettbasert informasjonsressurs for kvinner i fødselens første fase og teste hvordan den påvirket kvinners opplevelse av denne fasen og påfølgende fødselskarakteristikker. Formålene med de tre delstudiene tar utgangspunkt i ulike deler av prosessen. Delstudie 1 tok sikte på å utforske kvinners erfaring med informasjon og deres informasjonsbehov i fødselens første fase. Den andre delstudien beskriver utviklingen av en norsk nettside, Latens.no, og utforsker brukernes erfaringer med nettsiden for å øke brukervennligheten. I den tredje studien sammenlignes førstegangsfødendes opplevelse av fødselens første fase og påfølgende fødselskarakteristikker før og etter introduksjon av Latens.no. I delstudie 3 testes i tillegg den underliggende strukturen til den svenske versjonen av Early Labour Experience Questionnaire for førstegangsfødende (SWE-ELEQ_PP) i en norsk setting.

Metoder og datamateriale: To kvalitative studier og en kvantitativ studie ble utført. Delstudie 1 var en kvalitativ studie med fem fokusgruppeintervjuer. Seksten førstegangsfødende som alle hadde opplevd å være hjemme i den første fasen av fødselen ble inkludert. Data ble analysert ved hjelp av systematisk tekstkondensering og studien hadde en utforskende og beskrivende tilnærming. Deretter utviklet vi en nettside

i samarbeid med et tverrfaglig forskningsteam bestående av helsepersonell, brukere, en grafisk designer og en programvareutvikler. I delstudie 2 ble utviklingsprosessen beskrevet og nettsidens brukervennlighet evaluert. Totalt åtte deltakere beskrev sine erfaringer i semistrukturerte individuelle intervjuer og gjennomførte ulike oppgaver på Latens.no i tenke-høyt intervjuer. Deltakernes tilbakemeldinger ble analysert ved hjelp av tematisk analyse. I delstudie 3 ble et prospektivt før- og etter-design brukt. Kohorter før og etter intervensjon ble rekruttert (før intervensjonen: n= 174, etter intervensjonen: n= 178) fra fødeavdelingen ved Oslo Universitetssykehus. Spørreskjemaet SWE-ELEQ-PP ble distribuert blant inviterte førstegangsfødende på barseloppholdet ved sykehus. Data om fødselskarakteristikker ble innhentet via journalsystemet 'CSAM Partus'. Forholdet mellom fødselskarakteristikker og andre demografiske variabler ble analysert ved hjelp av Kjikvadrat- og t-tester. Bekreftende faktoranalyse ble brukt for å evaluere modelltilpasning, og den interne konsistensen til skalaen ble målt ved Cronbachs α-koeffisient.

Hovedresultater: Det viktigste temaet i delstudie 1 omhandlet informasjon. For kvinnene var det avgjørende å ha tilgang til pålitelig informasjon til rett tid. Men for å virke beroligende på kvinnene i fødselens første fase, måtte informasjonen ledsages av anerkjennelse og støtte fra både jordmødre, og partnere eller andre støttepersoner. Samlet sett bekreftet deltakerne i delstudie 2 brukervennligheten til nettsiden, samtidig som de ga forbedringsforslag. Basert på resultater fra spørreskjemaet i delstudie 3, forbedret Latens.no ikke kvinnenes opplevelse av fødselens første fase. Ved analyse av fødselskarakteristikker fant vi imidlertid at kvinner i intervensjonsgruppen ble innlagt på fødeavdelingen med større åpning enn de i kontrollgruppen. I tillegg mottok færre kvinner i intervensjonsgruppen riestimulerende medikamenter under fødselen. Antall telefonkonsultasjoner økte også etter at intervensjonen ble innført. Bekreftende faktoranalyse at SWE-ELEQ-PP viste tilstrekkelig goodness-of-fit, til tross for lav faktorladning på spørsmål 9.

Konklusjon: Funn fra den første studien tyder på at enkel tilgang til pålitelig informasjon til rett tid, sammen med anerkjennelse og støtte fra jordmødre og partnere, kan berolige

kvinner i fødselens første fase. Bruken av tenke-høyt-metoden i den andre studien bidro til å innhente detaljerte tilbakemeldinger, bekrefte nettsidens brukervennlighet, og ga forslag til forbedringer. Til tross for dette forarbeidet, klarte vi ikke å måle en forbedret opplevelse av fødselens første fase etter innføring av en digital informasjonsressurs. Derimot så vi at kvinnene som hadde tilgang til Latens.no ble innlagt på fødeavdelingen med større åpning og mottok mindre riestimulerende medikamenter. Til tross for at vi ikke klarte å oppdage en signifikant effekt på kvinners opplevelse av fødselens første fase, tyder funn fra avhandlingen på at brukermedvirkning og bruk av tenke-høyt-metoden er nyttig i utviklingen av digitale ressurser. Denne studien har avdekket at kvinner ønsker informasjon i fødselens første fase, og at en nettside kan være en passende måte å formidle denne informasjonen på. Dette er imidlertid kun en enkelt studie, og mer forskning om kvinners informasjonsbehov i fødselens første fase er nødvendig, inkludert studier som utforsker hvordan informasjon kan gis for å hjelpe kvinner til å føle seg mer komfortable med å være hjemme under i denne fasen av fødselen.

Nøkkelord: Fødselens første fase; Opplevelse av fødselen første fase; e-helse; Informasjonsbehov; Latensfase; Fødselskarakteristikker; Tenke-høyt-metoden; Brukervennlighet; Brukertilfredshet; Nettside

List of papers

Paper 1

Myhre EL, Lukasse M, Reigstad MM, Holmstedt V, Dahl B. A qualitative study of Norwegian first-time mothers' information needs in pre-admission early labour. Midwifery. 2021;100:103016.

Paper 2

Myhre EL, Garnweidner-Holme L, Dahl B, Reigstad MM, Lukasse M. Development of and Experiences With an Informational Website on Early Labor: Qualitative User Involvement Study. JMIR Form Res. 2021;5(9):e28698.

Paper 3

Myhre EL, Lukasse M, Dahl B, Reigstad MM. Early labour experience and labour characteristics after introduction of an electronic early labour educational intervention. Sex Reprod Healthc. In review.

List of figure and tables

Figure

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Selected abbreviations

SAM- Suitability Assessment of Materials for evaluation of health-related information for adults

EFA- exploratory factor analyses

CFA- Confirmatory factor analyses

STROBE- the Strengthening the Reporting of Observational Studies in Epidemiology

RMSEA- root mean square error of approximation

SRMR- standardized root mean square residual

CFI- comparative fit index

TLI- Tucker-Lewis index

OUH- Oslo University Hospital

ELEQ- Early labour experience questionnaire

STC-Systematic text condensation

SWE-ELEQ-PP-the Swedish version of the Early labour experience questionnaire for primiparous women

USN-University of South-Eastern Norway

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1 Introduction

This chapter provides a rationale for conducting this research. Following the introduction, chapter two includes a brief presentation of person-centredness, as the research conducted in this thesis is underpinned by a person-centred approach. The chapter concludes with an overview of the three substudies and their key aims. Methods, procedures, and ethical and methodological considerations are presented in chapter three, followed by a summary of the findings in chapter four. In chapter five the results are discussed in light of previous research and theories, followed by comments on the strength and weaknesses of the research. In the sixth and final chapter I offer concluding remarks on the project and discuss implications for practice and further research.

1.1 Setting the scene

Although labour is a continuous process, it is often divided into stages. The latent first stage of labour is also called *early labour* and is characterized by period of regular contractions prior to 4–6 cm of cervical dilatation (1–5). Early labour can be considered a time of conflict, as women perceive a need to be cared for and midwives seek to prevent them from coming to the hospital earlier than necessary. There are indications that women, labour companions, and health professionals all find early labour difficult to manage well (6), and a lack of satisfaction with the care given in early labour prior to hospital admission has been reported (7).

This study originated from an intention to develop an intervention that could improve the early labour experience. Findings from a Cochrane review on assessment and support during early labour for improving birth outcomes suggested that early labour interventions might have an impact on increased maternal satisfaction (8). As hospital admission in early labour is associated with higher risks of medical intervention (9–17), immediate admission to the hospital was not considered a viable intervention for this study. Ideally, both home visits and one-to-one structured midwifery care could be very interesting interventions to test in a Norwegian setting. However, it was not realistic to assume that such interventions would receive further funding after the study.

None of the studies in the Cochrane review included an online educational intervention (8). Another protocol for a proposed Cochrane review, however, included this as a valid alternative intervention to be tested (18). Existing literature on women's experiences of early labour suggests labouring women often have very limited knowledge about early labour (19). Appropriate information and advice could help them feel safe at home and guide them in deciding when to seek help at the hospital. Thus, ensuring easy access to relevant and reliable information could be a way of supporting women and helping them cope with early labour. Pregnant women want information and wish to use that information to participate in care decisions (20). Additionally, access to information could enable labour companions to feel more confident and thereby provide better support at home (6).

There is a vast amount of information that could be helpful for women in early labour, and digital media can provide this information in a comprehensible way. Digital media are used extensively by pregnant women, and the internet has become a popular source of health information among pregnant women (21, 22). The internet offers advantages, including the possibility of re-reading, tailoring, and updating information. However, much of this media is commercially funded, and there is a lack of easy-to-access, free-of-charge, high-quality relevant information about early labour. Pregnant women and their labour companions must search the internet to the best of their ability and evaluating the quality and accuracy of information may be challenging. In fact, a recent review on internet use among pregnant women seeking health information concluded that health care providers have a responsibility to provide valid and reliable online educational resources (23).

2 Background and definitions

This chapter presents a description of early labour, followed by an explanation of why it is difficult to clearly define. It includes a description of how care in early labour is organized in Norway, and in other relevant countries. The chapter also provides background information on the early labour experience, a justification of how access to information can improve the early labour experience, and an explanation of why digital media is a good way to provide information. Finally, it outlines the rationale behind the person-centred approach used in the thesis.

2.1 Defining early labour

In the midwifery and gynecology curriculum it is common to describe and define the birth process as a series of stages and phases (24, 25). The first stage lasts from the start of the contractions and until the cervix is fully dilated (10 cm). The time between when the cervix is fully dilated and the baby is born is denoted as the second stage, and the third stage is the time from when the baby is born until delivery of the placenta. These stages are further divided into phases, with the first stage being divided into the latent phase, also called early labour, and the active phase (24, 25).

Labour onset is thought to be determined by complex interactions between foetal and maternal hormones, and despite major advances in the science of reproduction, there is still no clear understanding of the biology of the initiation of labour (24, 25). This may, at least to some extent, explain why early labour has not been clearly defined either in relation to the onset of early labour, its duration, or the transition from early labour to the active phase of labour. While there is still no evidence that defining early labour will impact birth outcomes (1), it can be argued that there is a need for more clarity around the latent phase of labour if midwives are to provide evidence-based care (26).

Onset of early labour is commonly defined by the onset of what labouring woman perceive as painful contractions. It is a process, not an event, and it can be difficult to pinpoint exactly when Braxton Hicks contractions develop into labour contractions (24).

Further, women might interpret other symptoms, such as gastrointestinal changes or ruptured membranes, to be their first signs of labour (27). Because the beginning of labour is a subjective measure determined by the women experiencing it, and usually occurs outside of the hospital, it is difficult to define and an unreliable marker for clinicians and researchers. For the same reasons, a standard length of early labour is difficult to establish, and the duration varies widely from one woman to another.

Transition from early labour to the active phase is generally marked by an emphasis on the level of cervical dilatation. A predetermined dilatation level is a reliable marker that can be easily assessed by health personnel. Yet the transition from early labour to the active phase has been a subject of discussion for many years, and current definitions depend on the country, the health personnel, and the guidelines used (1–5). In the 1950s, Friedman introduced the concept of separate phases of labour, and for decades, the definition of early labour was influenced by his work, with 3–4 cm cervical dilatation defined as the beginning of the active phase (28). In more recent years, Friedman's work has been challenged, mainly by the findings of Zhang et al. (29–35). According to Zhang et al. (35), the rate of cervical dilatation accelerates after 6 cm and allowing labour to continue for a longer period before 6 cm of cervical dilatation may reduce the rate of cesarean deliveries. Although debate is still ongoing (36–40), we might be moving towards a change in guidelines. In 2014 the American College of Obstetricians and Gynecologists released an obstetric care consensus statement suggesting that labour progresses at a rate considerably slower than historically believed, and that cervical dilatation of 6 cm should be considered the threshold for the active phase of most women in labour (41). Consequently, US guidelines now define the onset of the active phase by cervical dilatation of 5–6 cm (3), and in the most recent guidelines from World Health Organization (WHO), 5 cm is defined as the transition marker (1). The National Institute for Health and Care Excellence (NICE), however, still recommends 4 cm cervical dilatation as the threshold for the active phase (4), and clinical practice guidelines in Norway also adhere to this definition as of now (2).

To summarize, early labour is the time between the beginning of labour contractions and the active phase of labour. It starts with a woman's perception of painful contractions and usually ends between 4 and 6 cm of cervical dilatation. The duration of early labour varies widely.

2.2 A rose by any other name would smell as sweet

Research and curricula have many names for early labour, with 'latent first stage' or the 'latent phase' being the oldest and most familiar terminology. However, the midwifery curriculum recognizes that the latent phase is increasingly being referred to as 'early labour' (24). In the WHO recommendations 'Intrapartum care for a positive childbirth experience', the guideline development group recognizes that the "latent first stage" is sometimes described as the 'early' or 'passive' first stage but explains that they prefer the continued use of 'latent first stage' as this terminology is familiar and the introduction of a new term might require additional training (1). They do, however, in the very same document, use the term 'early labour' several times when describing the stage (p. 30, 56, 57, 58 and 59) (1).

Defined, time-bound phases of labour are important for clinical and research purposes. Additionally, estimates of the different phases may benefit women by helping them prepare for and cope with the experience of labour. It has been argued, however, that women consider labour to be a continuous process (42, 43), and that researchers and health personnel should explore descriptions of labour that resonate better with how women experience labour and birth (42).

As 'latent first stage', 'latent phase' and 'early labour' are used interchangeably in the literature, all three terms have been used in the work leading up to this thesis. For example, all terms were used in the literature search. And when deciding on a name for the website, Latens.no was chosen. *Latensfasen* is the Norwegian translation of 'the latent phase', a term familiar to both health personnel and pregnant women. However, labour is obviously a continuous process, and in my opinion the term 'early labour' best reflects this. Although I acknowledge the argument that 'latent first stage' is (as of now)

a more familiar term, I think it is more important to recognize how women view their labour and thus decided to promote the use of 'early labour' when writing up the thesis.

2.3 Organization of care in early labour

The organization of both intrapartum care and care in early labour varies considerably across countries and settings. For example, depending on the healthcare system, intrapartum care can be managed by midwives, obstetricians, or family doctors. In the relatively small country of Norway the organization of this care also varies, mainly due to a great variation in geography and population. Most commonly, care throughout pregnancy is provided by the primary health care system, and during active labour it is provided by the specialist health care system. As early labour occurs in between pregnancy and active labour, there is a risk of it falling through the cracks. Although practice may and does vary, clinical practice recommendations in Norway state that while follow-up of early labour must be adapted to individual needs, women in early but not active labour should generally not be admitted to the hospital (1, 2). Implementation and evaluation of the intervention in this study were performed at Oslo University Hospital (OUH), the largest hospital in Norway, which is located in an urban setting. Standard care in early labour at OUH usually consists of one or several telephone consultations during which the midwife seeks to determine whether the woman needs to come to the hospital, either because she is in active labour or for a medical reason. If the midwife concludes based on the information received that the woman does not yet require admission, she will inform the woman of this and give advice on when to contact the unit again. If necessary, the woman is invited to come to the hospital for a consultation, which may or may not lead to admission.

2.4 Experience of early labour

The labour experience is complex, but its importance is widely acknowledged (44), and a positive childbirth experience is a significant end point for all women undergoing labour (1). Because most women manage their early labour at home, the importance of their experience of that phase of labour is often underestimated (45). However, given the

premise that women view childbirth as a continuous process, the early labour experience should be viewed as an important part of the whole birth experience. Additionally, the early labour experience may affect the rest of the labour by 'setting the tone'.

Uncertainty, anxiety and a lack of confidence in their ability to cope with pain seem to be central issues in women's experiences of early labour (46–49), and a metasynthesis and a systematic review both report a lack of satisfaction with care in early labour prior to hospital admission (6, 7). Findings from the metasynthesis of first-time mothers' experiences of early labour suggest that women's needs when planning a hospital birth are not adequately met in early labour (7). A mismatch between expectations and experiences was found, and women frequently expressed uncertainty in interpreting signs and symptoms to determine the start of labour (7). The systematic review examining evidence of women's, labour companions', and health professionals' experiences of management of early labour concludes that women find early labour difficult to manage well (6).

2.4.1 Interventions to improve the experience of early labour

Various interventions involving early labour care have been tested. Many early labour interventions primarily aim at delaying hospital admission or decreasing intrapartum intervention rates (50–55). Some studies have also reported how interventions affect the experience of early labour as primary or secondary outcomes (52, 54–56). One randomized controlled trial (RCT) comparing early labour assessment to direct admission found that women receiving early labour assessment were more satisfied with their care (55), while another RCT found that women who received home visits rated their early labour experience more positively compared to women who received telephone support (56).

A Cochrane review on assessment and support during early labour for improving birth outcomes was published in 2017 (8). The review included five randomized controlled trials with a total of 10,421 women. Three comparisons between groups were made: early labour assessment at home or at the hospital versus immediate admission to

hospital; home visits by midwife versus telephone triage; and one-to-one structured midwifery care versus usual care. The findings suggest that early labour interventions may reduce the use of epidural analgesia and labour augmentation in addition to increasing maternal satisfaction. None of the studies included an online educational intervention (8). Another protocol for a proposed Cochrane review, however, included this as a possible alternative intervention to be tested (18).

2.4.2 Measurement of early labour experience

The birth experience can be measured in numerous ways and by various tools (57) and is often viewed as a multifaceted concept that includes everything from the beginning of labour until the beginning of motherhood (44). Although early labour experience is likely to influence birth experience, applying a tool that is tested and validated to measure the former could provide inaccurate results in relation to the latter. Janssen et al. recognized the need for a measure to assess women's experiences of or satisfaction with early labour care, and in 2013 they published a study describing the development and psychometric properties of the Early Labour Experience Questionnaire (ELEQ) (58). The ELEQ consists of 26 self-report items rated on a 5-point Likert scale. It measures women's affective experience of early labour, perceptions of midwifery care, whether they believed they went to the hospital at the right time, and whether they would recommend the type of early labour care they received to a friend (58). The questionnaire is relatively short, easy to administer, and can be used to assess women's experiences of different aspects of early labour care.

2.5 Information needs in early labour

It is important for women in early labour to have access to information suited to their needs, delivered in the right amount and at the right time. When women have realistic expectations for labour and birth, they are more likely to experience their birth as positive (59). It is recommended that information about what to expect in early labour be shared both antenatally and in early labour (1–4). However, to provide appropriate information about early labour, we must first understand women's information needs. Furthermore,

the information must be provided in a way that allows for women to easily access it, comprehend it, evaluate it in relation to their personal circumstances, and apply it (60). For most women there is arguably a difference in knowledge between the first pregnancy and subsequent pregnancies. The research in this thesis will focus on first-time mothers with no previous experience of early labour.

Several studies have investigated general information needs in pregnancy and labour (19, 61), and there are also studies that have focused on information-seeking behavior in maternity care (22, 62-65). However, evidence on first-time mothers' information needs in the Norwegian setting is scarce. Moreover, there is little evidence on first-time mothers' information needs *specifically* in early labour, both nationally and internationally. In a Swedish study investigating first-time mothers' care preferences during prolonged early labour, authors found that participants all knew about the importance of staying home during early labour, but they had trouble understanding the different phases and stages and wanted more information especially on early labour (66). Still, as the focus of the study was prolonged early labour, it cannot be assumed that findings are transferrable to all first-time mothers.

2.5.1 Development of online educational resources

The European Commission (67) has set a goal of digital transformation, and the improvement of digital consumer health education is one of the means to reach this goal (22). Digitalization offers new opportunities in health care, and researchers have pointed to a need to develop digital sources of professional information about pregnancy and childbirth as it seems that printed material does not match the information needs of the current generation of pregnant women (22). Digital media are used extensively by pregnant women (23), and they offer certain advantages, namely that information can be re-read, tailored, and updated. However, the quality of health information available online remains questionable (68). Much of this media is commercially funded, and there is a lack of easy-to-access free-of-charge, high-quality relevant information about early labour. Women and their labour companions must search the internet to best of their ability and judging the quality and accuracy of what they find can be challenging.

Consumers' evaluation of online health information relies heavily on contextual factors such as personal beliefs and current information needs (68), leading to a risk of making misinformed decisions. The authors of a review on internet use among pregnant women seeking health information conclude that health care providers have a responsibility to make valid and reliable online educational resources (23).

2.5.2 User involvement

Ease of use is essential for online resources to improve healthcare, as poor usability affects the chances of achieving both adoption and positive outcomes (69). Since the origin of consumer health education in the 1990s (70), the number of health-related educational applications has exponentially increased (71). However, the number of studies reporting the results of usability testing has not increased at an equivalent rate, and few of the health-related educational applications publish their usability evaluation results (72).

There are many methods for evaluating usability. Questionnaires are a cost-friendly method to gather feedback from large sample sizes, and many questionnaires exist (69), with the System Usability Scale (SUS) (73) being the most frequently used (74). For in-depth information on user perceptions, interviews and focus groups can be suitable options (75). Eye tracking and other automated methods of objectively evaluating usability are also potentially useful but have not yet gained traction (72). Think-aloud testing, however, is effective in identifying usability problems with only a small number of participants (76). In a comparison of usability benchmarking instruments, think-aloud testing was found to be one of the most effective tools to test usability (77).

2.6 Person-centredness

The concept of person-centred practice has become increasingly important in health policy over the last few decades. Across the globe, governments and health organizations are making explicit their expectations that health care professionals and organizations should be person-centred (78). As part of the PhD programme in person-centred health care, the Pre-Care study had the objecting of conducting research using a person-centred

approach. Person-centred practice has become increasingly significant in contemporary health care policy, research, and practice, and there is a wide range of definitions of person-centred care and closely related concepts (79). McCormack and McCance define person-centred practice as 'an approach to practice, established through the formation and fostering of healthful relationships between all care providers, service users and others significant to them in their lives. It is underpinned by values of respect for persons, individual's right to self-determination, mutual respect and understanding. It is enabled by cultures of empowerment that foster continuous approaches to practice development' (80 p. 20). The research conducted in this thesis was guided by principles of person-centred healthcare research outlined by Jacobs et al (81), presented in the book "Person-Centred Healthcare Research" by McCormack et al (81).

There is increasing evidence of lack of person-centred care in maternity care, with patients reporting feeling that they had been treated with disrespect and neglect (82–85). Women in early labour are at particular risk of feeling this way in a situation where midwives try to keep women from early hospital admission in this stage of labour. Below I will outline how this project aimed to use a person-centred approach and in doing so hopefully contributes to counteracting feelings of neglect and disrespectful treatment.

Values such as respect, reciprocity, mutuality, and self-determination are all important in person-centredness and impact upon a person's way of relating, including observing, listening, thinking and acting (86). These relational values should be considered as the foundation for doing research and being a person-centred researcher (86). Jacobs et al. outline four different principles of person-centred research: 1) connectivity, 2) attentiveness and dialogue, 3) empowerment and participation, and 4) critical reflexivity (86). The principles are derived from the relational values and give direction for person-centred research in a research project (86). Below, I will briefly describe the four principles and relate them to my research.

1. *Main principle: Connectivity*

Connectivity is the main principle of person-centred research and refers to the view that human beings grow and flourish out of relationships and that knowledge is co-

constructed in the co-action of people (86). Online educational resources may be criticized for being a replacement for human interactions: instead of engaging with midwives on the phone or in person, women are encouraged to stay at home and read information on the internet. However, this is far from the intention. The intervention is only meant to be a supplement to the standard care that already exists. The midwives were instructed to communicate this thoroughly and explicitly when recommending Latens.no to their patients, as it was very important that they did not perceive the website as a replacement for human interactions and relationships but rather as a supplement. Additionally, Latens.no contained repeated messages like 'if you have any doubts, do not hesitate to call the hospital'. It has been argued that technology can facilitate healthcare services in different ways (87). It can lighten the often-heavy burden of healthcare professionals' daily work and offer service users tools they can use in their own time and place (87); the latter especially is what I wished to accomplish.

Further, the study aimed to promote connectivity by involving users and taking their perspectives into account. 'Connectivity as a main principle of person-centred research puts forward the view that we do not do research about others but do research with them as human beings' (86 p. 53). Users were directly involved in both substudies 1 and 2. The findings of substudy 1, the opinions and values of the users, were used in the further development of the project, and substudy 2 engaged users in the conceptualization, design, and final production of the website.

2. *Related principle: Attentiveness and dialogue*

Attentiveness is a matter of seeing oneself and others as human and requires the capacity to be contextually aware (86). The studies in this thesis involved women who had recently given birth and their partners. I do not consider this group of people marginalized or otherwise vulnerable. Nevertheless, they were in a life situation that was new and unfamiliar to them, and I therefore did my best to ensure that the dialogue was respectful when recruiting, performing interviews, and handing out questionnaires.

A challenge in implementing true person-centred health care is that the goal of shared decision-making is not often realized (88). Instead, the dialogue often consists of the

communication of a decision by health personnel and the mere agreement of the woman (88). An online educational resource may facilitate increased common understanding, thus promoting dialogue based on mutual attention and respect.

3. *Related principle: Empowerment and participation*

This project facilitated participation and user-involvement in the development phase, as already explained. It also facilitated empowerment and participation in the later phase of the project. The facilitation of decision making through information sharing is a condition for person-centred research (89). Implementing an online educational resource allowing easy access to reliable information might facilitate empowerment, making women even more qualified to be involved in decision-making in early labour. Empowerment is based on the idea that individuals are experts on themselves and know best what they need (90). If knowledge is viewed as a prerequisite for empowerment, it might be argued that this project facilitates empowerment.

4. *Related principle: Critical reflexivity*

Researchers need to be aware of their own positions and interests and to explicitly situate themselves within the research (91). In the Materials and methods section of this thesis, I will elaborate on how the methods chosen are mainly descriptive. Nevertheless, conducting research requires the researcher to adopt a self-critical reflexive attitude towards how their own experiences, background, and assumptions may influence the study (92). Even descriptive research is imposed in all stages of the research process, from the questions asked, to the formulation of the problem, to the analysis, and finally to writing and representation (91). As a midwife, I engaged with women in early labour for many years, and I find it challenging to be aware of my own positions and interests as they are so inherent in me. This needed continuous attention and work throughout the process. Throughout, I tried to be attentive to the way my background and experiences affected the way I collected, read, and interpreted data. As an example, during data collection at the hospital, I had to reflect on my position when deciding what to wear. Was I there as a midwife? As a researcher? Or as both a midwife and a researcher? When recruiting I often visited patient rooms, and wearing my own clothes made it feel like a

private visit. Still, I was not there in my capacity as a midwife and wearing a uniform could be misinterpreted. I ended up choosing a middle way with my own pants and a uniform top.

2.6.1 Woman-centred care vs. person-centred care

Woman-centred care as a concept implies that midwifery focuses on women's individual needs, aspirations, and expectations rather than the needs of the institution or professionals (93). It recognizes the need for women to have choice and control, as well as their expertise in decision making (93). It has been argued that while 'patient-centred care' and 'woman-centred care' focus primarily on the recipient of care, 'person-centred care' reflects a broader orientation that takes account of context and other relationships that may exist in a given environment (94). Women's experiences are at the core of this research. The project aims at women making choices and taking control, and it recognizes women's expertise in decision-making. In that sense, it could be argued that the project is woman-centred. It can also be argued, however, that the project focuses on more than women's individual needs. For example, results of the intervention may include more timely admissions to the hospital and better use of midwifery resources, results that have an impact on the bigger context and not only individual needs. However, even though a person-centred approach has a broader orientation than woman-centred care, the former still includes many of the principles of the latter. Thus, the way I see it, the two are not mutually exclusive.

2.7 Research aims

Overall, this PhD project aimed to develop an online educational resource for women in early labour and to test how it affected women's experiences of early labour and subsequent labour characteristics. The aims were:

- to explore women's experiences with information and their information needs in pre-admission early labour;

- to describe the development of a Norwegian website, Latens.no, for people seeking information on early labour and to explore users' experiences with the website to increase its user-friendliness;
- to compare first-time mothers' experiences of early labour and subsequent labour characteristics before and after introducing an online early labour educational intervention, and to test the underlying structure of the Early Labour Experience Questionnaire (ELEQ) in a Norwegian setting.

These aims formed the basis of three substudies and, together with the overall aim, the discussion in chapter 3. A schematic overview of the studies, their aims, their connection to the overall aim and the methods of data collection and analysis is presented in Table 1.

Table 1. Overview of substudies 1, 2 and 3

	Substudy 1	Substudy 2	Substudy 3
Title	A qualitative study of Norwegian first-time mothers' information needs in pre-admission early labour	Development of and experiences with an informational website on early labour: A qualitative user involvement study	Early labour experiences and labour characteristics after introduction of an online early labour educational intervention
Aim	To explore women's experiences with information and their information needs in pre-admission early labour.	To describe the development of a Norwegian website, Latens.no, for people seeking information on early labour and to explore users' experiences with the website to increase its user-friendliness.	To compare first-time mothers' experiences of early labour and subsequent labour characteristics before and after introducing an online early labour educational intervention, and to test the underlying structure of the ELEQ in a Norwegian setting.
Connection to the overall aim	Develop knowledge about information needs in early labour to inform the content of the online educational resource	Describe and user-test of the online educational resource	Evaluate effects of the online educational resource
Data collection and method of analysis	- Five focus group interviews - Qualitative systematic text condensation	- Semi-structured individual interviews and think-aloud testing with eight participants - Qualitative thematic analysis	- Questionnaires and data from the medical record system from participants in pre- and post-intervention cohorts with 174 and 178 participants respectively - Quantitative analyses including Chi-square statistics, t-tests and confirmatory factor analyses

3 Materials and methods

This chapter seeks to provide transparency through in-depth descriptions of the methods applied to each substudy. Additionally, challenging choices specifically related to each substudy will be discussed. A few more general methodological considerations not covered in this chapter will be presented in the discussion chapter. Methodology and choices made will largely be presented in chronological order. As an example, power calculation is outlined when presenting sample and data collection despite being a statistical exercise.

The overall aim of this thesis was to improve women's early labour experiences prior to hospital admission by developing and testing the effect of an informational website. Usability is a complex concept, and to develop a user-friendly website, the use of multiple methods was considered appropriate. When combining qualitative and quantitative methods, each serves a different purpose and builds on what is learned from the other (95). In this thesis, qualitative methods were applied to pinpoint the problems that needed to be addressed, while quantitative methods provided an overall measure of usability. This allowed the different methods to both build on and complement each other by serving different evaluation purposes.

Conducting a study with multiple methods requires methodological expertise to guide the study throughout its different stages and ensure the application of the most appropriate procedures at each point (96). Specific training in methodology is essential to ensure research design adequacy when applying different methodologies in parallel (96). My supervisors are highly competent in both qualitative and quantitative research. However, to offset the complexity of using multiple methods, the methods applied to each of the substudies were all manageable for a novice researcher while still being the most appropriate ones.

3.1 Knowledge base / information needs in early labour (substudy 1)

In substudy 1 I wanted to increase my understanding of information needs in early labour from the women's perspective and therefore chose an exploratory and descriptive design. Multi-site focus group interviews were conducted, as group discussions provide direct evidence about differences and similarities in opinions and experiences (97). Because the main purpose of the study was to inform the development of the information website, and not to develop theory, systematic text condensation (STC) was used to analyse the data. This method is suitable to develop new descriptions without applying a theoretical framework (98, 99).

3.1.1 Ethical considerations in substudy 1

The study was conducted in accordance with the World Medical Association Declaration of Helsinki Ethical Principles for Medical Research Involving Human Subjects (100), and approval was granted by the Norwegian Centre for Research Data (NSD: 60109, see appendix 1). Additionally, the study was assessed by the Regional Committee for Medical and Health Research Ethics in South-Eastern Norway (REC: 2018/540). It was considered to be outside the remit of the Health Research Act (2018), which applies only to research that aims to generate new knowledge about health and disease, and not patient experiences (appendix 4). A staff member at each well-baby clinic provided participants with both written and oral information about the study and what we wanted to talk about by (appendix 7). It was a deliberate choice to not let anyone directly involved in the research inform about the study to avoid participants feeling pressured into attending. Additionally, participants were given several days to consider if they wanted to participate. They were informed that participation was voluntary and that they could withdraw from the study at any time without giving reasons, and informed consent was obtained from all participants. During the interviews we were mainly interested in discussions related to information needs in early labour. However, talking about early labour and experiences could bring up difficult topics or cause unprocessed experiences

to resurface. All participants were therefore given the opportunity to talk to the first author after the focus group interview in case anyone required debriefing.

3.1.2 Sample and recruitment

Findings from the first substudy would later inform the development of Latens.no. Inclusion and exclusion criteria were set accordingly, and only people in the target group of Latens.no were considered eligible. Inclusion criteria included mothers having given birth to one child in cephalic presentation, ≥ 37 weeks, with a spontaneous start of labour. Strategic selection (101) was sought by including only women who were at home in early labour as they had the best potential to shed light on the issue. It was not desirable to set a time limit on how long they stayed at home; what was important was that the woman herself felt she spent a part of her labour at home. I strived to include women with a variety of background characteristics and both with and without a partner.

Exclusion criteria were conditions in pregnancy that precluded women from staying home in early labour and induction of labour. Additionally, the context was well-baby clinics located at a maximum of one hour's drive from the hospital. This was because I wanted the perspectives of women who could stay at home in the early labour and therefore needed to make assessments themselves in this stage. This would not be as relevant in all areas in Norway, as distance requires women to come to the hospital early due to the long journey (and they do not risk being sent home). As Latens.no is only available in Norwegian, we decided to perform the interviews in Norwegian only; thus, all participants needed to be able to read and speak Norwegian to understand the information and the consent form and to participate in the focus group interview.

In previous publications on expectations and experiences of early labour, time of recruitment spans from a few hours to 20 years after birth (6, 7). As none of the published articles on this subject justifies the time of recruitment, I had several discussions with my supervisors to decide the best time to recruit participants. After careful consideration we chose to recruit within 3–17 weeks after birth. After giving birth, it takes time to gain

strength, and to be able to reflect. Still, we wanted to ensure that the women's experiences were still fresh in their memory.

Participants were recruited with the help of midwives and public health nurses working at well-baby clinics. To recruit participants with varied background characteristics, both rural and urban well-baby clinics were contacted. Out of seven well-baby clinics, five clinics responded positively and helped by identifying eligible women, informing them about the study, and inviting them to participate. In all, 29 women were invited to join the study and 22 agreed to participate. However, six participants who had accepted the invitation did not attend the focus group interviews; hence, we ended up with a small-scale convenience sample (101) of 16 women.

To ease facilitation, the focus group interviews were organized to coincide with already planned maternity groups. Maternity groups are cost-free, and invitations go out to all mothers. Still, recruitment through well-baby clinics might exclude women who, for different reasons, choose not to attend. Additionally, it is possible that the timeframe excluded some women who did not yet feel ready to talk and that we recruited women who generally felt okay about early labour.

It is recommended to aim for groups of five to eight participants in focus group interviews (102). Despite this recommendation, I aimed for a slightly lower number, four to six participants, as my informants had newborn children who would naturally be present in the interview. With as many as eight participants, I worried there would be too many disruptive elements and therefore difficult to get a good flow in the interview. In the end, five focus group interviews were conducted with four, two, two, six and two participants. All our participants had newborn babies with them. This required special effort and may be a possible explanation for why some invited mothers did not attend. Because constraints of the field situation must be taken into account, it may be relatively rare for a project to meet all focus group design criteria (97), and out of respect for the respondents who did attend, we chose to conduct all focus group interviews as planned. However, for the groups consisting of only two participants to be characterized as focus groups, there needed be a pronounced interaction between the participants (102), and

we did in fact experience both noticeable interaction and rich information in the conversations.

Although we ended up with a small-scale convenience sample, our participants had different background characteristics and thus had the potential to illuminate different perspectives of the subject, enabling us to capture as many of the variations as possible. The participants gave birth at four different hospitals in South-Eastern Norway and received post-natal care at five different well-baby clinics. They lived in both urban and rural areas and their ages ranged from 24 to 38 years. One of the participants was a single mother, supported by her own mother while at home in early labour. The rest lived with a male or female partner who was with them in early labour. Four of our 16 participants had a non-Western immigrant background. We did not feel it was required for the purpose of this study to collect further background characteristics as our hypothesis was not that background variables predict information needs. In addition, we did not meet the women until the start of the focus group interviews, and at this stage, it was not appropriate to collect sensitive information.

3.1.3 Interview guide and data collection

Initially, a focus group interview guide was developed in collaboration between the authors. The interview guide was then piloted on a group of five midwife colleagues who had given birth themselves (data from this pilot focus group was not included in the study). The pilot resulted in only slight modifications to the interview guide. We started the interview by going around the table, letting everyone introduce themselves and giving each participant the opportunity to share something about their early labour. The remaining questions were mainly about what information the participants felt was lacking and/or appreciated in early labour (Table 2). All the main questions in the interview guide remained unchanged through all the interviews. A few of the remaining questions, however, were added or altered after the first few interviews.

Table 2. Interview guide in 'A qualitative study of Norwegian first-time mothers' information needs in pre-admission early labour' (103)

The main questions are numbered. The remaining questions were only asked if needed to keep a good flow in the focus group interview.
1. Can you tell me a bit about your early labour? - What role did your partner have in this phase of labour? 2. What did you know about early labour beforehand? - How did you get this knowledge? - Did early labour last as long as you thought it would? - Was there anything you thought you knew about early labour that turned out not to be true? 3. What information did you receive when you contacted the hospital for the first time? - Did you understand the information you were given? - Was the information useful? - Would it be useful to have this information in writing? 4. What information did you feel was lacking when in early labour? - If nothing, what information did you perceive as useful? 5. What information do you think a website with information on early labour should contain? - At what time in your pregnancy would you access such a website? - How would you find such a website? - What would you google in early labour? 6. Do you have any examples of what constitutes a good website?

All interviews took place in a suitable location provided by the well-baby clinics. I acted as moderator in all focus group interviews. I did not know any of the participants and presented myself as both a midwife and a researcher. My supervisors took turns as secretary, taking notes. The participants were instructed to take turns to talk. Moreover, they were told that the moderator would only interrupt the focus group interview when necessary. Interruptions were rarely necessary during the interviews and were mainly used for clarification. The interviews lasted for 29–53 min (mean 40 min) and were audio-recorded and transcribed verbatim by me.

3.1.4 Analyses

Systematic text condensation (STC), as described by Malterud, was used to analyse the data. This four-step strategy for thematic cross-case analysis represents a pragmatic

approach to analysis of different types of qualitative data while maintaining a responsible level of methodological rigor (98, 99, 104). According to Malterud, a broad range of theories can be applied to support STC analysis (98). No theoretical ambitions were applied when analysing the material. Considering the study's aim, I did not see a need to search for underlying meanings in what our participants said but rather acknowledged their statements and reported experiences as the source of knowledge.

Unlike many other qualitative analysis methods, STC does not start with a broad range of subgroups, concentrating instead on relatively few topics and code groups. I did not find this approach very suitable for NVivo or other analytic tool; thus, multiple Microsoft Word documents and the 'cut-and-paste' function were used to organize meaning units into code groups.

The four steps of analysis in systematic text condensation

Step 1: Total impression – from chaos to themes

In step one, all the transcriptions of the focus group interviews were read to gain a general impression of the whole. As suggested by Malterud (98), we approached the data with an open mind, trying to bracket our preconceptions while still acknowledging our interpretive position determined by the research question. Analysis benefits from being conducted by two or more researchers, which creates a wider analytic space (98). To some extent, all supervisors were involved in the analysis process, but the in-depth part of the analysis was carried out by me under the supervision of and in close collaboration with Professor Bente Dahl. Despite great differences in our experience performing systematic text condensation, we had worthwhile discussions concerning how we understood the content and meaning of the preliminary themes. The following preliminary themes were agreed upon in this step of the analysis:

- Information on how early labour vary from person to person
- Information credibility
- Information needs at different times in pregnancy
- A wish for information in general

- How to handle contractions and early labour
- To have a person with you at home
- Gatekeepers/ to feel welcome at the hospital
- Feelings of mastery

Step 2: Identifying and sorting meaning units – from themes to codes

In this step, meaning units describing the women's early labour experiences related to knowledge and information were identified and organized into code groups. Meaning units are text fragments containing information about the research question. They may be short or long and are not necessarily limited to sentences. In STC it is recommended to include too much rather than too little text (98). With the preliminary themes from step 1 in mind, we re-read all interviews line-by-line, and identified meaning units. Simultaneously, we revisited and revised the preliminary themes from the first step, elaborating their names and features, to form the basis for code groups (98). By the end of this stage, our empirical data were reduced to a contextualized selection of meaning units sorted into the following thematic code groups:

- Gatekeepers/ to feel welcome at the hospital
- Easy access to trustworthy information at the right time
- Meeting the unexpected despite preparation
- To have someone with you at home

Step 3: Condensation – from code to meaning

In the third step, subgroups in each code group were identified, and meaning units in all subgroups were summarized and condensed (98). Initially, concentrating on one code group at a time, we sorted the meaning units in each group into subgroups. We then reduced the content of each subgroup into different condensates by reviewing every meaning unit within each subgroup. A condensate is an artificial quotation that maintains as much of the original terminology as possible. We made the condensates by starting with a particularly rich meaning unit and adding text from other surrounding meaning units. As an example, this is a part of the condensate from the code group *Easy access to trustworthy information at the right time:*

I remember spending a lot of time searching the internet several weeks before the birth. I thought it was very nice to read a little in advance. Just to let your let your thoughts develop and see what is normal and abnormal and things like that, to get information and, yes, be ready. Then maybe I felt that I could have a little more control at the beginning. Being able to learn a little in advance helped in all parts of the pregnancy. Oh, to know, what am I waiting for? I had not spent so much time getting acquainted with exactly that phase of labour beforehand. It was sort of the birth that was the focus. But it is wise to inform [yourself] about this phase quite early so at least you know. Then you can re-read it when you feel you have the need. But I read a lot in the three weeks before my due date, when on maternity leave. And when it's approaching, when you think the birth is soon. For example, a couple of weeks before, I had some contractions that I thought might be the beginning of labour. Then I would probably have appreciated information. And of course, during the birth, once it has started. To find out the differences. Like, what's this? Is this the important thing? Do these criteria apply to me? Does this reflect what I'm experiencing right now? At least I felt that [I] just [needed] to recognize it. Even if you have heard it before, you just want to read it over and over again.

In this process, our understanding of the material evolved, and we adjusted the code groups accordingly. When writing the condensate in the code group *To have someone with you at home* we realized that although it contained meaningful information, there was not enough content for it to stand alone. The information in the code group involved feeling safe and supported. As our participants achieved that sense of security both by talking to a midwife and by having a partner nearby, we merged the two code groups *To have someone with you at home* and *Gatekeepers/ to feel welcome at the hospital* and named the new code group *Safe and supported by partner and staff,* leaving us with these three code groups:

- Easy access to trustworthy information at the right time
- Meeting the unexpected despite preparation

- Safe and supported by partner and staff

Step 4: Synthesizing – from condensation to descriptions and concepts

In this step, a description of the content was drawn up and presented as an analytic text (98). Condensates were developed into analytic texts in the third person presenting the most notable meaning and content. In the results section of the article, analytic texts for each subgroup were presented in separate paragraphs. In addition to choosing a relevant quote to illustrate each subgroup, it is advisable to embed examples in the analytic text to further illuminate the results (98). This is the analytic text derived from the part of the condensate presented above:

> *One woman explained that she had spent considerable time reading about early labour on the Internet prior to her labour, preparing herself and learning what was and what was not normal. This made her feel more in control of her early labour. Others said that they had not given early labour much thought before it happened, as the birth had been their focus. Still, most women actively looked for information about labour when their maternity leave started, three weeks before their due date. Furthermore, they expressed a desire for information about early labour when they were in early labour themselves and explained that they wanted to read information over and over again. (103)*

Initially, the results section in our article was written as suggested by Malterud, without excessive use of quotes. However, one of the reviewers in the chosen journal requested more quotes. To accommodate the reviewer's request while adhering to Malterud's method, we decided to put some of the running text into quotation marks to show that these words were taken directly from the informants.

Further, in this fourth and last step, we reviewed the category headings to make sure they provided brief yet revealing statements of our interpretations. The following three code groups were agreed upon:

- Easy access to trustworthy information at the right time
- Surprised at how early labour manifested

- Limitations of information

According to Malterud, analysis also includes the assessment of one's findings related to existing research findings (98), and this was undertaken as part of the discussion. Table 3 displays our final code groups with subgroups and examples of meaning units, and an extensive presentation of meaning units, subgroups and code group can be found in supplementary Table 1 attached to the published article.

Table 3. Code groups and subgroups in substudy 1 with examples of meaning units

Code groups	Subgroups	Examples of meaning units
Easy access to trustworthy information at the right time	Type of information	To find out the differences. Like what's this? Is this the important thing? Do these criteria apply to me? Or, well, not like... I mean, you can't have a blueprint for exactly when it starts, can you? But it's more like, is there anything here that... Does this reflect what I'm experiencing right now?
	Time of information needs	But I read a lot in the three weeks before my due date. And when it's approaching, when you think the birth is soon. For example, a couple of weeks before, I had some contractions that I thought might be the beginning of labour.
	Where information is obtained from	It was the only thing… it was the only thing I did. Because I felt like I needed help, or information… from someone with knowledge. It was the only help I could get. I couldn't talk to the hospital for hours. So the only thing left to do was to google and read.
	Trustworthiness of information	These mum forums that you find when you search the web, they're like… you can't always trust them. It's almost… like upsetting. Reading them upsets you.
Surprised at how early labour manifested	Prepared, yet still lacking knowledge	I was not aware that it could be that painful and protracted. So that was a surprise, really. So we… we were prepared that it could take a long time. I was just surprised that it could… so quickly… that it happened so fast, got very painful so fast. That caught me by surprise. It was a situation we did not know how to react to.
	How to manage	After a while, I began to think it was torture. Like I was in a torture chamber, where you just go around, waiting for… when will the pain come? And you don't know how long you'll be trapped in there.
Limitations of information	To feel safe and supported	I would not have made it without him (her partner) I think. Or I probably would have managed but .. …thank God he was there.
	To feel welcome	I was actually pleasantly surprised at the way they made it quite clear we could come to the hospital. And we could decide on it ourselves, and we didn't have to sit alone at home worrying. So that was… that felt really good. That we weren't… didn't feel pressure to stay at home for longer than we felt comfortable with.

3.2 Development of Latens.no (substudy 2)

The paper derived from substudy 2 describes the development of Latens.no, which involved both the actual building of the website and different forms of quality control to ensure content quality and increase usability. To ensure content quality and usability whilst simultaneously accommodating users' literacy levels, the website was developed in an iterative process involving a multidisciplinary research team, health personnel, people in the target group, a graphic designer and an expert in software development. Figure 1 illustrates the process of developing the website.

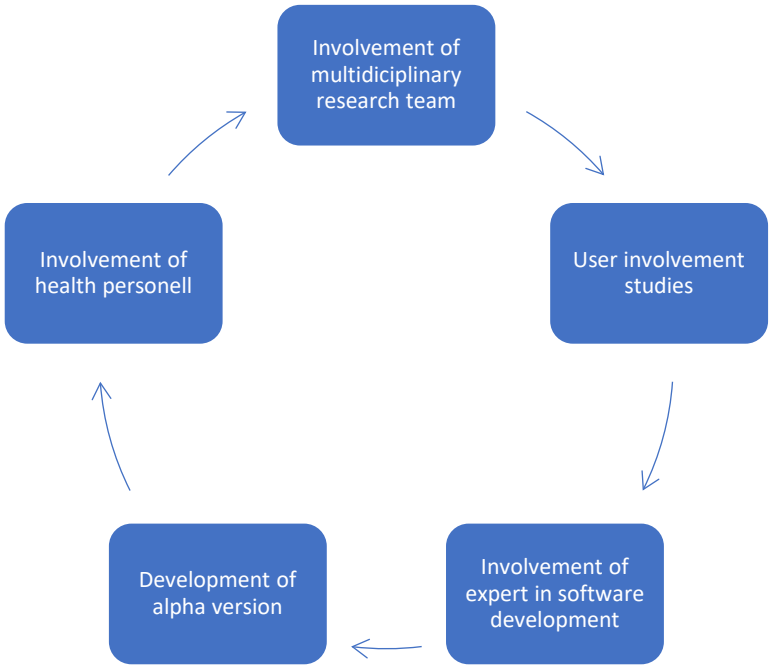

Figure 1. Illustration of the iterative process of developing the website (105)

3.2.1 Ethical considerations in substudy 2

We did not ask our participants to share anything that might be considered difficult to talk about. They were asked to describe their general preferences related to information websites about pregnancy and birth in addition to testing an alpha version of Latens.no. However, all had recent experiences related to pregnancy, birth, or both, and it was difficult to predict what feelings or reactions might resurface. The study was conducted in accordance with the World Medical Association Declaration of Helsinki (100).

Participants were provided with information via text message or mail. No reminders were sent, giving participants as much time as they needed to consider whether they wanted to respond and participate. They were informed and reassured that participation was voluntary and that they could withdraw from the study at any time without giving reasons (appendix 8). Informed consent was obtained from all participants. We did not record our participants' national ID numbers, but in order to briefly describe background characteristics some personal information was collected. Additionally, our participants' voices were registered in audio recordings, which also constitutes personal information. Thus, a notification form was sent to NSD, and approval for the study was granted (NSD: 228701, see appendix 2).

3.2.2 Procedure

Involvement of multidisciplinary research team and health personnel

An alpha version of Latens.no was built in close collaboration with Viggo Holmstedt, an associate professor of information systems at University of South-Eastern Norway. I provided him with content, and he performed the technical aspects. Screenshots of the alpha version of the site are available in multimedia Appendix 1 and 2 attached to the published paper on the substudy (105). All content was informed by findings from article 1 and the literature. The alpha version consisted of a front page with a top banner with a logo, a menu, and a search option. Additionally, the front page provided a picture and a description of the content. Users could access 10 different pages from the menu or search option. All pages had relevant textual content about early labour, combined with illustrative images or videos and an option to click on subheadings if the user wanted more detailed explanations. Many pages also contained informative images or short videos. Most pages had internal hyperlinks linked to related content on Latens.no; external hyperlinks linking to relevant, trustworthy information; or both. Images, illustrations, and videos originated from several different places: from stock image agencies online; directly from the photographer, colleagues, or me; and made to order by graphic designers Grete Edland Westerlund and Mia Gundersen.

To ensure quality, I made an initial assessment of the alpha version with the help of the Suitability Assessment of Materials (SAM) questionnaire for the evaluation of health-related information for adults, a validated method for evaluating written health-related education material (106). I assessed categories and factors known to enhance people's understanding of printed materials (content, literacy demand, graphic illustrations and lists, layout and typography, learning stimulation and motivation, and cultural appropriateness), deemed them either superior, adequate, or not suitable, and made changes accordingly.

The multidisciplinary research team consisted of midwives and a gynecologist. However, to ensure professional quality, we wanted to involve midwives who work on a daily basis with women in early labour. I showed the alpha version to three midwives and observed as they provided oral feedback while systematically looking through the entire website. Additionally, the alpha version was posted in a closed Facebook group of 76 members (all midwives or nurses). We requested honest feedback on design and content and although responses were mainly likes or comments such as 'this is very good', a few members of the Facebook group provided constructive feedback. This involvement of health personnel resulted in minor changes, mainly to language, such as removing small words that are often associated with something negative (e.g. but and unfortunately) and adding improved explanations for some of the most-used words and phrases.

3.2.2.1 User involvement

Usability is a key factor in successful website implementation, and different methods of testing usability were considered, including eye-tracking technology. Eye tracking would probably be very useful in determining the usability of Latens.no as it provides insight into which features users perceive as interesting, uninteresting, confusing, and so forth. However, eye-tracking tests are expensive and time-consuming, and as of now scarcely used in eHealth usability evaluation (72).

After considering both economic and time resources we decided to use the think aloud method to ensure suitability and usability for the target group. The think aloud method

is a widely used and accepted method of usability testing (72). The method involves users completing a set of representative tasks while verbalizing their thoughts. This process seeks to gain an understanding of users' thought processes while interacting with the system and to identify usability problems (107, 108). The think aloud testing process will be presented below.

3.2.3 Recruitment and sample

We started purposeful recruitment at well-baby clinics in South-Eastern Norway in February 2020. Midwives working at well-baby clinics invited eligible women and their partners to participate. Due to a combination of limited response rates and midwives' heavier workload from the COVID-19 pandemic we proceeded to recruit via snowball sampling in March 2020. The last participant was recruited in June 2020.

Initially, we recruited women who had recently given birth to their first baby, along with their partners. Our expectation was that their recent experience would provide the knowledge and insight required to perform the testing adequately. However, their considerable knowledge about early labour soon proved to be a concern. They navigated the website with such ease that it raised concerns about whether they would be critical enough in their feedback on Latens.no. We therefore proceeded to test with the help of women who were pregnant with their first baby and their partners.

As Latens.no only exists in Norwegian, being able to read and understand the language was a prerequisite for all participants. This may have limited the diversity in our sample. We did, however, manage to recruit participants with different education levels and in different age groups (see table 4) and received detailed and distinctive feedback.

Table 4. Characteristics of participants (N=8) in 'Development of and Experiences with an Informational Website on Early Labor: Qualitative User Involvement Study' (105)

Characteristic	Participants, n
Age	
26–30	2
31–37	5
38–41	1
In partnership	
Yes	7
No	1
Reason to have knowledge about early labour	
Pregnant	4
Had recently given birth	2
Partner to pregnant person	1
Partner to woman who had recently given birth	1
Education level[a]	
Upper secondary, final year	1
Post-secondary non-tertiary education	1
First stage of tertiary education, undergraduate level	4
First stage of tertiary education, graduate level	1
Second stage of tertiary education (postgraduate education)	1
Participation of partner in early labour	
Partner present	1
Partner present in some part of early labour	2
Had not made plans for this	3
Planned for partner to be present	2
Devise used to perform test	
Mobile phone	6
PC	2

[a]The Norwegian Standard Classification of Education (NUS2000) (109)

3.2.4 Interview guide and procedure

The interview guide begins with a few questions related to general preferences regarding information websites about pregnancy and birth in terms of both content and design. Participants were then instructed in how to verbalize their cognitive decision-making process while completing tasks on Latens.no. They were told to think aloud while performing the tasks: 'say what you are thinking, what you are doing, what you are looking at, and what you are feeling'. I modelled how to do this by performing a task on a random news website. I then asked the participants to complete 10 tasks consisting of hypothetical situations that could occur in early labour with the help of information on Latens.no (table 5). The participants were not given access to Latens.no before the testing

started and were thus navigating the website for the first time during the testing procedure. The testing was completed after a brief follow-up interview in which participants were given the opportunity to clarify their thinking and add more thoughts on design or content.

Table 5. Interview guide in 'Development of and Experiences with an Informational Website on Early Labor: Qualitative User Involvement Study' (105)

Questions to be asked prior to the introduction of the website: 1. To the informants who had given birth: Do you have any experience with using a website in early labour? To the informants who had not yet given birth: Do you have any experience with using a website to find information on pregnancy and birth? – If yes: What made a good website good, and what made a poor website poor? 2. In your opinion, what should a website on early labour contain? 3. How do you think it should be designed? Tasks to be performed on the website using the 'think aloud' method: *We want to find out if it is easy to find information related to early labour. A few hypothetical situations will now be described. I want you to find solutions for the situations using the website. I want you to think aloud while performing the tasks. Say what you are thinking, what you are doing, what you are looking at, and what you are feeling.* 1. At irregular intervals, you feel that your belly is painful and tight, but you are not sure if it is contractions or Braxton Hicks contractions. Can you find any information on the website that can help you assess this? 2. You have had contractions for a while, and then you discover spots of blood on the toilet paper after you use the toilet. Is this normal? 3. You are having contractions, but they are not painful enough for you to consider calling the hospital. Then your water breaks. Can you find out what you should do next? 4. You wonder what you should eat when you are at home with contractions. Can you find any recommendations on the website? 5. You want to get in touch with those responsible for the website to give feedback. Can you find the contact information? 6. Can you find out what it is wise to pack for the hospital? 7. You cannot seem to find a position that is comfortable when you are having contractions. Can you find something on the website that gives advice on whether you should stand or lie down? 8. You feel that you have had contractions for a very long time, but when you call the hospital, you are told to stay home a little longer. Can you find out if it is normal to have contractions for as long as you have? 9. When you call the hospital, the midwife talks about your 'cervix.' What is the cervix? 10. How can your partner/you contribute when at home in early labour? Questions afterwards: 1. How did you experience finding the information? 2. What do you think about the design of the website? 3. What do you think about the way the information is presented? What do you think about the use of images? Should there be more pictures? What type of pictures? Illustrations or real photographs?

3.2.5 Data collection

I observed all the think aloud tests and performed the brief interviews before and after, either in a meeting room at USN or in the participants' homes according to their preference. Participants were asked to carry out the test on the device they would normally use when searching for health-related information online, a smartphone, personal computer, or tablet. The interviews and testing procedure combined lasted for 9–23 min (mean 14 min). For most of this time, participants used the website. The interviews were audio-recorded and transcribed verbatim by Totaltekst, a professional word processing company.

3.2.6 Analysis

When analysing the data in the second substudy, we used thematic analysis, following the study by Braun and Clarke (110, 111). This method is a theoretically flexible approach to analysing qualitative data. It can both report experiences, meanings, and the reality of participants as a realist method, or it can examine how experiences are the effects of a range of discourses operating within society as a constructionist method (111). The aim in this substudy was to explore users' experiences with Latens.no to increase its user-friendliness. Therefore, we used thematic analysis as a method to reflect reality rather than 'to unpick or unravel the surface of "reality"' (111 p. 81).

In thematic analysis, there is no right or wrong method for determining prevalence (111), and when deciding what would count as a theme, we did not adhere to rigid rules on what 'size' a theme needed to be. Rather, our criterion was whether it captured something important in relation to the usability of Latens.no. Our goal was to present a nuanced yet detailed description of experiences with the use of Latens.no and not an overall description of the entire dataset. In the process of analysis, we focused on identifying themes at the semantic level and did not look for anything beyond what our participants said. Further, we coded for our specific aim, making our thematic analysis approach more theoretical than inductive.

The different aspects of the analysis process outlined above were considered prior to the thematic analysis and were continuously assessed through the process. In addition, Braun and Clarke's phases of analysis were followed throughout the analysis (111). NVivo was used to identify and organize the codes and themes (version 12; QSR International). The main data analysis was performed under supervision and in collaboration with Professor Lisa Garnweidner-Holme. However, all authors of paper 2 were involved in the last stage of the analysis, in which the themes were discussed until a consensus was reached. An outline of the steps and a description of what I did in each step follows below, and table 6 displays main themes and subthemes with examples of initial codes and data extracts.

Description of the process

Phase 1: Familiarizing yourself with your data

Totaltekst transcribed the interviews consecutively. Because transcription of the data was delegated, reading, and re-reading the data several times was important in this phase. In the process of reading and re-reading I noted down initial ideas on what was interesting about the data.

Phase 2: Generating initial codes

In this phase I worked through the entire dataset systematically, identifying interesting aspects that could form the basis for themes. I coded for all semantic features that seemed interesting and as many potential patterns as possible. The goal was to present a description of experiences with the use of Latens.no and not an overall description of the entire dataset. However, in this phase of the process it was difficult to decide what might be interesting later. As a result, not all initial codes were related to the usability of health information websites. NVivo (version 12; QSR International) was used to organize the codes.

Phase 3: Searching for themes

As themes are broader than codes, this stage required me to re-focus by starting to analyse the codes from phase 2. I collated the codes by considering how they could be combined to form potential overarching main themes and subthemes within them.

Phase 4: Reviewing themes

In this phase I refined the themes by checking how they worked in relation to the initial codes and the entire data set. I re-read all the collated codes for each theme and subtheme, and made small adjustments until all codes, subthemes and themes appeared to form a coherent pattern. I then re-read the entire dataset, checked the validity of the themes in relation to the dataset, and made sure no additional data within themes had been missed in earlier coding stages.

Phase 5: Defining and naming themes

This stage of the analysis required several discussions with all co-authors of paper 2. The goal was to present a description of experiences with the use of Latens.no. However, in addition to their specific experiences with Latens.no, participants shared useful knowledge about informational websites in general. Differentiating between the two was difficult in some instances. Therefore, we needed to go back and forward many times, looking at the overall story of the analysis, searching for themes specifically relevant to the usability of the website, and refining the specifics of each theme. We discussed until we reached a consensus, and finally, we agreed on the clear definitions and names of the subthemes and themes.

Phase 6: Producing the report

Braun and Clarke (111) propose report production as the final step of the analysis process. It was important that the write-up of the analysis provide a coherent, interesting, and logical account of the story of the data, both within and across themes, while still adhering to the somewhat strict guidelines provided by the journal. A report should provide enough data extracts to demonstrate the prevalence of each theme. The process

of choosing the best quotes from our participants began with me collating several examples of data extracts. Then, in collaboration with all authors of paper 2, I selected the extracts that best captured the essence of each aspect of the story.

Table 6. Main themes and subthemes in substudy 2 with examples of initial codes and data extracts

Main themes	Subthemes	Initial codes (examples)	Data extract (examples)
Positive feedback related to content on Latens.no	The information on Latens.no is relevant	Latens.no contained what she felt she needed	I think the pages with the drawings and the pictures and the information, it feels like exactly what I would have needed.
		Can relate to the information on Latens.no	At least based on the knowledge I have from before, I felt that I get a nice explanation for it.
	Latens.no is perceived as trustworthy	You can see that Latens.no is made by people with knowledge on the subject	Professional, I think. Yeah, I can see that it is made by people who know what they are talking about. There are few typos and things like that.
		Comments related to 'contact information' on Latens.no	I see at the bottom of the page, it says 'For questions or comments to the website, feel free to contact us at Latens.no'.
	The text on Latens.no is easy to read	Latens.no was easy to read, without disturbing elements	Easy to relate to, without too much fuss. And without too much of that 'click here, click here, click here' to move further and further and further in.
		I liked the text on l Latens.no because it was straightforward	I found it easy to understand. Not everyone is a nurse or a medical student and who knows what. So it was kind of easy to understand it. At the same time, it wasn't written in kindergarten language. So it was really easy to understand.
		It is nice that the text on Latens.no is short, concise and easy to read	Very short and concise, very much of it, I think. So really very fine, not a whole dissertation before you find what you need to know. It's so easy to read and easy to get the answer you're looking for.
Positive feedback related to design on Latens.no	Colors and images make Latens.no attractive	A suitable number of pictures on Latens.no	I really think it was just the right number of pictures. It should not be too much either. Just a little bit… mood-based, in a way. And so… very good.
		Did not notice the pictures on Latens.no	I did not notice the pictures much, really. But it's probably a bit like that… But I, yes, I really think it was very… quite alright, to me.
		The use of colors on Latens.no is appealing	Such nice use of colors and stuff, I think.
		Latens.no has a pleasant design	It has a pleasant design, I must say. Yes. It has pleasant colors that suit—I think it really suits the subject.
		I liked the layout on Latens.no	Yes. And then I also think it was nice that it was… so 'layout-wise', I think it was good.

		Latens.no is a very feminine website	It's a very feminine website. That's it. And that's how it is… I guess it will hit the target group.
	Latens.no is clearly structured and easy to use	Found Latens.no clearly structured and straightforward	You have divided it into sections under subheadings in a way that is so crucial to navigating fast. It's crucial – at least crucial to me.
		Because you can zoom on the phone, the font size on Latens.no is unproblematic	For me the font size is unproblematic because I can zoom on the phone.
		Appreciate that Latens.no is systematized	Mm-hmm. It was very nicely set up because it is in categories. Yes. Very nice and systematized.
		It was encouraging and reassuring that Latens.no was so easy to navigate	It was very encouraging and reassuring to see that it is so easy, at least on Latens.no. It was extremely easy.
		The search engine on Latens.no was easy to use	Very simple, important that the menu button was easy to find, it was easy to search…
		It was not difficult to find information on Latens.no	This is the easiest I ever have… Really. That's exactly how it should be.
		The headings on Latens.no were clear	It was not like when you tap into one of them you have to read a lot to find out what it is. Because you have those headings all the way. When you see that, ok, this was not it. Then you can just go back and look at another one.
Suggestions for improvement on Latens.no	Requests and suggestions for improvement of features	Wanted to split information for women and partners on Latens.no	Yes, you could separate the practical information, like you have one with practical information for the woman, and one with practical information for the guys, or whoever it is. Separate them, maybe? Or 'What can I do to feel better at home?' – I reckon that one is meant for the person who is giving birth. So maybe it could be clear instructions on what you can do as a father, or…yes.
		The search engine on Latens.no is difficult to use	I think it was… it was difficult to use the search… search engine, or that search… that search field. I did not quite get through.
		The menu on Latens.no can have a more exiting appearance	I do not know, maybe [some] dots, or colors. I do not know. Maybe… It was very sterile in a way.
		It must be clear that you can click on the subheadings on Latens.no	The only thing is that it must be clear that this can be clicked on, but everyone can use data as a tool today, I think. That this is something you can click on. But I do not know if it was a little like "drt, drt, drt" there or something.
	Requests and	Wanted larger font on Latens.no	No, well, I think the font on the mobile version might be a bit small.

	suggestions for improved readability	I noticed some spelling mistakes on Latens.no	As a teacher I also saw some [laughter] typos, but it's kind of just like hyphenation errors.
		There was a lot of text on the front page of Latens.no	It was a bit like, when you first enter the website, there is a lot of information, right there. It is a bit, it looks a bit much.
		The start page on Latens.no could have been a larger	That… Yes, it could have been something more, [a] bigger start page, in a way. With pictures and stuff.
	Negative feedback related to inconsistent layout	Some might stress over inconsistent layout of subheadings on Latens.no	But I kind of like the colors and that there are… subheadings and such. And then there is… but the one where you had to press them… and in some places and not in others. There may be someone who is sitting at home and is very stressed who does not understand it.
		The fact that Latens.no uses different font sizes bothers me	A thing that bothers me a little bit, kind of like, that it has different text fonts.
	Negative feedback related to images	Text on top of pictures can be hard to read on Latens.no	There's just one thing. If the pictures change color from black, then it must be a slightly dark color, I think. Do not use pink on the letters, because then it can be a little too diffuse. But yes. That's the only thing, I think.
		Feels that the pictures on Latens.no might be too big	Maybe the pictures are too big. But it's nice too.
		Latens.no could have more pictures	I am a fan of pictures. So, there could probably be more pictures. Because, yes, for us that are visual.

3.3 Evaluation of Latens.no (substudy 3)

In the third study, a prospective before-and-after-design was used to assess whether access to the online educational intervention improved women's experiences in early labour. The Swedish version of the early labour questionnaire for primiparous women (SWE-ELEQ-PP) (58) was used to measure women's affective experiences of early labour, perceptions of nursing care, and whether they believed they went to the hospital at the right time. Further, differences in labour characteristics before and after the intervention were assessed as secondary outcome measures. In addition to comparing our two groups (before and after intervention), we performed a confirmatory factor analysis to test the questionnaire based on a previous exploratory factor analysis study (112) performed among a similar population.

3.3.1 Ethical considerations in substudy 3

The Regional Committee for Medical and Health Research Ethics in South-Eastern Norway (REC: 2018/1236, appendix 5) considered the research to be outside the remit of the Health Research Act (2018). Latens.no is intended as a supplement to regular care, and participation in the study was voluntary. Still, ethical considerations were necessary, both because inclusion required the women to spend time on the questionnaire during their postpartum stay and because we were handling personal data. Approval for the study was granted by the Norwegian Centre for Research Data (NSD: 107878, appendix 3) and the local data protection official at Oslo University Hospital (18/12350, appendix 6), and the study was conducted in accordance with the World Medical Association's Declaration of Helsinki (100). Participants were provided with oral and written information and given time to consider whether they wanted to participate (appendix 9). Informed consent was obtained from all participants, who were informed that participation was voluntary and that they could withdraw from the study at any time without giving reasons and without it affecting their care.

3.3.2 Sample and data collection

Implementation of Latens.no was evaluated in a before-and-after-study conducted at Oslo University Hospital, Ullevål for three months in 2019 and 2020. A pre-intervention cohort was recruited in January–April 2019. To reduce bias due to differences in labour ward activity, we planned to collect data from the two cohort groups during approximately the same months in two consecutive years (avoiding summer). However, the COVID-19 pandemic restricted access to the hospital in spring 2020, and we were not able to recruit the post-intervention cohort until September–December 2020. Inclusion criteria included nulliparous women with one foetus in cephalic presentation ≥ 37 weeks gestation and a spontaneous start of labour who stayed at home for some part of their early labour. Women with pre-existing conditions or conditions arising in pregnancy which precluded staying at home in early labour were excluded as were non-Norwegian speaking women.

Participants' experience of early labour was defined as the primary outcome measure and used in the power calculation, which was performed in cooperation with statistician Ragnhild Sørum Falk. Since the ELEQ questionnaire measures women's experiences in labour care across three domains, we performed four sample size calculations (one for each subscore, as well as for the total score) before adhering to the one that required the most participants. Baseline values similar to those presented by the developers of the ELEQ were used (56, 58). We hypothesized that women receiving the intervention would have a better experience (> 10% change in score) of early labour across all three domains. With a significance level of 5% and a power of 80%, we needed a sample size of at least 173 participants in each group (baseline/after invention). Ideally, when determining sample size requirements for Confirmatory factor analysis (CFA), careful evaluation of the specific model is required (113). However, the sample size determined from the primary outcome is within several widely cited 'rules of thumb' (114, 115). Thus, in close cooperation with the statistician, it was decided that CFA could be performed.

To comply with requirements from the data protection officer at OUH, recruitment had to be done by personnel with legal access to medical records. Midwives working at OUH identified eligible women as they were admitted to the labour ward. At the planning stage, we had planned to involve midwives working in the post-natal ward in the recruitment process, but due to the midwives' high workload, this turned out to be challenging. However, as I was still employed at OUH at this stage, and thus had legal access to medical records, I was able to recruit the women myself. Although this was time-consuming, it was a rewarding task. After verifying that the women were eligible according to the inclusion criteria, I informed them about the study, invited them to participate, and asked for consent during their postpartum stay at the hospital. Completed questionnaires were retrieved on the same or the following day, either by me or by hospital staff. Data related to labour characteristics were retrieved retrospectively from the medical record system CSAM Partus using an identification key.

3.3.3 Intervention and measurement

As previously described, Latens.no is an online educational intervention consisting of a website with easy-to-access, free-of-charge, high-quality, relevant information and advice related to early labour that is openly available online (116). The website was launched in July 2020, and information about the website was widely distributed to the target group through text messages, pamphlets (appendix 11), and health personnel.

The ELEQ was used to assess affective experiences and satisfaction with early labour care (58). When evaluating labour care quality, valid feedback from women about their experiences of care is crucial, and to our knowledge, the ELEQ is the only valid questionnaire measuring early labour care. It measures women's affective experiences during early labour on a self-administered scale and was developed and validated in a Canadian setting in 2013 and subjected it to further testing in a Swedish setting in 2018 (58, 112). Permission to translate and use the ELEQ was obtained from both Janssen et al. and Ängeby et al. (58, 112), and both versions were translated into Norwegian and checked by means of back translation. As both the Norwegian and Swedish languages and the two countries' maternal health care systems are closely related, the Norwegian version is quite similar to the Swedish version. As in the Swedish study (112), we removed the item 'Would you recommend this type of early labour to a friend?' because no alternative treatment options for childbirth are available in Norway. Midwives are responsible for care in Norway's and Sweden's maternity wards; subsequently, 'nurse' was translated to 'midwife' throughout. Items were rated on a five-point Likert scale ranging from 1 ('Yes, definitely') to 5 ('Not at all'). To ensure that women were evaluating the care they received prior to hospital admission, they were instructed to 'Please answer these questions in relation to the time you spent in early labour before you came to the hospital'.

Fifteen women who had recently given birth pilot tested the Norwegian version (none of whom were included in the study). During pilot testing, several respondents remarked that Q22 ('Did the midwife and the doctor work as a team in providing your care?') was difficult to answer. Consequently, an 'I don't know' option was added to the answers for

this question. Other than this remark, the pilot test showed that the overall questionnaire was acceptable and understandable in Norwegian. The Norwegian version of the questionnaire can be viewed in appendix 10, and the original version and the Swedish version are available through the respective publications (58, 112).

Although the ELEQ had been subjected to testing through exploratory factor analysis, both by the developers and in a Swedish setting, confirmatory factor analyses for further validation of the questionnaire were suggested (112). Maternity care in Norway and Sweden is quite similar; therefore, we chose to apply the Swedish version of the ELEQ for primiparous women (SWE-ELEQ-PP) on our sample and to initially perform confirmatory factor analysis, as suggested, to test the dimensional structure in an additional population.

3.3.4 Statistics

For the descriptive analyses, IBM's Statistical Software Package for the Social Sciences (SPSS) was used (117). Confirmatory factor analysis was performed in Stata (118).

To determine if there were differences in age and pre-pregnancy body mass index between pre-/post-intervention participants, independent samples t-tests were run. Expected cell frequencies were greater than five, and therefore chi-square tests were conducted between pre-/post-intervention participants and education, marital status, total family income, working status of participant, country of birth and mother tongue. A Fisher's exact test was conducted to check for associations between pre-/post-intervention participants and partner's employment status. To control for potential confounding factors, standard linear regression was used.

As suggested by the developers of the ELEQ, pre-/post-intervention groups were compared in 'intention-to-treat' analyses. As all participants in the 'after'-group had access to Latens.no, participants were analysed according to the group to which they were originally assigned, regardless of whether they had used the website actively. Answers to the ELEQ were originally categorical variables. However, given the answer options on the questionnaire, we had an appropriate number of categories, observations

in most all categories and what we can assume to be equal distance between the categories, and the mean reflected meaningful summary measures (as assessed by boxplots). Therefore, answers were treated as continuous variables and analysed using an independent t-test and Levene's test as in previous publications using the ELEQ (56, 112).

Independent samples t-tests were run to determine if there were differences in time from first telephone contact to admission, number of telephone consultations in early labour between pre-/post-intervention participants and cm dilatation upon admission. Chi-square tests were used to test for differences between pre-/post-intervention in terms of number of visits to labour ward prior to admission, number of women who visited the hospital prior to admission, use of epidural analgesia, use of oxytocin, and mode of delivery. Statistical significance was assumed at $p < 0.05$ throughout (119).

In studies based on self-reported questionnaires, missing values may occur, and we had one questionnaire in the post-intervention group with 3 unanswered questions (12%). Two (1 in each group) had 2 unanswered questions (8%), and 19 questionnaires (9 in the pre-intervention group, 10 in the post-intervention group) had 1 unanswered question (4%). In relation to items, our missing data were not systematic. The questionnaire with more than 10% of the items unanswered was removed before analysis, and for the remaining unanswered questions, data were imputed using the mean of all responses to that item, as per the developer's suggestion (58). To accommodate for difficulties answering Q22 raised in the pilot testing, 'I don't know' was added as an option to Q22. In analyses, this was imputed as 'neither/nor'.

Confirmatory factor analysis (CFA) was performed to test the factor structure of the SWE-ELEQ-PP. As previously mentioned, the ELEQ was first developed in Canada (58). Janssen et al. give a thorough description of the development and psychometric properties of the questionnaire. Nevertheless, as the ELEQ was validated exclusively in a Canadian setting, Ängeby et al. (112) chose to psychometrically test the ELEQ on a Swedish sample using exploratory factor analysis (EFA) instead of CFA. To our knowledge, neither the Canadian nor the Swedish version has previously been subjected to CFA. As midwifery care in

Sweden is very similar to midwifery care in Norway, we decided to confirm the Swedish version rather than the Canadian version. As in the current study, the Swedish study removed the item 'Would you recommend this type of early labour care to a friend?'. Hence, using SWE-ELEQ-PP makes it easier to compare results with Swedish studies, if desired.

CFA was performed in cooperation with statistician Ragnhild Sørum Falk, and the model tested was estimated through covariance matrices using maximum likelihood estimation. Through various fit statistics, model fit was assessed, with the root mean square error of approximation (RMSEA) ≤ 0.08, standardized root mean square residual (SRMR) ≤ 0.08, comparative fit index (CFI) ≥ 0.95 and Tucker-Lewis index (TLI) ≥ 0.95 (120). To assess the internal consistency reliability, we used Cronbach's α coefficient values, and values > 0.70 were regarded as desirable (121).

The research followed the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement (122).

4 Main findings

This chapter summarizes the main findings of the three articles and indicates how substudy 1 provided a premise for substudies 2 and 3, and how substudy 2 was a prerequisite for the successful implementation of substudy 3. More detailed findings can be found in the respective papers.

4.1 Main findings in substudy 1

Five focus group interviews, with a total of 16 participants, were conducted. Three themes emerged as a result of the systematic text condensation analysis. The first and most important theme involved information. Having accessible trustworthy information at the appropriate time was crucial to the women. In the second theme, the women described being surprised by how early labour manifested, despite having been prepared. In the third theme, women expressed their need for acknowledgement and support, revealing that information alone was not sufficient to meet all their needs. Table 7 presents an overview of the code groups and subgroups. An extensive presentation of subgroups and code groups with examples of associated meaning units can be found in the Materials and methods chapter on page 28.

Table 7: Overview of code groups and subgroups in substudy 1

Code groups	Subgroups
Easy access to trustworthy information at the right time	Type of information
	Time of information needs
	Source of information
	Trustworthiness of information
Surprised at how early labour manifested	Prepared, yet still lacking knowledge
	How to manage
Limitations of information	To feel safe and supported
	To feel welcome

The findings increased our understanding of how midwives can support women when they stay at home in early labour and suggest that easy access to a suitable amount of trustworthy information at the appropriate time, along with acknowledgement and support from both midwives and partners or other supporting persons, helps reassure women in early labour. The findings from substudy 1 confirmed that our hypothesis that a website could have a positive effect on experience of early labour, was a valid intervention to be tested. Additionally, some of the findings provided specific advice concerning the content of Latens.no.

4.2 Main findings in substudy 2

Although not a finding per se, substudy 2 includes a detailed description of the process of building Latens.no. Additionally, a total of eight participants verbally described their experiences and completed tasks on the prototype of Latens.no and during think-aloud interviews. Based on the analysis of participants' feedback, nine subthemes and three main themes were identified. Table 8 provides a short description of the subthemes that informed the three subthemes, namely ‘positive feedback related to the content on Latens.no’, ‘positive feedback related to design’, and ‘suggestions for improvement’. In general, the participants expressed the need to find information on early labour on the internet. Intertwined in the themes, participants talked about information they had looked for but did not find. They also described different types of information they would appreciate. Some asked for concrete information, such as information about Braxton Hicks contractions, the duration of early labour, and what to do when contractions start, and a few expressed a desire to be reassured that their experiences were normal.

Table 8. Main themes and subthemes in substudy 2

Positive feedback related to content on Latens.no • The information on Latens.no is relevant • Latens.no is perceived as trustworthy • The text on Latens.no is easy to read Positive feedback related to design on Latens.no • Colors and images make Latens.no attractive • Latens.no is clearly structured and easy to use Suggestions for improvement on Latens.no • Requests and suggestions for improvement of features • Requests and suggestions for improved readability • Negative feedback related to inconsistent layout • Negative feedback related to images

Overall, the participants both confirmed the user-friendliness of the website and at the same time provided information to help improve it.

Because we expected that changes made based on this user-centred design study would further increase the usability and acceptability of Latens.no, we could proceed to test the website's influence on women's experience of early labour and on several obstetric outcomes in a prospective *before and after* study.

4.3 Main findings in substudy 3

A total of 352 women were included in the study: 174 pre-intervention and 178 post-intervention. No significant differences in the overall score (as measured by the SWE-ELEQ-PP total score) or the subscale scores on emotional well-being, emotional distress, or perceptions of midwifery care were found between the groups. Women in the post-intervention group reported feeling more relaxed during early labour at home (3.23 ±

1.14 vs 3.52 ± 1.11, p = 0.02). However, women in the pre-intervention group had significantly higher scores on the items measuring whether the midwife listened carefully to what they had to say (4.60 ± 0.68 vs 4.37 ± 1.01, p = 0.01), treated their family and/or friends with respect (4.77 ± 0.54 vs 4.43 ± 0.92, p < 0.001) and treated them in a rude way (4.66 ± 0.85 vs 4.40± 1.13, p = 0.01).

There was a significant increase in cervical dilatation in the post-intervention group (4.1 ± 2.2 vs. 5.1 ± 2.3, p < 0.001), and oxytocin use decreased significantly from 59.2% pre-intervention to 44.4% post-intervention (p = 0.006). Further, the intervention led to an increase in telephone consultations (2.3 ± 1.0 vs. 2.6 ± 1.3, p = 0.01). Table 9 presents clinical labour characteristics related to giving birth.

Table 9. Labour characteristics of the pre- and post-Intervention participants (N = 352) in substudy 3

		Pre-intervention (*n* = 174)	Post-intervention (*n* = 178)	Total (N = 352)	*p* value*
Cm dilatation on admission M ± SD		4.1 ± 2.2	5.1 ± 2.3	4.6 ± 2.3	< 0.001
Time from first telephone contact to admission (in minutes) M ± SD		745 ± 718	795 ± 864	770 **± 794**	0.55
Number of telephone consultations in early labour M ± SD		2.3 ± 1.0	2.6 ± 1.3	2.5 ± 1.1	0.01
Number of women who visited the hospital prior to admission (n. %)					0.60
	Yes	63 (36.2)	59 (33.1)	122 (34.7)	
	No	110 (63.2)	119 (66.9)	229 (65.1)	
	Missing	1 (0.6)	0	1 (0.3)	
Number of visits to labour ward prior to admission (n. %)					0.40
	0	110 (63.2)	119 (66.9)	229 (65.1)	
	1	48 (27.6)	50 (28.1)	98 (27.8)	
	More than 1	15 (8.6)	9 (5.1)	24 (6.8)	
	Missing	1 (0.6)	0	1 (0.3)	
Mode of delivery (n. %)					0.26
	Vaginal delivery	125 (71.8)	134 (75.3)	259 (73.6)	
	Operative vaginal delivery	35 (20.1)	37 (20.8)	72 (20.5)	
	Caesarean section	13 (7.5)	7 (3.9)	20 (5.7)	
	Missing	1 (0.6)	0	1 (0.3)	
Use of epidural analgesia (n. %)					0.13
	Yes	126 (72.4)	115 (64.6)	241 (68.5)	
	No	47 (27.0)	63 (35.4)	110 (31.3)	
	Missing	1 (0.6)	0	1 (0.3)	
Use of oxytocin (n. %)					0.006
	Yes	103 (59.2)	79 (44.4)	182 (51.7)	
	No	70 (40.2)	99 (55.6)	169 (48)	
	Missing	1 (0.6)	0	1 (0.3)	

**p value analysed with independent samples* t*-tests and Levene's test of variances or chi-square test accordingly*

CFA results showed an acceptable fit overall. In terms of goodness-of-fit statistics, CFI (0.839) and TLI (0.820) are both below what is considered acceptable. The RMSEA (0.078) and SRMR (0.067), however, were within acceptable ranges, indicating that the three factors derived from SWE-ELEQ-PP can be validated. Reliability testing using Cronbach's α resulted in 0.86 for perceptions of midwifery care, 0.79 for emotional well-being, 0.77 for emotional distress, and 0.88 for the total score.

The CFA did, however, indicate a poor fit for Q9 ('While you were in labour at home did you feel tense?'). All factor loadings were between 0.31 and 0.80, except for Q9, which had a factor loading of 0.19. Overall R^2 was 0.99, and throughout, the R^2 values were between 0.10 and 0.65, except for Q9, which had an R^2 of 0.03.

Table 10. Confirmatory factor analysis of the Swedish Version of the Early Labour Experience Questionnaire for Primiparous Women (SWE-ELEQ-PP) (N = 352)

	Cronbach's α	Std. factor loading	*p* value	R^2
Emotional well-being	0.79			
While you were in early labour at home did you feel:				
Q4: Happy?		0.45	< 0.001	0.21
Q1: Safe?		0.64	< 0.001	0.41
Q5: Excited?		0.31	< 0.001	0.10
Q8: Comfortable?		0.58	< 0.001	0.34
Q7: Relaxed?		0.67	< 0.001	0.45
Q2: Confident?		0.72	< 0.001	0.51
Q13: In control?		0.70	< 0.001	0.49
Emotional distress	0.77			
While you were in early labour at home did you feel:				
Q14: Confused?		0.56	< 0.001	0.31
Q3: Scared?		0.68	< 0.001	0.46
Q9: Tense?		0.19	0.001	0.03
Q11: Anxious?		0.71	< 0.001	0.51
Q6. Distressed?		0.71	< 0.001	0.51
Q12: Insecure?		0.72	< 0.001	0.52
Perceptions of midwifery care	0.86			
When you were at home in early labour, and had telephone contact or were on a visit before, did the midwife:				
Q15: …give you the information you wanted?		0.79	< 0.001	0.62
Q16: …reassure you when you needed it?		0.80	< 0.001	0.65
Q17: …spend enough time with you?		0.72	< 0.001	0.52
Q18: …listen carefully to what you had to say?		0.74	< 0.001	0.55
Q19: …treat your family and/or friends with respect?		0.50	< 0.001	0.25
Q20: …respect your wishes about going to the hospital?		0.61	< 0.001	0.38
Q21: Did you feel that you had confidence in the midwife?		0.74	< 0.001	0.55
Q22: Did the midwife and the doctor work as a team in providing your care?		0.46	< 0.001	0.21
Q23: Did you feel that the midwife always was at ease and calm with you?		0.36	< 0.001	0.13
Q24: Do you feel that the midwife treated you in a rude way?		0.36	< 0.001	0.13
Overall	0.88			0.99
Latent variable covariances				
	Emotional well-being	Distress	Perceptions of midwifery care	
Emotional well-being	1.00			
Distress	0.83	1.00		
Perceptions of midwifery care	0.37	0.38	1.00	

In summary, Latens.no did not improve early labour experience based on the SWE-ELEQ-PP results. When assessing the labour characteristics, however, we found that women in the post-intervention group presented at the labour ward with greater cervical dilatation than those in the pre-intervention group. Moreover, the post-intervention group received less oxytocin during labour. The number of telephone consultations also increased significantly after the intervention was introduced. Despite poor fit of Q9, the CFA of the SWE-ELEQ-PP is an acceptable fit.

5 Discussion

The research presented in this thesis highlights the complexity of early labour care. Findings from the first study suggest that easy access to trustworthy information at the right time, together with acknowledgment and support from midwives and partners, can reassure women in early labour. In the second study participants both confirmed the website's user-friendliness and provided suggestions for improvement. Despite this, one of the main findings in this thesis is that the introduction of an online educational resource for women in early labour did not improve the labour experience. However, women who had access to Latens.no presented at the labour ward with greater cervical dilatation and received less oxytocin.

In this chapter, the overall consistency of the substudies will be outlined, and the key findings connected to each specific research aim discussed in relation to available research and a person-centred perspective. The themes will be discussed under the following headings: *Overall consistency of substudies 1–3, Women's experiences with information and their information needs in pre-admission early labour, User-friendliness of Latens.no, First-time mothers' experiences of early labour and subsequent labour characteristics before and after introducing Latens.no, Methodological considerations.*

5.1 Overall consistency of substudies 1–3

This thesis can be viewed as a process; the first study laid the groundwork for the subsequent studies, and the second study was a prerequisite for the successful completion of the third study. As described in the introduction, the existing literature on information needs in early labour is both limited and imprecise. A needs assessment was therefore a logical first step in the process. The first study aimed at exploring women's experiences with information and their information needs in pre-admission early labour. It was important to determine whether the intervention was desirable for users, as well as to obtain specific feedback regarding its content, context, and design. Technology-supported interventions that begin with a comprehensive needs assessment are more

likely to be person-centred since they can be tailored to meet the needs of individuals (87).

A description of the development process, including of health care professionals' involvement, was part of the second step of the process and the second study. Additionally, a vital part of the second step was to explore users' experiences with the website. The continuous involvement of those likely to be affected by the implementation of Latens.no (i.e. end users and health care professionals) served both to evaluate user-friendliness and enhance the project's person-centredness.

The third and final step of the process aimed at evaluating how implementation of Latens.no affected women's experiences of early labour and subsequent labour characteristics, and thus at evaluating the project as a whole.

5.2 Women's experiences with information and their information needs in pre-admission early labour

Women's experiences with information and their information needs in early labour were explored through a qualitative study consisting of five focus group interviews (substudy 1). Findings pertaining to information needs showed that women placed a high value on access to information. Interestingly, our participants did not necessarily need large amounts of information, yet they were quite explicit about the need for specific information about early labour. However, for women to feel safe at home, this information had to be complemented by acknowledgement and support from both midwives and partners or other supporting persons.

Participation is a crucial principle in person-centred healthcare research (81), and our findings pertaining to information were used directly in the development of Latens.no, facilitating early participation from end users. The use of internet technology to deliver health information can be person-centred given it meets the needs of individuals (87). Using the internet is an easy way to reach the public to enhance health literacy and increasing the availability of high-quality health information on the internet is suggested

as a means of reaching the Norwegian government's goal of improving the health literacy of the population (123, 124). In the past, however, numerous technology-supported interventions and information campaigns were developed purely because the technology to build them existed, and not based on the users' needs (87). Thus, in addition to serving as a needs assessment, the results of this study were used to involve users with the objective of making the website personally relevant for them and ensuring that the project is person-centred.

The most important finding in the first study involved information. The women in our study felt that access to information about what to expect and/or what were considered normal early labour would have better helped them to cope with early labour. Several previous studies have examined the information needs of pregnant woman (19). We argue, however, that information needs may differ across different stages of pregnancy and labour. Additionally, the large amount of information available regarding pregnancy and birth can be overwhelming if it is not organized and presented in a meaningful way (63). Hence, our findings related to information needs specifically about early labour, and the timing of that information, were essential for proceeding with the project. In 2022, a systematic review on understanding information needs and barriers to accessing health information across all stages of pregnancy was published (61), in which the authors stated that it is essential to understand information needs during all stages of pregnancy to enable women to access high-quality, tailored, and layperson-friendly health information. Their aim was to better understand information needs throughout pregnancy and to find opportunities to meet them (61). However, the authors defined the stages of pregnancy as prepregnancy, pregnancy, and postpartum. Due to the lack of differentiation between early and late pregnancy, as well as the lack of specific information about early labour (61), the systematic review was unable to provide further insight into information needs specific to early labour, which demonstrates the continued importance of our first study.

Another important finding in the first study was that information alone did not meet all women's needs. These findings were not surprising and reflect contemporary issues in research around midwifery care. Similar findings were reported in the *Lancet Series on Midwifery*: information and education are essential to women, but care should also be personalized to their individual needs and provided by compassionate, empathic, and considerate staff (125). Although this finding was expected, it highlights the fact that Latens.no can never be a replacement for standard care but is rather a complement to it. Further, it made us aware that we could use the website as a channel to enhance communication between women and midwives both by allowing women to learn, and thereby enabling mutual understanding, and by encouraging contact with the hospital in early labour.

The women in our study had varying degrees of preparation for childbirth, and many expressed surprise at how early labour unfolded. Our results call attention to an unsatisfactory aspect of childbirth preparation. In the published article (103) we discuss potential reasons why many women were frustrated when dealing with their early labour. As childbirth is unpredictable in nature, it is difficult to individualize information. Even with the best preparation, something unexpected will sometimes occur. An essential aspect of midwifery involves embracing the natural, physiological processes of childbirth (126), and based on the results of the first study in this thesis, I argue that childbirth preparation and information should emphasize how to 'let go', anticipate uncertainties, and build confidence in one's ability to give birth.

5.3 User-friendliness of Latens.no

Despite the exponential growth of eHealth apps, the number of studies reporting the results of usability testing on these apps has not increased at the same rate. Currently, only a small percentage of digital health applications publish their usability evaluation results (72). Nevertheless, user-friendliness is an essential component when assessing a website both to determine whether users can find the information they want on the website prototype and to identify potential usability problems (127).

In total, eight participants completed tasks on Latens.no and verbalized their experiences in think-aloud interviews. Results included both positive feedback regarding content and design and suggestions for improvement. Overall, however, there was less negative feedback than we had expected. Participants found the information on the website relevant, trustworthy, and easy to read and the design attractive and easy to use. This may be explained in part by the efforts made when developing the website, including involving users and midwives and refining the site based on SAM. Moreover, the results of this study are consistent with previous studies evaluating the feasibility and acceptability of mobile health lifestyle apps and medical apps for the purpose of supporting health care during pregnancy in high-income countries (128). Based on their systematic review, the authors conclude that mobile health technology is frequently considered to be effective, easy to use, and simple (128).

Due to the limited amount of negative feedback, the adjustments to Latens.no made based on the study were minor and mainly concerned design. Nevertheless, the study was an important part of the website development process. It confirmed user-friendliness, facilitating the advancement of the project as a whole, and ensured that a person-centred approach was used throughout the process of developing Latens.no. The needs and demands of the individual end users must be taken into consideration at every stage of the process in order to achieve the desired level of use and effectiveness (87). By facilitating participation and user-involvement in this stage of the project, the users had a voice in choices and actions that matter.

5.4 First-time mothers' experiences of early labour and subsequent labour characteristics before and after introducing Latens.no

Previous research indicates that early labour interventions may increase maternal satisfaction, as stated in the introduction (8, 55, 57). However, the overall results of the SWE-ELEQ-PP do not indicate that Latens.no resulted in an improved experience of early labour. We did, however, find that women in the post-intervention group had

significantly greater cervical dilatation upon presentation at the labour ward than those in the pre-intervention group and received less oxytocin during labour. A significant increase in telephone consultations was also observed after the intervention was implemented.

It is important to note that the pre-intervention cohort in this study was recruited before the COVID-19 pandemic, whereas the post-intervention cohort was recruited during the second wave of COVID-19 in Norway (September–December 2020). An increase in symptoms of depression and anxiety among pregnant and postpartum women during COVID-19 has been reported (129, 130). A systematic review of perinatal mental health outcomes during COVID-19 indicates a heightened sense of unpredictability and uncertainty, increased stress, and diminished emotional and practical support (129), all factors that may impact women's experiences of early labour (131). Moreover, COVID-19 resulted in changes to hospital guidelines that prevented partners from being present at the hospital; this, in turn, may have led to unmet support expectations and, subsequently, negative experiences for women. In light of this, it might be that a null finding in our study of women's early labour experiences actually may represent a positive effect under "normal" circumstances. Further, results from the SWE-ELEQ-PP show that participants with access to Latens.no felt significantly more relaxed while in early labour at home compared to participants in the pre-intervention group, which may indicate that digital support is a pragmatic but valuable supplement in improving women's experiences of early labour care.

One of the most noteworthy findings of the third study, however, is that the post-intervention group presented at the labour ward with more cervical dilatation and required less oxytocin than the control group. Women with access to Latens.no presented at the labour ward with a mean dilatation of 5.1 cm (SD ± 2.3) as compared to 4.1 cm (SD ± 2.2) in the pre-intervention group ($p < 0.001$). As explained in the introduction, we might be moving towards a change in guidelines regarding the transition from early labour to the active phase with a dilatation of up to 6 cm. In that regard, our findings indicate that participants who had access to Latens.no were admitted to the

labour ward in a timelier manner. This finding suggests that women who are provided with a suitable amount of trustworthy information at the right time might be able to cope better at home in early labour and be more competent in deciding when to go to the hospital. A person who has more knowledge, skills, and confidence when it comes to managing her health is more likely to engage in positive health behaviors and to achieve better health outcomes (132). A randomized trial of structured antenatal training sessions to improve the birth process support this explanation (133). In the trial, women who received antenatal training arrived at the maternity ward in active labour more often than women in the reference group (133). Presuming this to be the case, I argue that Latens.no facilitates person-centred care by allowing women to develop the knowledge, skills and confidence they need to make informed decisions. It is possible, however, that the COVID-19 pandemic may have influenced these results. Women might have delayed going to the labour ward out of fear of being separated from their partners or contracting COVID-19.

It is interesting to note that more individuals in the pre-intervention cohort considered that they had gone to the hospital at the right time, although the difference was not statistically significant. This may be due to the aforementioned ambivalence between women's perspectives and medical definitions of early and active labour (42) or the fact that some women prefer being in a hospital setting and deferring to medical providers. Either way, it serves as an example of the complexity in early labour care.

The findings from substudy 1 showed that many women were reluctant to call the hospital despite wanting to talk to health professionals (103). As a result, several statements were included on Latens.no to inform women that midwives welcome telephone calls. There was a significant increase in the number of telephone consultations in the group with access to Latens.no. Although changing care guidelines due to COVID-19 leading to more questions and uncertainty might also have contributed to the result, it is a positive finding. Considering the finding that women with access to Latens.no were admitted to hospital in a timelier manner, this finding may lend support

to the hypothesis that women are able to actively participate in the decision-making process regarding their care when given the right tools.

Overall, the confirmatory factor analyses (CFA) of the Swedish version of the ELEQ for primiparous women shows an acceptable fit. In the original Canadian study, authors established a three-factor model (58). Their analysis revealed that women's affective experiences of early labour could be subdivided into two factors measuring their sense of emotional well-being and feelings of emotional distress, with their perceptions of midwifery care being the third factor (58). Authors of the Swedish study found a similar pattern among the primiparous participants in their exploratory factor analyses (EFA) and labelled the factors in a similar manner to the original version (112). Ängeby et al. did, however, find that Q22 and Q24 loaded on the 'perceptions of midwifery care' factor, as opposed to the original Canadian study where they were presented as single items. Q22 and Q24 respectively asked whether 'the midwife and the doctor work as a team in providing your care' and whether 'you feel that the midwife treated you in a rude way'. Ängeby et al. suggest their finding may be a result of the fact that midwives in Sweden are responsible for the care of women during labour, and that midwives' subordination to the medical paradigm results in midwives behaving as 'gatekeepers' to the medical system (112). As midwifery care in Sweden is very similar to midwifery care in Norway, we chose to perform a *confirmatory* factor analysis rather than an *exploratory* factor analysis on our data material. However, it is reasonable to believe that these two questions would load under the factor 'perceptions of midwifery care' in an exploratory factor analysis of our data material due to the similarities in midwifery care in Norway and Sweden and because the CFA of our material showed an acceptable fit. I support Ängeby et al.'s suggestion that the loading of Q22, 'Did the midwife and the doctor work as a team in providing your care?', under the factor 'perceptions of midwifery care' is a result of the fact that midwives in Sweden (and Norway) are responsible for the care of women during labour. Midwives traditionally have a strong position in both Norway and Sweden. However, as discussed in paper 1 in this thesis, there are indications that midwives' ways of caring for women on the phone have improved in the last few years because of the increased focus on early labour (103). Results from substudy 1

demonstrate that participants were not left feeling that they were being kept at home (103), which hopefully reduces the view of midwives as 'gatekeepers'. Instead, I propose that the previously discussed complexity in early labour care, and the fact that women, labour companions and health professionals all find early labour difficult to manage well, might to some extent explain the results of the loading of Q24, 'Did you feel that the midwife treated you in a rude way?'.

5.5 Methodological considerations

Several methodological choices were made throughout the process to maintain high methodological quality. They are outlined and discussed in the Materials and methods section and will not be repeated here. However, there are methodological strengths and limitations that need to be considered. Under the heading 'Reflexivity, internal validity, and external validity' I illuminate some methodological considerations in relation to the qualitative studies (substudy 1 and substudy 2). I then discuss the strengths and limitations in the quantitative study (substudy 3) under the heading 'Validity and reliability'.

5.5.1 Reflexivity, relevance, internal validity, and external validity

Numerous attempts have been made to evaluate the quality of qualitative research (134). Malterud proposes reflexivity, relevance, internal validity, and external validity as overall meta-criteria for assessing qualitative studies (99, 135).

The concept of *reflexivity* is based on the understanding that researchers are unable to remain impartial, unbiased, or objective (99). There is no question of whether I have influenced my work; rather, the question is to what extent have my professional and personal background, my motivations for carrying out the study, and my knowledge and presuppositions influenced the research process (99)? Further elaboration on my reflections on reflexivity and how it may have affected my results are presented under the heading 'Related principle 3: Critical reflexivity' (p. 13-14).

In this context, *relevance* refers to the use that can be made of the knowledge generated (99). Scientific knowledge should provide original knowledge that can be applied to something, and the relevance requirement is especially relevant in research in fields that are close to practice, such as this thesis. (101). Malterud suggests that healthcare research is rarely truly original, in the sense that there is far between truly ground-breaking breakthroughs (99). It is still a demand, however, that the knowledge adds something new compared to what we already know. Consequently, thorough literature searches, critical reading, and careful assessments were conducted prior to the initiation of substudy 1. Several studies had investigated general information needs in pregnancy and labour and information seeking behavior in maternity care (19, 22, 61-65). However, there was little evidence on first-time mothers' information needs specifically in early labour, something that justified implementation of substudy 1.

The *internal validity* of a qualitative study depends on the degree to which the study has addressed the stated purpose, as well as the appropriateness of the chosen methods (99). Reflections upon choices regarding methods used for qualitative analysis should be included as part of a discussion of internal validity, and the reasons and rationale behind the choices made in this regard are thoroughly described in the Materials and methods chapter. Further, it is important to consider whether the recruitment strategy employed provided relevant information in line with the study aim (101). Despite difficulties in recruiting for substudy 1 and study 2 (see p. 19–21 and 31), I believe that we were able to recruit information-rich participants. Even though qualitative studies are rarely based on empirical data from a large number of participants, a sample with good information power can provide a basis for development of knowledge (99). The information power in a sample can be used as a guideline when deciding on number of participants (99). The combination of a focused aim and participants who conveyed considerable and varied information, contributed positively to the information power in substudy 1 and 2. Along these lines, I argue that the relatively low number of participants in the two studies should not be viewed as a weakness. However, when deciding on a recruitment strategy for substudy 1, I believed that women who had gone through early labour at home would have the best potential to shed a light on the issue. In hindsight, I saw that including

partners probably would have yielded participants with different perspectives. This was taken into consideration when planning a recruitment strategy for the next study, and it was decided that it was important to include both women who had recently given birth to their first child and their partners in substudy 2.

The size of the focus groups is a limitation in substudy 1 (see p. 19-21). Five focus group interviews were conducted with four, two, two, six, and two participants. This might be considered a threat to the internal validity of substudy 1 as larger groups might have resulted in a different dynamic and yielded different results. However, it has been argued that focus group interviews should not be cancelled due to small size; nor should the data that emerges be discarded as this could cause a loss of knowledge and be an affront to the people who sought to participate (136). Nevertheless, in retrospect, I see that I should have planned even better when developing a recruitment strategy involving mothers with newborn babies.

External validity refers to the generalizability of the findings beyond the context in which they were generated (99). Latens.no was designed to be implemented in an urban setting, where users lived relatively close to a hospital. This influenced the inclusion and exclusion criteria in study 1, thus limiting transferability to some extent. I strived to include women with a variety in background characteristics, and both with and without a partner, and this succeeded. However, it is a limitation that we were not able to include recently arrived immigrants and others who do not master the Norwegian language. Nevertheless, the study's ability to convey a heightened understanding of information needs in early labour in settings outside the study setting is also indicative of transferability. The fact that several findings in substudy 1 reflect contemporary issues around information needs in early labour in other high-income countries supports external validity. Additionally, participants in both substudy 1 and substudy 2 differed in background characteristics and had the potential to shed light on different perspectives on the subjects in question.

5.5.2 Validity and reliability

Implementation of Latens.no was evaluated in a before-and-after study. A before-and-after study can be an effective tool for assessing the impact of educational programmes, among other things (137). It is, however, subject to history bias. History bias occurs when researchers fail to consider relevant events that precede an intervention or occur simultaneously during the intervention, which could affect the outcome (138). When planning for substudy 3, history bias was taken into consideration. As we knew that the number of births fluctuates somewhat throughout the year, and that the summer months are normally busier in the labour ward at Oslo University Hospital, we planned to collect data from the two cohorts in approximately the same months in two consecutive years (avoiding summer). The COVID-19 pandemic, however, was not foreseen in the planning phase. Thus, the nature of this study, including the history bias of COVID-19, does not allow for causal inferences to be drawn from our data. Nevertheless, it is important to consider the rigor with which the study was conducted. As it is a quantitative study, rigor can be assessed through the measurement of validity and reliability (139).

Validity is a quality criterion that refers to how well a study measures what it is intended to measure (140). *Statistical conclusion validity* refers to providing evidence that the relationship inferred between variables is real and that the intervention was given a fair test (140). Design decisions can influence whether a true statistical relationship exists. Due to the COVID-19 pandemic, results from the before-and-after study were challenging to interpret, possibly resulting in poor statistical conclusion validity. However, based on a previous study using the same questionnaire on a similar population, a thorough power calculation was performed and adhered to in the before-and after study, indicating that the results reported in substudy 3 could in fact be detected in a study. Additionally, with regard to sample size requirements for CFA, our sample size was within several widely cited 'rules of thumb'.

Internal validity states the degree of certainty with which it can be inferred that the intervention caused observed effects (140). The history bias previously outlined poses a major threat to the internal validity of substudy 3. Strategies to enhance internal validity

included searching for selection biases by comparing groups with respect to key background variables. Additionally, pre-/post-intervention groups were compared in an 'intention-to-treat' analysis to best mirror actual practice conditions where not all participants would use Latens.no.

As in qualitative research, a quantitative study's *external validity* is how generalizable its results are to other settings or samples (140). Representativeness is an important aspect of external validity. A strength of substudy 3 is the heterogeneity of the participants despite the exclusion of non-Norwegian speaking women. The patient base of Oslo University Hospital includes patients with a variety of ethnic backgrounds. The fact that our data material reflects this implies that findings can be applied to a broader group in similar clinical settings.

Construct validity concerns the details in the study and the construct they intend to represent. Study 3 made use of a questionnaire validated for inquiry related to experiences of early labour. Additionally, the Norwegian version of the questionnaire was pilot tested by fifteen women who had recently given birth to ensure that the wording made sense to our participants in relation to their early labour experience. Construct validity also involves the identification of incidental causes, effects, settings, and participants that may be present in a study. Because I personally informed all participants about the study, researcher expectancy may have entailed a threat to construct validity. Through subtle (non-intended) communication about desired outcomes, I may have influenced participants responses. I did, however, inform all participants in both the before and after groups and made an effort to appear neutral.

Reliability refers to the degree of consistency or dependability with which the ELEQ measures early labour experience. The reliability of the questionnaire is a major criterion for assessing its quality and adequacy (140). It is therefore a major strength that substudy 3 made use of a validated questionnaire, and in addition performed CFA for further validation. Further, the use of patient reported experience measures in the evaluation of the study strengthens person-centredness, as patients' perceptions of their health and experiences are fundamental when providing percent-centred care.

6 Conclusion

Results indicate that it is challenging for women to prepare for early labour, and regardless of how prepared they felt beforehand, unexpected circumstances arose. Findings from the first study suggest that easy access to online information at the right time, together with acknowledgment and support from midwives, can reassure women in early labour. In the second study we demonstrate that a multidisciplinary approach may be used to develop and test an online educational resource, and that users may provide suggestions for improvements using the think-aloud method. In the third part of this thesis, we were unable to demonstrate that the introduction of an online educational resource for women in early labour improved early labour experience. However, women who had access to Latens.no presented to the labour ward with greater cervical dilatation and received less oxytocin.

6.1 Implications for clinical practice and future research

The findings from this thesis suggest that women desire information when in early labour. However, it is important for midwives to note that information alone does not meet all the needs of these women. Women in early labour benefit from easy access to specific information about early labour, including what to expect and what are considered normal early labour experiences, and they appreciate repetition. When caring for women in early labour, midwives should strive to provide that information, whilst at the same time keep in mind that it is important to support by listening and understanding. Further, unexpected things often happen in early labour as childbirth is by nature unpredictable. Preparation for and information about childbirth should therefore emphasize how to 'let go', anticipate uncertainties, and build confidence in one's ability to give birth.

WHO insists that 'a positive childbirth experience' is a significant end point for all women undergoing labour (1), and more research is warranted to guide women, partners, and midwives in better managing early labour. When assessing early labour experiences, it is important to use a validated instrument. Based on findings from this thesis, SWE-ELEQ-PP can be recommended for use in a Norwegian population.

The role of the pregnant woman has changed over the past few decades. Whereas previously, health personnel were seen as the sole decision makers, women themselves are now more involved. The Norwegian authorities aim to create health services that are adapted to individuals' needs (124). Pregnant women should be able to make decisions regarding their own health and have a right to receive information that they can understand in such a way that it allows them to make their own decisions, alone or in consultation with a health professional (124). More research about women's information needs in early labour is therefore warranted, including studies that explore how information can be provided to help women feel more comfortable staying at home during early labour. As a result of person-centred health education and empowerment, people are able to become active partners in the coproduction of health through improved communication and decision-making in clinical settings, which may lead to better health outcomes (141).

As pregnant women are already heavily utilizing digital media, it is likely that their experiences of early labour will be influenced by technology in addition to in-person interactions. We have demonstrated that seeking information online regarding pregnancy may provide a sense of empowerment and prepare for interactions with health care providers. Given it is developed and implemented in a way that ensures personal relevance for the users, I believe that technology in health care can facilitate person-centred care, social support, well-being, and outcomes related to giving birth. Thus, further investigation into the use of technology for information in early labour is also warranted.

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A qualitative study of Norwegian first-time mothers' information needs in pre-admission early labour

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ABSTRACT

Objective: To explore women's experience with information, and their information needs in pre-admission early labour.

Design: A qualitative study with an exploratory and descriptive approach.

Setting: Five focus group interviews with women attending post-natal care at five different well-baby clinics in South-Eastern Norway in 2019.

Participants: Sixteen first-time mothers who had given birth to a baby 3–17 weeks prior to the focus group interview. All had experience of staying at home in early labour.

Findings: Three themes emerged from the analysis. The first and most substantial theme involved information. The women considered it necessary to have easy access to a suitable amount of trustworthy information at the appropriate time. The second theme described that the women were surprised at how early labour manifested, despite having prepared for it. The third theme was about receiving acknowledgement and support, revealing that information did not meet all woman's needs.

Key conclusions and implications for practice: The women found it challenging to prepare for early labour, and no matter how prepared they felt beforehand, unexpected situations arose. Easily accessed online information from reliable sources was useful in early labour, but in order for women to feel safe at home, this should be complemented by telephone conversations with skilled and welcoming midwives in the labour ward. More knowledge about women's information needs in early labour is required, including studies exploring how the information should be provided to help women feel safe when staying at home in early labour.

Introduction

The period of painful uterine contractions prior to five centimetres of cervical dilatation is often referred to as the 'latent phase' or 'early labour'. The World Health Organisation favours the use of the term latent phase (World and Health Organization, 2018). In this article, we use 'early labour', as this captures the fact that the phase is part of the labour process, and as stated by Dixon et al. (2013), women do not consider labour to be different phases. For some women, early labour is short, while for others it may continue for hours or even days (Gross et al., 2009; Tilden et al., 2019; Ängeby et al., 2018).

Two large retrospective cohort studies (Holmes et al., 2001; Klein et al., 2004), and one interventional study (Rota et al., 2018) have investigated outcome differences between women presenting in early and active labour. Results suggests hospital admission in early labour is associated with increased risk of medical interventions, including electronic foetal monitoring (Klein et al., 2004), epidural analgesia (Holmes et al., 2001; Rota et al., 2018), oxytocin stimulation (Holmes et al., 2001; Rota et al., 2018) and caesarean section (Holmes et al., 2001; Rota et al., 2018). Still, WHO recommends delaying admission only for research purposes (World and Health Organization, 2018). However, clinical practice recommendations in Norway state that women in early but not active labour should generally not be admitted to hospital (McNiven et al., 1998; Norsk Gynekologisk Forening, 2014). This is consistent with NICE UK guidelines, who emphasise that the decision should be made in consultation

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with the women (National Institute for Health and Care Excellence, 2017).

Several studies describe a lack of satisfaction with care provided in early labour prior to admission (Beake et al., 2018; Eri et al., 2015). In 2015, Eri et al. published a metasynthesis exploring first-time mothers' experiences of early labour (Eri et al., 2015). The findings suggest that women's needs are not adequately met in early labour, describing a mismatch between women's expectations and experiences. Women expressed uncertainty in interpreting possible signs and symptoms to determine the start of labour requiring admission (Eri et al., 2015). It was important to know how far labour had progressed, and if everything was normal. Further, in a systematic review, Beake et al. concluded that women, labour companions and health professionals found early labour difficult to manage well (Beake et al., 2018). Nevertheless, delaying admission until active labour results in fewer epidurals and fewer caesarean deliveries (Tilden et al., 2015), which are factors that likely influence satisfaction and experience of care.

In all, previous findings suggest easy access to relevant and reliable information could be a way of supporting and empowering women to cope with early labour. Research on enhancing women's confidence for labour suggests that women desire information during pregnancy and want to use that information to participate in care decisions (Avery et al., 2014). Additionally, this could enable labour companions to feel more confident and thus provide better support at home (Beake et al., 2018). To provide this information, we must first understand these women's information needs. Several studies have examined the information needs of pregnant woman (Ghiasi, 2019), and first-time mothers' information needs in pregnancy seem to be increasing (Chung et al., 2020; Singh et al., 2002). Advances in information technology facilitate the transfer of knowledge, but it is important for health professionals to consider the amount and type of information they communicate (Carolan, 2007; Chung et al., 2020). The NICE UK guidelines recommend information about what to expect in the early stage of labour to be shared both in antenatal care and in early labour. (National Institute for Health and Care Excellence, 2017). However, the research to date has not been able to provide specific advice on first-time mothers' information needs particularly in early labour. A Swedish study from 2015 investigated first-time mothers' care preferences during prolonged early labour (as defined by the authors to be > 18 h) (Angeby et al., 2015). They discovered that participants all knew about the importance of staying home during the early labour. Nevertheless, they had trouble understanding the different phases and stages of labour, and wanted more information especially about the latent phase. However, as the study focused on women with prolonged early labour, it cannot be assumed that the results are transferable to all first-time mothers.

Beake et al. point out the need for further research on the increasing use of web-based information (Beake et al., 2018). This article presents findings from the first study in *The PreCare Study: Pre-admission early labour care: An electronic educational intervention to improve information flow in early labour care and women's pre-admission early labour experience*, set in Norway, and founded by The University of South- Eastern Norway. *The PreCare Study* aims to develop and test a website with easy-to-access high-quality information about early labour. This first study will inform the development and content of the website. In subsequent studies, we will test the website to ensure suitability and usability for the target group. In addition, we will investigate whether the website improves women's knowledge of early labour, experience in early labour, and explore if use of the website affects clinical birth outcomes related to giving birth. The aim of this study was to explore women's experience with information in early labour, and what information women who had gone through labour missed and/or appreciated in early labour.

Methods

As we wanted increased understanding into information in early labour from the women's perspective, an exploratory and descriptive design was chosen. We used systematic text condensation (STC) to analyse the data, a method suitable to develop new descriptions without applying a theoretical framework (Malterud, 2012b, 2017). STC is inspired by Giorgi's phenomenological analysis and modified by Malterud and presents a strategy for thematic cross-case analysis (Malterud, 2012b). Multi-site focus group interviews were conducted in South-Eastern Norway between May and October 2018. Group discussions provide direct evidence about differences and similarities in opinions and experiences (Morgan, 1997). In addition, our participants already had planned maternity groups, which facilitated focus group interviews.

The inclusion criteria were that women were first-time mothers having given birth to one child in cephalic presentation, ≥ 37 weeks, with a spontaneous start of labour and having stayed at home in early labour (as defined by the women themselves). Exclusion criteria included induction of labour and conditions in pregnancy that precluded women from staying at home in early labour. The participants needed to be able to read and speak Norwegian to understand the information and the consent form and to participate in the focus group interview.

To achieve variety in background characteristics, seven well-baby clinics, both rural and urban, were contacted. Five clinics responded in a positive manner and helped recruit first-time mothers within 3–17 weeks after birth. Women were identified, informed about the study and invited to participate by their midwife or public health nurse at the well-baby clinic.

Staff invited twenty-nine women to join the study and twenty-two agreed to participate in a focus group interview. Six participants did not attend, leaving us with a sample of sixteen women. The participants received post-natal care at five different well-baby clinics, and gave birth at four different hospitals in South-Eastern Norway. The age of the participants ranged from 24 to 38 years, and they lived in both urban and rural areas. Four of the participant had immigrant non-western background. One of the participants was a single mother, who had support from her own mother while in early labour. The rest lived with a partner (male or female) who was with them in early labour.

Five focus group interviews were conducted, with respectively four, two, two, six and two participants in each group. A focus group interview guide containing a few open-ended questions about what information the participants missed and/or appreciated in early labour was developed in collaboration between the authors (Table 1). The guide was piloted on a group of five midwife colleagues who had given birth themselves, and slightly modified, but the data from this pilot focus group was not included in the current study. The first author was the moderator in all focus group interviews, she was not known to any of the participant, and presented as both midwife and researcher. The other authors alternated as secretary, taking notes. The participants were instructed to take turns to talk and told that the moderator would only interrupt the focus group interview when necessary. The focus group interviews lasted for 29–53 min (mean 40 min) and were audio-recorded and transcribed verbatim.

Data analysis

As mentioned, we used STC to analyse the data. This four-step strategy for thematic cross-case analysis (Table 2), represents a pragmatic approach to analyses of different types of qualitative data, while maintaining a responsible level of methodological rigour (Malterud, 2001, 2012b).

In step one, the first and last author read through all the focus group interviews to gain a general impression of the preliminary themes. Secondly, meaning units describing the women's early labour experiences related to knowledge and information were identified and organised into code groups by both authors. In step three, we identified subgroups in each code group (Table 3), and meaning units in all subgroups were summarised and condensed. Lastly, a description of the content was drawn up and presented as an analytic text (Malterud, 2012b, 2017).

Table 1
Interview guide.

Interview guide The main questions are numbered. The remaining questions were only asked if needed, to keep a good flow in the focus group interview.
1. Can you tell me a bit about your early labour? - What role did your partner have in this phase of the labour? 2. What did you know about early labour beforehand? - How did you get this knowledge? - Did early labour lastfor as long as you thought it would? - Was there anything you thought you knew about early labour that turned out not to be true? 3. What information did you receive when you contacted the hospital for the first time? - Did you understand the information you were given? - Was the information useful? - Would it be useful to have this information in writing? 4. What information did you miss when in early labour? - If nothing, what information did you perceive as useful? 5. What information do you think a website with information on early labour should contain? - At what time in your pregnancy would you access such a website? - How would you find such a website? - What would you google in early labour? - Do you have any examples on what constitutes a good website?

Table 2
The four steps of analysis in systematic text condensation.

Total impression-from chaos to themes.
Identifying and sorting meaning units- from themes to codes
Condensation- from code to meaning
Synthesizing- from condensation to descriptions and concepts

Ethical considerations

The study was conducted in accordance with the WMA Declaration of Helsinki Ethical Principles for Medical Research Involving Human Subjects (World Medical Association, 2017). Participants were provided with written information, and given time to consider whether they wanted to participate. Written informed consent was obtained from all participants. They were advised that participation was voluntary and that they could withdraw from the study at any time without giving reasons. All participants were given the possibility to talk to the first author after the focus group interview should they require debriefing. The study was assessed by the Regional Committee for Medical and Health Research Ethics in South-Eastern Norway (REC: 2018/540) and was considered to be outside the remit of the Health Research Act (2018), which applies only to research that aims to generate new knowledge about health and disease, and not patient experiences. Approval for the study was granted by the Norwegian Centre for Research Data (NSD: 60109).

Findings

Three themes emerged as a result of the analysis. The first and most substantial theme involved information. The women considered it necessary to have easy access to a suitable amount of trustworthy information at the appropriate time. The second theme described how the women were surprised at how early labour manifested, despite having prepared for it. The third theme was about receiving acknowledgement and support, revealing that information did not meet all woman's needs. In Table 3, we present an overview of the code groups and subgroups. Table 4 provides an example of a meaning unit, subgroup and code group. An extensive presentation of meaning units, subgroups and code group is found in supplementary Table 1 (S.1).

Easy access to trustworthy information at the right time

The women felt that access to information on what to expect or on what were considered normal early labour experiences would have helped them cope with early labour. They wished they had information about signs and symptoms of the start of labour, about contractions, and the differences between labour contractions and Braxton Hicks contractions. Some found it difficult to assess when their contractions started and stopped, and one woman pointed out that it was difficult to know if she was in labour, since she had never done this before. They did not necessarily need large amounts of information, but wished for useful, readily accessible information about the "usual stuff" that was easy to comprehend and relate to. They were preoccupied with the different stages of labour, and one woman stated that learning about the different stages calmed her down because she knew that things were supposed to happen in a certain order, and that early labour took place at home. They also wished for information about when to phone the hospital, and advice and ideas on what they could do at home, and some wanted detailed information about the physiology of early labour, such as cervical and hormonal changes and statistics. The women also appreciated practical information about what to take to hospital, and what happens when you arrive there. Being in control of the practicalities was important in an otherwise chaotic situation. One woman wished she had known that early labour usually progresses slowly:

Because… I felt a bit kind of… in fact, I thought I was suddenly going to give birth when my contractions were three minutes apart and lasted

Table 3
Overview of code groups and subgroups.

Code groups	Subgroups
Easy access to trustworthy information at the right time	Type of information Time of information needs Where information is obtained from Trustworthiness of information
Surprised at how early labour manifested	Prepared, yet still lacking knowledge How to manage
Limitations of information	To feel safe and supported To feel welcome

Table 4
Example of meaning unit within a subgroup and code group.

Code Group	Subgroup	Meaning unit
Surprised at how early labour manifested	Prepared, yet still lacking knowledge	I was not aware that it could be that painful and protracted. So that was a surprise, really. So we… we were prepared that it could take a long time. I was just surprised that it could… so quickly… that it happened so fast, got very painful so fast. That caught me by surprise. It was a situation we did not know how to react to. (focus group # 1)

for 45 s. I was thinking, now the baby's coming. But it actually took a few more hours. (Focus group # 2)

One woman explained how she had spent considerable time reading about early labour on the Internet prior to her labour, preparing herself and learning what was normal, and what was not normal. This made her feel more in control of her early labour. Others said that they had not given early labour much thought before it happened, as the birth had been their focus. Still, most women actively looked for information about labour when their maternity leave started, three weeks before their due date. Furthermore, they expressed a desire for information about early labour when they were in early labour themselves and explained how they wanted to read information over and over again:

To find out the differences. Like what's this? Is this the important thing? Do these criteria apply to me? Or, well, not like… I mean, you can't have a blueprint for exactly when it starts, can you? But it's more like, is there anything here that… Does this reflect what I'm experiencing right now? (Focus group # 5)

The women obtained information from different sources. Some had learned "the basics" at antenatal classes, others appreciated written information, such as books, newspapers, pamphlets or articles, and one woman said she preferred to watch videos to gain knowledge. Talking to family and friends was also an option, as were conversations with the midwife at the antenatal check-ups. In addition, all participants had searched the Internet for information. Webpages mentioned were Google and Norwegian official sites. One woman pointed out that when she was at home with contractions the Internet was easily available. Another explained that she and her partner were both very hungry for knowledge, and found the Internet to be the only solution:

It was the only thing… it was the only thing I did. Because I felt like I needed help, or information… from someone with knowledge. It was the only help I could get. I couldn't talk to the hospital for hours. So the only thing left to do was to google and read. (Focus group #2)

One woman pointed out that having access to a reliable website would have helped her in early labour. Women found it challenging to know which information they could trust, and critically assessed all information. One immigrant woman preferred to receive her information from someone she knew who had experienced labour herself. However, most women preferred more carefully prepared information, like "official" or "well known" websites. They remarked that when they recognised the information or had heard something similar before, they could more easily trust the source. "If it sounded familiar, I trusted it". They suggested that the information they received should be credible, because there is so much information to choose from on the Internet. As one woman put it:

These mum forums that you find when you search the web, they're like… you can't always trust them. It's almost… like upsetting. Reading them upsets you. (Focus group # 1)

Surprised at how early labour manifested

Some participants thought they had gathered enough information, while others had not familiarised themselves with this stage of labour at all. Most had learned about the different stages of labour, but lacked knowledge about early labour. They felt that the focus had been primarily on the birth. Although they had read a great deal, they found that unexpected things arose, causing uncertainty. The women expressed surprise and frustration at the sensation of their contractions. One participant explained that she was'… frustrated, because my contractions were so powerful and so frequent, but still nothing happened'. Another disclosed that she had prepared for her first birth to take some time and was surprised to discover that it did not take very long. In addition, several participants were surprised when their waters broke. As stated by one woman: 'I was thinking that my waters would not break, because this only happens to 10%. But it did'. Others were surprised that it was difficult to be certain as to whether their waters had broken or not. For some, early labour was a greater ordeal than the rest of labour, and they were distressed when at home:

After a while, I began to think it was torture. Like I was in a torture chamber, where you just go around, waiting for… when will the pain come? And you don't know how long you'll be trapped in there. (Focus group # 2)

The participants managed their early labour in different ways. Some women stated they handled it well. They managed to "keep calm", "breathe through their contractions" and "have a positive feeling in between contractions". One participant felt that women were made for giving birth, while another said she could feel the baby moving and therefore reasoned that everything was fine. Yet another woman talked about how "time went by both fast and slowly, time and space disappeared". Some found it difficult to interpret and keep track of their contractions and many participants felt insecure at the lack of regularity in their contractions. The women had prepared in different ways but even those who were well prepared expressed some degree of uncertainty:

Well, it's not easy, is it? (laughs) No matter how much you prepare, you're kind of not properly prepared anyway. (Focus group # 4)

Limitations of information

Our findings show that information did not meet all woman's needs. The participants found a sense of security in having a partner or other support person who kept a cool head with them at home. One woman mentioned the feelings of insecurity as a first-time mother, in spite of "having a lot of head-knowledge". She lacked control over what was happening, and did not feel comfortable on her own in the situation. As early labour progressed, the women appreciated others helping them with practicalities, making sure they ate and drank, and phoning the hospital if they were unable to call themselves. Others preferred to be alone, "focusing on what was going on" and "thinking about what was going to happen". Yet they underlined the importance of feeling welcome each time they phoned the hospital. They felt reassured talking to a friendly and understanding person who confirmed their thoughts about what was happening. One woman explained how a sense of security was vital to her in her early labour, and she felt it was important to receive proper attention. Nevertheless, it was not necessarily the content of the phone call that was important for the participants:

I felt that they talked to me in a very nice way on the phone… they listened to me and… yes, that's what I felt. I can't remember in detail what… But I definitely remember I felt it was a good feeling to talk to the midwives on the phone. (Focus group # 4)

Most women were not left with a feeling of being kept at home. Instead, they had a sense of an open door to the hospital: they were welcome when they felt the need to come in, and this reassured them. One woman explained that as long as she could ring the hospital as often as she liked and come in when she felt the need, she felt fine staying at home for a long time. Nevertheless, some felt they had to stay at home too long. One woman stated that the midwives were too rigid regarding her contractions, and found that they actively prevented her from going to the hospital, which led to her becoming demotivated. Another woman explained how she did not appreciate being told to wait for regular contractions, because she never had regular contractions, everything was just chaotic. She stated that due to the pain, she "could not think clearly, and just wanted help". One participant had heard that if you were afraid, you could come to the hospital. However, she was not afraid, she was just in pain, which made her sad. One woman revealed that she simply went to the hospital without calling first, because if she called they would enquire about her contractions, and another admitted to a white lie about the frequency of her contractions in order to be admitted. The women were happy when it was finally time to go to hospital, but at the same time they could not shake off the fear of being sent back home. Some were told that the hospital was full, which made them conclude that capacity issues were the reason that they had to stay at home. The participants argued that no one knows your situation as well as you do, and that you need to trust yourself. They argued that it should be easy to phone the hospital, and that going there for a check-up should be an easily available option. Being able to participate in decisions was appreciated:

I was actually pleasantly surprised at the way they made it quite clear we could come to the hospital. And we could decide on it ourselves, and we didn't have to sit alone at home worrying. So that was… that felt really good. That we weren't… didn't feel pressure to stay at home for longer than we felt comfortable with. (Focus group # 1)

Discussion

In this study, we have explored information needs related to early labour. No matter how well prepared they were, most women in our sample experienced something unexpected in their early labour. Consequently, they needed support from midwives and partner/ support person, and easy access to trustworthy concrete information.

Our findings reflect the contemporary issues in research around information needs in early labour care in other high-income countries (Beake et al., 2018; Ghiasi, 2019). The findings demonstrated that despite different degrees of preparation, many women expressed surprise at how their early labour evolved, and were frustrated in dealing with it. The unpredictable nature of giving birth makes it challenging to individualise preparation for childbirth. No matter how prepared one is, something unexpected will often occur. However, in accordance with previous studies, our results call attention to an unsatisfactory aspect of childbirth preparation (Beake et al., 2018). There was variation in how the participants managed their early labour, including surprise and frustration, and for some early labour was a greater ordeal then the rest of labour. The women who handled early labour well used a variety of coping strategies such as staying positive, trusting the body's ability to give birth and being able to let time and space disappear. Altogether, these results indicate that childbirth preparation should emphasise preparation on how to "let go", be ready to anticipate uncertainty, and build confidence in one's ability to give birth.

However, as revealed in this study, information does not meet all needs in early labour. Women also have the need for support, safety and feeling welcome at the hospital. Previous research shows that the feeling of not being seen or heard during childbirth contributes to a negative birth experience (Henriksen et al., 2017; Hodnett, 2002). Here, our findings complement those of previous studies. The women in our study described the importance of feeling welcome even when calling the hospital several times. It was vital to receive proper attention when they called, and they reacted to the midwives' tone of voice and choice of words. Talking to someone that listened and acted in an understanding manner was of greater importance than the content of the telephone conversation. This concurs with other research demonstrating that pregnant women are sensitive to the way the midwives speak to them, and that they want to be listened to by sympathetic midwives (Beake et al., 2018; Eri et al., 2015).

Interestingly, most women spoke warmly of the midwives they talked to on the phone. They were not left with a feeling of being kept at home, but rather had a sense of an open door at the hospital, and that they were welcome when they felt the need to come in. These findings are somewhat surprising, given that other research from Norway shows that women's needs in this stage of labour are not met, and that first-time mothers in early labour feel they have to negotiate their credibility with midwives (Eri et al., 2010, 2015). One possible explanation for our results might be that midwives' ways of caring for women in early labour on the phone have improved in the last few years due to the increased focus on this stage of the labour.

While the majority of our participants found a sense of security in having a partner or other support person with them at home, some women preferred being alone. Previous studies confirm that labour companions at home can give both support and pressure (Beake et al., 2018; Eri et al., 2015). Traditionally, women in early labour were cared for by family members or other women with experience of childbirth (Janssen et al., 2009). However, because of increased medicalisation in Western society, assistance by experienced women at home is now rare. One participant in our study was with her mother at home, while the remainder had support from a partner or were alone. Although most women felt more secure having a partner or other support person with them at home, this was just as much about practicalities as emotional support. All participants, however, demonstrated the need for support by the midwife on the phone. Women giving birth today have grown up in a society where childbirth tends to be viewed as a clinical phenomenon, which can be best managed by hospitalisation and by the use of science and technology (Van Teijlingen, 2004). This may explain why in our study the women needed contact with health personnel in addition to the support from their partner, which emphasizes the midwife's unique role.

An interesting finding was that women called for specific information about early labour. Prior studies investigating information needs of pregnant woman list labour/delivery as a frequently mentioned topic (Ghiasi, 2019). Furthermore, research has shown that women require realistic information on what early labour may feel like and what to expect (Avery et al., 2014; Beake et al., 2018). To our knowledge, the present study is one of the first to explore information needs in early labour, and we have been unable to find other clear descriptions of specific information needs at this stage. In their postnatal reflections, the participants in our study made it clear that they did not necessarily need large amounts of information. However, they were quite specific about the need for easily accessible information about the "usual stuff", such as what to expect, signs and symptoms of the start of labour, and the differences between labour contractions and Braxton Hicks contractions. In addition, they expressed that they were not prepared for the unpredictability of labour.

Having easy access to information was important to the women. In addition to being able to find information whenever and wherever they wanted, easy access made them able to re-read the information. During pregnancy, but especially in early labour, repetition was welcome. They appreciated hearing the same information many times; it was reassuring and made them trust the information more. Furthermore, our results demonstrated that credibility was an important aspect of the information, and all participants critically assessed both the source and content of the information they received. This is a positive finding, given the fact that the ease of accessing online health information, paired with the lack of moderators to filter the content, make health information credibility an extremely important issue (Yang and Beatty, 2016). However, the

participants differed as to what they considered trustworthy information. This finding reflects that of Yang and Beatty (2016), who found that while participants perceived health information provided by experts to be more credible, perceptions were moderated by demographic characteristics. For example, in our study, immigrant women were more likely to trust information from friends and relatives than from healthcare personnel.

In a systematic literature review of sources of information accessed by pregnant woman, Ghiasi (2019) found formal sources such as healthcare providers to be the most common. The women in our study obtained information from many different sources, including formal ones. However, digital media and the Internet were by far the sources they discussed the most. Ghiasi's (2019) review included studies published between January 2002 and May 2018, which may explain our findings, since the use and quality of the Internet, social media and smartphone applications have developed considerably since 2002. A study from the Netherlands reported that 95.6% of pregnant women used the Internet as an information source before or during their pregnancy (Jacobs et al., 2019). Thus, the Internet has become a very popular source of health information amongst pregnant women.

Study strengths and limitations

Our research group consisted of four persons with different healthcare backgrounds (physician and nurse-midwives) and considerable experience of antenatal, intrapartum and postnatal care. This provided us with a solid knowledge base and diverse perspectives.

The study provides important knowledge about women's specific information needs in early labour. We recruited at different well-baby clinics at different locations. However, several women who had accepted the invitation did not attend the focus group interviews, hence we ended up with a small-scale convenience sample (Patton, 2015). One possible explanation for why some invited mothers did not attend is that they all had newborn babies. The fact that our participants had newborn babies required special attention. As constraints of the field situation must be taken into account, it may be relatively rare for a project to match all focus group design criteria (Morgan, 1997). Three of our groups only consisted of two participants. In order for this to be characterized as focus groups, there must be a pronounced interaction between the participants (Malterud, 2012a). Out of respect for the respondents, we chose to conduct all focus group interviews as planned, and we experienced both noticeable interaction and rich information in the conversations.

The sample included women living in urban and rural areas, originating from both Western and non-Western cultures, of different socioeconomic status and educational level. We found that the sample provided sufficient information power to elucidate the study aim, thus strengthening the study's validity (Malterud et al., 2016).

The time of recruitment in previous publications on experiences and expectations of early labour spans from a few hours to 20 years after birth (Beake et al., 2018; Eri et al., 2015). However, to our knowledge, no published article on this subject justifies the time of recruitment. We chose to recruit within 3–17 weeks after birth because we wanted to ensure that the women's experiences were still fresh in their memory. However, as it takes time to gain strength, and to be able to reflect after birth, we wanted to allow a few weeks to pass by before we recruited. As mentioned, this time frame might be why some invited mothers did not attend. In addition, it is possible that we recruited women who generally felt OK about early labour, and that some women may not have felt ready to talk at this point.

Implications for practice

We found that the study increased our understanding of how midwives can support women when they stay at home in early labour. Women's birth experiences need continuous attention. Our findings suggest that easy access to a suitable amount of trustworthy information at the appropriate time, along with acknowledgement and support from both midwives and partners or other supporting persons, have a positive impact in reassuring the woman in early labour. Midwives should encourage women to feel the 'door is open', and as women are sensitive to midwives' tone of voice and choice of words, it is vital to pay proper attention to this during telephone calls. However, more knowledge about women's information needs in early labour is required, including studies exploring how the information should be provided to help women feel safe when staying at home in early labour. Additionally, further research should consider including the information needs of the partners.

Conclusion

The women in this study found it challenging to prepare for early labour, and no matter how prepared they felt beforehand, unexpected situations arose. Easily accessed online information from reliable sources was useful in early labour, but in order to feel safe at home it had to be complemented by telephone conversations with skilled and welcoming midwives in the labour ward.

Declaration of Competing Interest

None declared.

CRediT authorship contribution statement

Enid Leren Myhre: Conceptualization, Methodology, Formal analysis, Investigation, Data curation, Writing - original draft, Writing - review & editing, Visualization, Funding acquisition. **Mirjam Lukasse:** Conceptualization, Methodology, Formal analysis, Investigation, Writing - review & editing, Supervision, Project administration, Funding acquisition. **Marte Myhre Reigstad:** Investigation, Writing - review & editing, Supervision, Funding acquisition. **Viggo Holmstedt:** Software, Resources, Writing - review & editing. **Bente Dahl:** Conceptualization, Methodology, Formal analysis, Investigation, Writing - original draft, Writing - review & editing, Supervision, Funding acquisition.

Ethical approval

The study was assessed by the Regional Committee for Medical and Health Research Ethics in South-Eastern Norway (REC: 2018/540) and was considered to be outside the remit of the Health Research Act (2018). The Norwegian Centre for Research Data granted approval for the study (NSD: 60109).

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Supplementary materials

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Paper 2

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Original Paper

Development of and Experiences With an Informational Website on Early Labor: Qualitative User Involvement Study

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Abstract

Background: The period of regular contractions before 4 cm of cervical dilatation is often referred to as the *latent phase* or *early labor*. Women find it challenging to prepare for and cope with this phase of labor, and easily accessed web-based information from reliable sources may be useful in this preparation.

Objective: The aim of this study is to describe the development of a Norwegian website, Latens.no, for people seeking information on early labor and to explore users' experiences with the website to increase its user-friendliness.

Methods: We developed a website using an iterative process involving a multidisciplinary research team, health personnel, users, a graphic designer, and an expert in software development. We explored the website's user-friendliness using semistructured individual interviews and the think-aloud method. All interviews were audio recorded and transcribed. We then analyzed the participants' feedback on the website.

Results: Participants included women who had recently given birth to their first baby (n=2), women who were pregnant with their first baby (n=4), and their partners (n=2). Results from participants' experiences completing tasks included positive feedback related to the content of Latens.no, positive feedback related to the website's design, and suggestions for improvement. Participants wanted to find information on early labor on the internet. Moreover, they found the information on the website relevant, trustworthy, and easy to read, and the design was attractive and easy to use. Overall, the participants performed the tasks easily, with few clicks and minimal effort.

Conclusions: The think-aloud method, while performing tasks, allowed for detailed feedback. The participants confirmed the user-friendliness of the website but at the same time provided information enabling improvement. We expect that changes made based on this user-centered design study will further increase the usability and acceptability of Latens.no.

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KEYWORDS

early labor; latent phase; think aloud; usability; website; labor; pregnancy; user-friendliness; eHealth; user satisfaction

Introduction

Background

The period of regular contractions before 4 cm of cervical dilatation is often referred to as the *latent phase* or *early labor* [1]. This period can be considered a time of conflict between women's perceived need to be cared for and midwives' determination to prevent them from coming to the hospital earlier than necessary. We favor the term *early labor*, as women do not consider labor to consist of different phases [2], and it captures the fact that this phase is actually a part of the labor process.

The duration of early labor differs tremendously: although it can be short for some women, for others, it may continue for hours or even days [3-5]. A lack of satisfaction with care provided in early labor before hospital admission has been reported in prior studies [6,7]. A metasynthesis of experiences from first-time mothers in early labor suggests that women's needs are often not adequately met [7]. The authors describe a mismatch between women's expectations and experiences; in particular, women expressed uncertainty about interpreting signs and symptoms when determining the need for admission [7]. In a systematic review, Beake et al [6] concluded that women, labor companions, and even health professionals found early labor difficult to manage well.

Nevertheless, the National Institute for Health and Care Excellence guidelines recommend that women seeking advice when not in established labor should be encouraged to remain at or return home, unless doing so would lead to severe distress or a significant risk of birth without a midwife present [8]. Although some midwives offer home births in Norway, giving birth in a hospital is the norm. Clinical practice recommendations in Norway state that women in early but not active labor should generally not be admitted to the hospital [9]. This is in accordance with research investigating outcome differences between women presenting at the hospital in early versus active labor [10]. Results from several large studies suggest that hospital admission in early labor is associated with an increased risk of medical interventions, including electronic fetal monitoring [11], epidural analgesia [12,13], oxytocin stimulation [12,13], and cesarean section [12,13].

The National Institute for Health and Care Excellence guidelines recommend educating first-time mothers about early labor [8]. A randomized controlled trial found that women receiving structured antenatal training programs arrived at the maternity ward in active labor more often and used less epidural analgesia than those receiving routine care [14]. Furthermore, a systematic review investigating maternal confidence for physiologic birth suggests that women desire information during pregnancy and want to use that information to participate in care decisions [15]. Altogether, evidence suggests that easy access to relevant and reliable information could be a way of supporting and empowering women to cope with early labor. In addition, educating women's labor companions is recommended to enable them to feel more confident, and thus, provide better support at home [6].

The information needs of first-time mothers during pregnancy seem to be increasing [16,17]. Although knowledge is easily accessible because of advances in information technology, it is important for health professionals to consider the amount and type of information they communicate [16,18]. The increasing use of web-based information requires further research [6]. A systematic review of research on health information needs, sources of information, and barriers to accessing health information among pregnant women found that although several studies have examined the information needs of pregnant women, further qualitative research is recommended to explore pregnant women's perceptions of and satisfaction with the use of health information sources [19].

The PreCare Study

This study was part of the PreCare study (preadmission early labor care: an electronic educational intervention to improve information flow in early labor care and women's preadmission early labor experience). The overall aim of the PreCare study is to develop a web-based educational resource for women in early labor and to test its effectiveness on women's experience of early labor.

The PreCare study began by exploring women's experience with existing information and their knowledge needs in preadmission early labor. The findings suggest that easy access to a suitable amount of trustworthy information at the appropriate time has a positive impact on reassuring women in early labor [20]. Participants did not necessarily need large amounts of information but wished for useful, readily accessible information about the *usual stuff* that was easy to comprehend and relate to [20]. The results from this study informed the initial content of the website Latens.no.

In subsequent studies, we will investigate whether the website improves women's knowledge of early labor, experience in early labor, and explore whether the use of the website affects clinical birth outcomes related to giving birth.

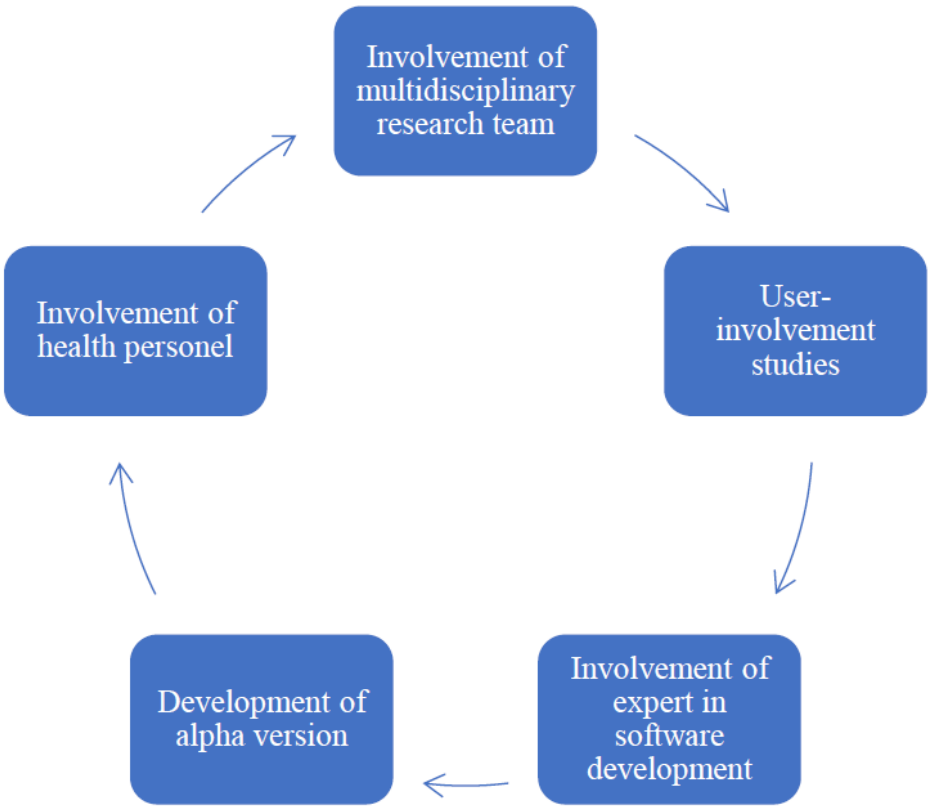
The aim of this study is two-fold: the first objective is to describe the development of Latens.no, whereas the second is to explore users' experiences with the website.

Methods

Development of Latens.no

To secure content quality and increase usability, the website was developed through an iterative process involving a multidisciplinary research team consisting of 3 midwives, a gynecologist, health personnel, people in the target group, and an expert in software development. In addition, the graphic designer provided custom-made illustrations. Figure 1 illustrates the website development process.

Figure 1. Illustration of the iterative process of developing the website.



Multidisciplinary Research Team and Health Personnel Involvement

We created an alpha version of the website with input from the first user-involvement study and discussions among the multidisciplinary research team. The alpha version of Latens.no consisted of a front page with an image and a description of the content, in addition to a top banner with a logo, a menu, and a search option (Multimedia Appendices 1 and 2). From the menu or search option, users could access 10 different pages with relevant content about early labor. All pages had illustrative images, text, and an option to click on subheadings if the user wanted more detailed explanations. The pages also had hyperlinks, both internal hyperlinks linked to related content on Latens.no, and external hyperlinks linking to relevant information, such as information from the World Health Organization. In addition, some pages contained informative images or short videos. The website was assessed by the first author (ELM) with the help of the Suitability Assessment of Materials (SAM) for evaluating health-related information for adults. The SAM provides a validated method for evaluating written health-related education material in terms of the categories and factors known to enhance people's understanding of printed materials [21]. Each factor (content, literacy demand, graphic illustrations and lists, layout and typography, learning stimulation and motivation, and cultural appropriateness) was assessed and deemed either superior, adequate, or not suitable. Changes to Latens.no were made accordingly.

In addition, we asked midwives who work on a daily basis with women in early labor for input by posting the alpha version in a closed Norwegian Facebook group of 76 members (all midwives or nurses and all Norwegian speaking). We requested honest feedback on both content and design. Responses were mainly *likes* or comments such as *this is very good*. However, a few members of the Facebook group provided constructive feedback. In addition, the first author observed that 3 midwives provided oral feedback while they systematically looked through the entire website. Minor revisions were then made based on feedback from the involvement of these health personnel. Changes were mainly aimed at language, such as removing small words that are often associated with something negative (eg, *but* and *unfortunately*) and adding improved explanations for some of the most-used words and phrases.

User Involvement

Initially, we asked the participants to describe their general preferences related to information websites on pregnancy and birth, in terms of both content and design. To assess their experiences using Latens.no, end users then tested an alpha version of Latens.no using the *think aloud* method [22]. By instructing participants to think aloud as they used the website, we aimed to collect participants' mental processing while carrying out a task, to discover potential usability problems. We asked the participants to complete 10 tasks with the help of the website while continuously thinking aloud. The tasks consisted of hypothetical situations that could occur in early

labor (Multimedia Appendix 3). The participants were not given access to the website before the testing started. The testing was completed after a brief follow-up interview to clarify the participants' thinking and possible misunderstandings. All interviews were audio recorded and transcribed verbatim.

Recruitment

Participants were purposely recruited at well-baby clinics in South-Eastern Norway from February to June 2020. Midwives at well-baby clinics invited eligible women and their partners to participate. Owing to the midwives' heavier workload from the COVID-19 pandemic and to limited response rates, we proceeded to recruit via snowball sampling. Initially, women who had recently given birth to their first baby were recruited, along with their partners. However, it soon became apparent that these participants had considerable knowledge on the subject of early labor. This raised concerns about whether they would be critical enough in their feedback on Latens.no. As a result, we continued the testing with the help of women who were pregnant with their first baby and their partners.

Ethical Considerations

The study was conducted in accordance with the World Medical Association Declaration of Helsinki [23]. Participants were advised that participation was voluntary and that they could withdraw from the study at any time without giving reasons. They were provided with information, given time to consider whether they wanted to participate, and informed consent was obtained from all participants. Approval for the study was granted by the Norwegian Centre for Research Data (NSD: 228701).

Data Analysis

We analyzed the data using thematic analysis, following the study by Braun and Clarke [24,25]. In the process of analysis, we did not look for anything beyond what our participants said, instead focusing on identifying themes at a semantic level. We followed Braun and Clarke's five phases of analysis throughout the process. First, after familiarizing ourselves with the data by repeated reading of each informant's transcripts, the first author (ELM) and last author (LGH) generated initial codes. As we coded for as many potential themes as possible, not all initial codes were related to the usability of health information websites. Next, all codes were collated into potential subthemes and main themes before we checked how the themes worked in relation to the initial codes and the entire data set. NVivo was used to identify and organize the codes and themes (version 12; QSR International). We then looked at the overall story of the analyses, searching for themes relevant to the usability of the website. Finally, we agreed on the clear definitions and names of the subthemes and themes. All 5 authors were involved in the end stage of the analysis and discussed the themes until we reached a consensus. We carried out a thematic analysis only on data relevant to how our informants experienced the site.

Results

Overview

A total of 8 participants verbalized their experiences and completed tasks on Latens.no and in think-aloud interviews. The characteristics of the participants are presented in Table 1.

In general, participants expressed a need to find information on early labor on the internet. They talked about the information they had looked for but did not find. In addition, they described the types of information they would appreciate. Some asked for concrete information: for example, about practice and false labor contractions, the duration of early labor, and what to do when contractions start. A few described how they wanted to be reassured that what they were experiencing was normal. The analysis of participants' feedback on Latens.no resulted in three main themes informed by nine subthemes (Textbox 1): positive feedback related to the content on Latens.no, positive feedback related to design, and suggestions for improvement.

Table 1. Characteristics of participants (N=8).

Characteristics	Participants
Age (years), n (%)	
26-30	2 (25)
31-37	5 (63)
38-41	1 (13)
In a partnership, n (%)	
Yes	7 (88)
No	1 (13)
Reason to have knowledge about early labor, n (%)	
Pregnant	4 (50)
Had recently given birth	2 (25)
Partner to pregnant woman	1 (13)
Partner to woman who had recently given birth	1 (13)
Level of education[a], n (%)	
Upper secondary, final year	1 (13)
Postsecondary nontertiary education	1 (13)
First stage of tertiary education, undergraduate level	4 (50)
First stage of tertiary education, graduate level	1 (13)
Second stage of tertiary education (postgraduate education)	1 (13)
Participation of partner in early labor, n (%)	
Partner present	1 (13)
Partner present in some part of early labor	2 (25)
Had not made plans for this	3 (38)
Planned for partner to be present	2 (25)
Device used to access Latens.no, n (%)	
Mobile phone	6 (75)
PC	2 (25)

[a]The Norwegian Standard Classification of Education (NUS2000).

Textbox 1. Main themes and subthemes.

Positive feedback related to content on Latens.no

- The information on Latens.no is relevant
- Latens.no is perceived as trustworthy
- The text on Latens.no is easy to read

Positive feedback related to design on Latens.no

- Colors and images make Latens.no attractive
- Latens.no is clearly structured and easy to use

Suggestions for improvement on Latens.no

- Requests and suggestions for improvement of features
- Requests and suggestions for improved readability
- Negative feedback related to inconsistent layout
- Negative feedback related to images

Positive Feedback on Content

Participants expressed that the information on Latens.no was relevant to them. Some explained how their own experience and knowledge made the information on the webpage more relevant. One participant appreciated that Latens.no contained all necessary information in one place, reducing the need to spend time using Google. This view was echoed by another participant:

> *I think the pages with the drawings and the pictures and the information, it feels like exactly what I would have needed.* [Interview 1]

Trustworthiness was of great importance to our participants when searching for information related to early labor. For instance, 1 participant expressed that she would prefer to receive web-based information about pregnancy and childbirth from health professionals. However, the majority of our participants assessed trustworthiness on other criteria. One participant emphasized that information needed to be up to date (although she did not indicate how she assessed this information). Another commented that typos and misspellings generally ruined the credibility of a website for her. A third noted that websites that looked unprofessional gave her a bad impression. Commenting on the content of Latens.no, one participant explained why she perceived it as trustworthy:

> *Professional, I think. Yeah, I can see that it is made by people who know what they are talking about. There are few typos and things like that.* [Interview 3]

Most of the participants remarked that Latens.no was easy to read. Several said that the fact that it had few unnecessary elements improved readability. One participant used the word *clean* and stated that this made the website comprehensible. Other statements related to the language used on the website. One participant commented that because the text was short, concise, and easy to read, it was easy to locate information. Another participant remarked on how she would return to this website, as opposed to many other websites, when in labor. She said she found the information interesting, and although she could probably find the information other places, Latens.no made it easy to understand. Furthermore, some participants pointed out that the website's use of *layman's terms* made it understandable. One participant reported the following:

> *I found it easy to understand. Not everyone are nurses and medical students and who knows what. So, it was kind of easy to understand it. At the same time, it wasn't written in kindergarten language. So, it was really easy to understand.* [Interview 7]

Positive Feedback on Design

Many participants provided positive feedback related to the design of Latens.no. When asked about images, one individual answered that he did not notice the images but still enjoyed the design. Several others commented on how they appreciated the images and said they found a suitable amount on Latens.no. Furthermore, several participants remarked that Latens.no had a pleasant design. One participant argued that its clean design was attractive, whereas others proposed that its feminine design was suitable for the target group. Several participants also expressed that the use of colors in Latens.no was appealing. For example, one participant reported the following:

> *It has a pleasant design, I must say. Yes. It has pleasant colors that suit—I think it really suits the subject.* [Interview 4]

As with other websites, participants valued that Latens.no was easy to navigate; they found it to be clearly structured and easy to use. Some noted that the headings and subheadings were clear, which made it easy to navigate. A few participants stated that the search engine was easy to use, and one explained that she liked that the content was categorized. Others simply said that information was easily obtained. One participant said she found it encouraging and reassuring that Latens.no was so easy to navigate. When asked to suggest modifications, one participant reported the following:

> *I do not think it should be modified too much. Because it can easily become too much. You have a menu. And you have your headings and subheadings—or, like, points—and then explanations beneath the points.* [Interview 6]

Suggestions for Improvement

Despite the overall positive response, there were suggestions on how to improve Latens.no. Some recommendations were related to improvements in the design features. One participant mentioned that the menu was plain and suggested the use of bullet points or colors, whereas others argued that it was not clear that the subheadings were clickable. A total of 2 participants remarked that they misunderstood the *contact information* section, with 1 participant suggesting that it was added to the menu. A total of 2 participants experienced difficulties in using the search engine. Some participants expressed a need to receive information from a *partner perspective* on what to do, what to expect, and what is happening, and another expressed a desire for separate information for women and partners:

> *Yes, you could separate the practical information, like you have one with practical information for the woman, and one with practical information for the guys, or whoever it is. Separate them, maybe? Or "What can I do to feel better at home?"—I reckon that one is meant for the one who is giving birth. So maybe it could be clear instructions on what you can do as a father, or, yes.* [Interview 2]

Other suggestions were related to readability. Some participants suggested that the font size was too small. Another commented that she noticed some spelling mistakes. One participant suggested that the front page could be *bigge*r, with more images, and 2 participants indicated that it contained too much text:

> *It was a bit like, when you first enter the website, there is a lot of information, right there. It is a bit, it looks a bit much.* [Interview 7]

The participants gave negative feedback related to the images on Latens.no. One participant noted that the text placed across

images could be hard to read, and another felt that the images might be too large. Another suggested the use of more images:

> *I am a fan of pictures. So, there could probably be more pictures. Because, yes, for us that are visual.* [Interview 3]

Finally, the website's inconsistent layout was critiqued. One participant pointed out the use of different font sizes and inconsistent formatting of subheadings:

> *A thing that bothers me a little bit, kind of like, that it has different text fonts.* [Interview 8]

Observations During Tasks

The interviews lasted an average of 14 minutes, with a range of 9-23 min; in most of this time, participants used the website. The participants continuously verbalized how they navigated the website while performing the tasks they were given. Therefore, a part of our empirical material consists of descriptions of what they were looking at and how they were navigating the site. All participants referred to the menu many times during the test. There are numerous quotes similar to this example (the participant was asked to find out what to bring to the hospital):

> *Let me see. I enter the menu again. And then I look at the list of links. Let me see. And then I click the link called "practical information," and there I see a packing list. So I found it there.* [Interview 4]

The search option was also frequently mentioned. Many found what they were looking for by performing simple searches. As noted earlier, however, 2 participants experienced difficulties in searching:

> *Then I simply search "blood on toilet paper." I am thinking that might be wise. No, I don't know if it will perform the search? Or am I doing something wrong? I don't think it will perform the search.* [Interview 5]

Overall, participants performed the tasks easily, with few clicks and minimal effort, and our empirical material contains many quotes, such as the following:

> *It was very easy to find, really.* [Interview 3]

Adjustments Informed by Study Findings

Latens.no was refined based on feedback from the interviews and think-aloud results (Multimedia Appendices 4-6). The search option was optimized, minor alterations were made to the menu, and small adjustments were made on the front page. We increased the font size to improve readability, and an additional round of proofreading was conducted to eliminate any spelling mistakes. We adjusted the subheadings, removed text across images, and made minor revisions to the image sizes. Although we received some feedback related to the number of images, we decided to keep the original number of images because several participants stated that the website's simplicity improved its readability. Finally, as Latens.no already contained separate information for women and partners, we made no adjustments related to this.

Discussion

Principal Findings and Comparison With Prior Work

The purpose of this study was to describe the development of a website with information on early labor and to explore the experiences of women and their partners using the website. All of the participants wanted to find information on early labor using the internet; moreover, they found the information on Latens.no relevant, trustworthy, and easy to read, and the design was attractive and easy to use.

The finding that all our participants had a desire to find information on early labor using the internet corresponds with findings reported in the first article in the PreCare study [20]; it also broadly supports the findings of other studies in this area [16,17,19,26]. As mentioned in the introduction, there appears to be an increasing need among first-time mothers for information about early labor [16,17]. The internet is an attractive option for obtaining pregnancy-related information because of its convenience, availability, and anonymity [27]. In a systematic review, Ghiasi et al [19] identified digital media as one of the most common health information sources for women during pregnancy. A descriptive cross-sectional study on the internet behavior of women who were pregnant or trying to conceive found that 95.6% of their participants used the internet as an information source before or during their pregnancy [26]. In line with previous studies, our participants searched the internet for both concrete information and reassurance that what they were experiencing was normal [26,28-30]. Finding various kinds of information related to contractions was frequently mentioned by our participants. This was also among the main topics that women searched for in other studies [29]. However, Bjelke et al [28] found that the primary reason pregnant women search the internet is to find information and read about people in the same situation, which is consistent with our finding that the women in our study wanted reassurance that what they were experiencing was normal. As noted earlier, we recruited both women who had recently given birth to their first baby and their partners, but we ultimately focused on women who were pregnant with their first baby and their partners. As such, many of our participants were first-time mothers and their partners. It is recommended that first-time mothers receive education about early labor through antenatal care [8]. However, they might need additional information, and previous studies on internet use among pregnant women indicate that first-time mothers are more likely to seek advice than multiparous women [29,30].

A meta-analytic review of tailored print health behavior change interventions demonstrated that personally relevant websites were more effective [31]. This corresponds to our study, in which a key finding was that participants found information on Latens.no useful and relevant. This may be because of user involvement from the beginning of the website's development. In their systematic review on the usability and effectiveness of mobile health technology, Overdijkink et al [32] recommended that the development of new health technology should be done together with the target group. Another reason the content was perceived as relevant could be that we had involved health

personnel who work clinically with women in early labor. This finding is encouraging and shows that Latens.no has the potential to be an effective web-based educational resource for women in early labor.

Our participants were concerned about trustworthiness, and indeed they generally found information on Latens.no to be trustworthy. In previous web-based studies, only approximately half of the pregnant women trusted the information they found [30]. In contrast, in a systematic review of internet use by pregnant women seeking information, the authors suggest that the majority of pregnant women with higher education perceive web-based health information to be trustworthy [29]. As the overall level of education among our participants was high, this may explain why our participants found information on Latens.no trustworthy.

The overall high level of education might also explain another important finding: our participants found the information on Latens.no easy to read. Vamos et al [33] explored women's experiences of accessing, understanding, appraising, and applying health information during pregnancy; they found that "women understand information best when visuals, statistics, tailored message and plain language is used." This may explain our findings and indicate that the efforts made in developing the website were effective: the use of custom-made illustrations, user involvement from the beginning to help tailor the message, and the SAM to ensure the use of plain language with appropriate writing style and sentence construction. Nevertheless, the content on Latens.no was written by health personnel, and previous research indicates that there may be a discrepancy between how providers and patients perceive language use on websites [34]. As such, it was reassuring that the target users found it easy to read.

Although we had refined the design of Latens.no using the SAM [21], our opinion on the visual appearance was that it was quite simplistic; as such, we expected to receive input on this aspect of the design. In contrast to our expectations, however, few participants received negative feedback regarding the quality of the design. Instead, the findings show overall positive feedback on design, and our participants found Latens.no to be easy to navigate, with an easy-to-use and clear structure. This might be a consequence of the SAM refinement, in which graphic illustrations, lists, layout, and typography were all tailored to best *fit* the users. These results are in line with previous studies evaluating the feasibility and acceptability of mobile health lifestyle and medical apps to support health care during pregnancy in high-income countries [32]. In their systematic review, the authors found that mobile health technology is often judged to be good, easy, and simple to use [32].

Finally, despite the limited negative feedback, minor adjustments made as a result of this study resulted in a more professional-looking website.

Strengths and Limitations

We consider it a strength that both LGH and ML have conducted several similar studies [35,36]. One limitation of this study is that it was conducted with a small sample, as is typical of qualitative studies [22]. We chose to apply the think-aloud method at the end of the qualitative interviews, as this is a widely used and accepted method of user involvement [37]. Latens.no is intended to function as a source of information not only in pregnancy but also during early labor; therefore, another limitation of this study is that we did not explore how our participants experienced Latens.no when in early labor. However, this was intended, as we did not want to impose a burden on our participants. Moreover, even though women's partners were recruited alongside the women, there were more women than men in the sample. However, all participants gave information-rich and detailed descriptions of their experiences with Latens.no, and we see our inclusion of even a limited number of partners as a strength. Previous research on internet use in pregnancy has focused primarily on pregnant women [29,30,32]. However, the partner is potentially an important resource in pregnancy and birth and should be included to a greater extent in further research. A final limitation is that non-Norwegian-speaking women were excluded from the study because Latens.no is currently available only in Norwegian.

Conclusions

The think-aloud method while performing tasks allowed for detailed feedback. The participants both confirmed the user-friendliness of the website but at the same time provided information enabling improvement.

We expect that changes made based on this user-centered design study will further increase the usability and acceptability of Latens.no. This website's influence on women's experience of early labor and on several obstetric outcomes will be tested in a prospective *before and after* the intervention study.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Screenshot of the front page (alpha version).
[PNG File , 144 KB-Multimedia Appendix 1]

Multimedia Appendix 2

Screenshot of the front page (alpha version), including menu and search function.
[PNG File , 167 KB-Multimedia Appendix 2]

Multimedia Appendix 3

Interview guide.
[DOCX File , 25 KB-Multimedia Appendix 3]

Multimedia Appendix 4

Screenshot of the front page (final version).
[PNG File , 104 KB-Multimedia Appendix 4]

Multimedia Appendix 5

Screenshot of the front page (final version), scrolled down.
[PNG File , 149 KB-Multimedia Appendix 5]

Multimedia Appendix 6

Screenshot of the front page (final version), including menu and search function.
[PNG File , 129 KB-Multimedia Appendix 6]

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Abbreviations

SAM: Suitability Assessment of Materials

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Paper 3

Myhre EL, Lukasse M, Dahl B, Reigstad MM. Early labour experience and labour characteristics after introduction of an electronic early labour educational intervention. Sex Reprod Healthc. In review.

Early labour experience and labour characteristics after introduction of an electronic early labour educational intervention

Introduction

Early labour can be defined as a period with painful contractions and cervical change, including cervical effacement and dilatation up to 5 cm [1]. In the literature, early labour is often referred to as the latent stage of labour [1, 2]. However, women do not consider labour to consist of different phases [3], thus we favour the term 'early labour', as it captures the fact that this phase is part of the labour process.

There is no established standard duration for early labour [1]. For some, it is short, while for others it may continue for hours and even days [4]. Women's experience with their early labour has received increased attention in recent years, and both a metasynthesis and a systematic review report a lack of satisfaction with the care given in early labour prior to hospital admission [5, 6]. However, results from several large studies suggest that hospital admission in early labour is associated with increased risk of medical interventions [7-9]. In accordance with NICE (National Institute for Health and Care Excellence) guidelines, clinical practice recommendations in Norway specify that women in early but not active labour should generally not be admitted to hospital [2, 10-11].

A randomized trial found that women receiving structured antenatal education programmes arrived at the maternity ward in active labour more often and used less epidural analgesia than those receiving standard care [12]. Evidence also suggests that easy access to relevant and reliable information could be a way of empowering and supporting women to better manage early labour, and participate actively in care decions as women desire information during pregnancy and want to use that information to participate in care decisions [13]. Further, information should be shared with

women's labour companions to enable them to feel more confident and thus provide better support at home [5].

NICE recommends that one-to-one information provision should be supplemented in other formats, such as digital information [14]. While advances in information technology make knowledge easily accessible, the increasing use of web-based information needs further research [5]. In a systematic review of research on health information needs, sources of information and barriers to accessing health information among pregnant women, the authors conclude that more research is warranted [15].

Valid feedback from women about their experiences of care is crucial for evaluating labour care quality. The Early Labour Experience Questionnaire (ELEQ) was developed to assess primiparous women's affective experiences and satisfaction with early labour care [16]. As the ELEQ was validated in a Canadian setting, Swedish researchers subjected it to further testing in a Swedish setting on primiparous and multiparous women [17]. Their findings suggest that the Swedish versions of the ELEQ are considered valid questionnaires for use in a Swedish setting; however, they suggest confirmatory factor analysis for further validation of the questionnaire [17]. To our knowledge, the ELEQ is the only valid questionnaire measuring early labour care. As labour care in Norway and Sweden is quite similar, we chose to apply the SWE-ELEQ-PP (the Swedish version of the ELEQ for primiparous women) in our sample, and to initially perform confirmatory factor analysis to test the dimensional structure in an additional population.

The PreCare study

This study is part of the PreCare study, whose overall aim is to develop a web-based educational resource for women in early labour and to test how it affects women's experience of early labour [18, 19].

The first part of the PreCare study explored women's experience with existing information and their knowledge needs in pre-admission early labour [19]. Findings from this study were used to build the

content of the website Latens.no, which was then developed through an iterative process involving a multidisciplinary research team, health personnel, users, a graphic designer, and an expert in software development [18].

The aim of the current study was twofold: to compare first-time mothers' experience of early labour and subsequent labour characteristics before and after introducing an electronic early labour educational intervention; and to evaluate the SWE-ELEQ-PP, to test how well the relationship between the observed variables and their underlying latent constructs fit our population.

Materials and Methods

Procedure and participants

A before-and-after study was conducted at Oslo University Hospital, Ullevål for three months in 2019 and 2020. The pre-intervention cohort was recruited January–April 2019, and the post-intervention cohort was recruited September–December 2020. Women considered eligible for participation included nulliparous women with one foetus in cephalic lie ≥ 37 weeks gestation and a spontaneous start of labour, who stayed home for some part of their early labour. Exclusion criteria included pre-existing or arising conditions in pregnancy that precluded staying at home in early labour, and non-Norwegian speaking women. Women considered eligible were invited to participate in the study and asked for consent during their postpartum stay at the hospital. Completed questionnaires were retrieved on the same or the following day. Data related to labour characteristics were retrieved retrospectively from the medical record system 'CSAM Partus' using an identification key.

Intervention

Latens.no is a web-based educational intervention. It consists of a website with easy-to-access, free-of-charge, high-quality relevant information and advice related to early labour, and is openly available online [20]. Topics covered on the website include information and advice related to early labour. For example, the differences between Braxton Hicks contractions and labour contractions,

and descriptions of what happens in early labour are explained in various formats. In addition, the website offers advice on several topics (e.g., 'How to Feel Better at Home', 'Movement and Rest' and 'When Do I Call the Hospital?') [20]. The website is considered a supplement to standard care, and it is repeatedly stated across the website that telephone calls are welcomed by the midwives when in early labour. The website was launched in July 2020, and information about it was widely distributed to the target group through text messages, flyers, and health personnel.

Measurement/the SWE-ELEQ-PP

An exploratory factor analysis of the Swedish version of the ELEQ for primiparous women presented a three-factor solution—emotional well-being, emotional distress, and perceptions of midwifery care—with 23 items [17]. Cronbach's α ranged from 0.81 to 0.86, indicating good internal consistency [17].

Permission to translate and use the ELEQ was obtained from Janssen et al. and Ängeby et al. [16, 17]; both versions were translated into Norwegian and checked via back-translation. The Norwegian version is quite similar to the Swedish version, since the Norwegian and Swedish languages and labour care systems are closely related. As in the Swedish study [17], the item 'Would you recommend this type of early labour to a friend' was removed before translation, because no alternative treatment options for childbirth are available in Norway. Similarly to Sweden, midwives are responsible for care in Norway's labour wards; 'nurse' was thus translated to 'midwife' throughout. All items were rated on a five-point Likert scale ranging from 1 ('Yes, definitely') to 5 ('Not at all'). All items were recorded such that a higher value represented a more positive rating. To ensure that women were evaluating the care they received *prior* to hospital admission, the following instruction was given: 'Please answer these questions in relation to the time you spent in early labour before you came to the hospital'.

The Norwegian version was piloted by 15 women who had recently given birth (none of whom were included in the study). The pilot test showed that the overall questionnaire was acceptable and

97 understandable in Norwegian. However, several respondents remarked that Q22 ('Did the midwife
98 and the doctor work as a team in providing your care?'), was difficult to answer; an 'I don't know'
99 option was therefore added to the answers for this question.

100 Ethical considerations

101 The study was conducted in accordance with the World Medical Association's Declaration of Helsinki
102 [21], and approval for the study was granted by the Norwegian Centre for Research Data (NSD:
103 107878) and the local data protection official at Oslo University Hospital (18/12350). Participants
104 were informed that participation was voluntary and that they could withdraw at any time without
105 giving reasons and without it affecting their care. They were provided with written and oral
106 information and given time to consider whether they wanted to participate, and informed consent
107 was obtained from all participants.

108 Statistical analyses

109 IBM's Statistical Software Package for the Social Sciences (SPSS, Version 26) was used for all the
110 descriptive analyses. Confirmatory factor analysis was performed in Stata.

111 An independent-samples *t*-test was run to determine if there were differences in age and pre-
112 pregnancy BMI between pre-/post-intervention participants. Chi-square tests were conducted
113 between pre-/post-intervention participants and marital status, education, total family income,
114 working status of participant, country of birth and mother tongue, as expected cell frequencies were
115 greater than five. A Fisher's exact test was conducted between pre-/post-intervention participants
116 and partner's employment status. Standard linear regression was used to control for potential
117 confounding factors.

118 Pre-/post-intervention groups were compared in 'intention-to-treat' analyses. Given the answer
119 options on the questionnaire, answers were treated as continuous variables and analysed via
120 independent *t*-test and Levene's test of variances. One questionnaire in the post-intervention group
121 had 3 unanswered questions (12%). Two (1 in each group) had 2 unanswered questions (8%), and 19

questionnaires (9 in the pre-intervention group, 10 in the post-intervention group) had 1 unanswered question (4%). Missing data were not systematic in relation to items. As per the developers' suggestion, the questionnaire with 10% or more of the items unanswered was removed before analysis [16], resulting in 174 participants in the pre-intervention group and 178 in the post-intervention group. For the remaining unanswered questions, data were imputed using the mean of all responses to that item, as suggested by constructors of the ELEQ [16]. After pilot-testing suggested that Q22 was difficult to answer, 'I don't know' was added as an option, as we had translated the middle option on the Likert scale to *verken eller* (meaning 'neither/nor')— 37.1% of our respondents chose this option, imputed as 'neither/nor' in the analysis.

When analysing participants' labour characteristics, independent-samples *t*-tests were run to determine whether there were differences in cm dilatation upon admission, time from first telephone contact to admission and number of telephone consultations in early labour between pre-/post-intervention participants. Chi-square tests were conducted between pre-/post-intervention participants and number of women who visited the hospital prior to admission, number of visits to labour ward prior to admission, mode of delivery, use of epidural analgesia and use of oxytocin. The statistical significance was assumed at p level < 0.05 throughout [22].

Confirmatory factor analyses (CFA) enabled us to test the SWE-ELEQ-PP, based on the previous exploratory factor analyses study [17] performed among a similar population. The model tested was estimated through covariance matrices using maximum likelihood estimation. Model fit was assessed through fit statistics, with the root mean square error of approximation (RMSEA) ≤ 0.08, standardized root mean square residual (SRMR) ≤ 0.08, comparative fit index (CFI) ≥ 0.95 and Tucker-Lewis index (TLI) ≥ 0.95 [23]. The Cronbach's α coefficient values were used to assess the internal consistency reliability, and values > 0.70 were regarded as desirable [24].

Results

Table 1 describes the participants' characteristics. The sample consisted of 352 women: 174 who were recruited before Latens.no was launched (pre-intervention), and 178 who were given access to Latens.no (post-intervention). The response rate was 90.2% in the pre-intervention cohort and 86.5% in the post-intervention cohort. There was no statistically significant difference between pre-/post-intervention participants in terms of marital status, total family income, working status, country of birth and mother tongue. As Table 1 shows, participants in the post-intervention group had a significantly higher educational level than those in the pre-intervention group (p = 0.03). However, in a linear regression model, education did not have a confounding effect on the outcome.

Table 1. Background characteristics of the Pre- and Post-Intervention Participants in the PreCare Study (N = 352).

		Study group			
		Pre-intervention (n = 174)	Post-intervention (n = 178)	Total (N = 352)	p value*
Age in years (M ± SD)		31.2 ± 3.8	31.3 ± 3.3	31.3 ± 3.6	0.73
Pre-pregnancy BMI of participant (M ± SD)		22.4 ± 3.2	22.6 ± 3.0	22.5 ± 3.1	0.71
Use of cigarettes or snus in pregnancy (n. %)					0.45
	Yes	2 (1.1)	5 (2.8)	7 (2.0)	
	No	171 (98.3)	172 (96.6)	343 (97.4)	
	Missing	1 (0.6)	1 (0.6)	2 (0.6)	
Marital status (n. %)					0.95
	Co-habiting	113 (64.9)	114 (64.0)	227 (64.5)	
	Married or other	61 (35.1)	64 (36.0)	125 (35.5)	
	Missing	0	0	0	
Education (n. %)					0.03
	Secondary or grammar school	21 (12.1)	9 (5.1)	30 (8.5)	
	Higher education	153 (87.9)	169 (94.9)	322 (91.5)	
	Missing	0	0	0	
Total family income (n. %)					0.43
	0–400,000	8 (4.6)	7 (3.9)	15 (4.3)	
	400,000–700,000	23 (13.2)	19 (10.7)	42 (11.9)	
	700,000–1,000,000	43 (24.7)	37 (20.8)	80 (22.7)	
	>1,000,000	93 (53.4)	114 (64.4)	207 (58.8)	
	Missing	7 (4.0)	1 (0.6)	8 (2.3)	
Working status of participant (n. %)					1.00
	Yes	165 (94.8)	170 (95.5)	335 (95.2)	
	No	8 (4.6)	8 (4.5)	16 (4.5)	
	Missing	1 (0.6)	0	1 (0.3)	

Working status of partner (n. %)					0.50
	Yes	167 (96.0)	171 (96.1)	338 (96.0)	
	No	3 (1.7)	6 (3.4)	9 (2.6)	
	Missing	4 (2.3)	1 (0.6)	5 (1.4)	
Country of birth (n. %)					0.22
	Norway	125 (71.8)	141 (79.2)	266 (75.6)	
	Other	46 (26.4)	37 (20.8)	83 (23.6)	
	Missing	3 (1.7)	0	3 (0.9)	
Mother tongue (n. %)					0.16
	Norwegian	127 (73.0)	145 (81.5)	272 (77.3)	
	Other	43 (24.7)	33 (18.5)	76 (21.6)	
	Missing	4 (2.3)	0	4 (1.1)	

**p value analysed with independent-samples* t*-tests and Levene's test of variances or chi-square/Fisher's exact tests accordingly*

Table 2 presents all the items on the SWE-ELEQ-PP with mean and standard deviation, and a comparison between the pre- and post-intervention groups. Neither overall score (as measured by the SWE-ELEQ-PP total score) nor the scores on the emotional well-being subscale, the emotional distress subscale or the perceptions of midwifery care subscale differed significantly between the groups. The item measuring whether they felt relaxed while in early labour at home was significantly higher among women in the post-intervention group (3.23 ± 1.14 vs. 3.52 ± 1.11, $p = 0.02$). However, the items measuring whether the midwife listened carefully to what they had to say (4.60 ± 0.68 vs. 4.37 ± 1.01, $p = 0.01$), treated their family and/or friends respectfully (4.77 ± 0.54 vs. 4.43 ± 0.92, $p < 0.001$) and treated them rudely (4.66 ± 0.85 vs. 4.40± 1.13, $p = 0.01$), were significantly higher among women in the pre-intervention group (Table 2).

Table 2. Descriptions and Comparisons Between Items Related to Pre- and Post-Intervention Women's Perceptions of Early Labour in the PreCare Study (N = 352).

	Pre-intervention		Post-intervention		
	Mean (SD)	Range	Mean (SD)	Range	*p* value*
Emotional well-being	**24.72 (5.16)**		**25.34 (4.90)**		**0.25**
While you were in labour at home did you feel:					
Q4: Happy?	3.52 (1.15)	1–5	3.40 (1.21)	1-5	0.34
Q1: Safe?	4.07 (0.95)	1–5	4.16 (0.89)	1-5	0.39
Q5: Excited?	4.43 (0.84)	1–5	4.49 (0.77)	1-4	0.48
Q8: Comfortable?	2.93 (1.30)	1–5	3.03 (1.23)	1-5	0.42
Q7: Relaxed?	3.23 (1.14)	1–5	3.52 (1.11)	1-5	0.02
Q2: Confident?	3.40 (1.04)	1–5	3.39 (1.10)	1-5	0.92
Q13: In control?	3.14 (1.13)	1–5	3.36 (1.11)	1-5	0.07
Emotional distress	**14.34 (3.08)**		**14.16 (3.30)**		**0.59**
While you were in labour at home did you feel:					
Q14: Confused?	3.37 (1.33)	1–5	3.38 (1.41)	1-5	0.93
Q3: Scared?	3.38 (1.20)	1–5	3.29 (1.24)	1-5	0.51

Q9: Tense?	4.59 (0.77)	1–5	4.55 (0.74)	1-4	0.63
Q11: Anxious?	3.01 (1.25)	1–5	2.93 (1.24)	1-5	0.58
Q6. Distressed?	2.60 (1.16)	1–5	2.67 (1.22)	1-5	0.56
Q12: Insecure?	2.49 (1.14)	1–5	2.48 (1.22)	1-5	0.93
Perceptions of midwifery care	**44.05 (5.06)**		**42.78 (6.81)**		**0.05**
When you were at home in early labour, and had telephone contact or were on a visit before, did the midwife:					
Q15: …give you the information you wanted?	4.43 (0.74)	2–5	4.33 (0.95)	1-5	0.31
Q16: …reassured you when you needed it?	4.20 (0.88)	2–5	4.07 (1.10)	1-5	0.23
Q17: …spend enough time with you?	4.47 (0.84)	2–5	4.40 (0.98)	1-5	0.50
Q18: …listen carefully to what you had to say?	4.60 (0.68)	2–5	4.37 (1.01)	1-5	0.01
Q19: …treat your family and/or friends with respect?	4.77 (0.54)	2–5	4.43 (0.92)	1-5	< 0.001
Q20: …respect your wishes about going to the hospital?	4.31 (1.01)		4.12 (1.15)	1-5	0.10
Q21: …did you feel that you had confidence in the midwife?	4.29 (0.92)	2–5	4.26 (1.02)	1-5	0.73
Q22: …did the midwife and the doctor work as a team in providing your care?	3.57 (0.92)	1–5	3.65 (1.05)	1-5	0.47
Q23: …did you feel that the midwife always was at ease and calm with you?	4.75 (0.60)	2–5	4.76 (0.59)	1-5	0.86
Q24: …do you feel that the midwife treated you in a rude way?	4.66 (0.85)	1–5	4.40 (1.13)	1-5	0.01
Single items					
Q10: While you were in labour at home did you feel supported?	4. 67 (0.60)	2–5	4.75 (0.59)	1-5	0.23
Q25: Did you feel you went to the hospital at the right time?	4.28 (1.14)	1–5	4.10 (1.32)	1-5	0.18
Total score	**97.14 (12.85)**		**96.28 (13.62)**		**0.54**

**p value analysed with independent* t*-test and Levene's test of variances. Note: All items were recorded such that a higher value represented a more positive rating*

Clinical labour characteristics related to giving birth are presented in Table 3. The cervix was significantly more dilated at time of admission in the post-intervention group (4.1 ± 2.2 vs. 5.1 ± 2.3, $p < 0.001$) and we found significantly reduced use of oxytocin in the post-intervention group, with 59.2% using it pre-intervention, and 44.4% using it post-intervention ($p = 0.006$). Additionally, the number of telephone consultations increased significantly after the intervention was introduced (2.3 ± 1.0 vs. 2.6 ± 1.3, $p = 0.01$) (Table 3).

Table 3. Labour Characteristics of the Pre- and Post-Intervention Participants in the PreCare Study (N = 352).

	Pre-intervention (*n* = 174)	Post-intervention (*n* = 178)	Total (N = 352)	*p* value*
Cm dilatation on admission M ± SD	4.1 ± 2.2	5.1 ± 2.3	4.6 ± 2.3	< 0.001
Time from first telephone contact to admission (in minutes) M ± SD	745 ± 718	795 ± 864	770 ± 794	0.55

Number of telephone consultations in early labour M ± SD		2.3 ± 1.0	2.6 ± 1.3	2.5 ± 1.1	0.01
Number of women who visited the hospital prior to admission (n. %)					0.60
	Yes	63 (36.2)	59 (33.1)	122 (34.7)	
	No	110 (63.2)	119 (66.9)	229 (65.1)	
	Missing	1 (0.6)	0	1 (0.3)	
Number of visits to labour ward prior admission (n. %)					0.40
	0 visits	110 (63.2)	119 (66.9)	229 (65.1)	
	1 visit	48 (27.6)	50 (28.1)	98 (27.8)	
	More than 1 visit	15 (8.6)	9 (5.1)	24 (6.8)	
	Missing	1 (0.6)	0	1 (0.3)	
Mode of delivery (n. %)					0.26
	Vaginal delivery	125 (71.8)	134 (75.3)	259 (73.6)	
	Operative vaginal delivery	35 (20.1)	37 (20.8)	72 (20.5)	
	Caesarean section	13 (7.5)	7 (3.9)	20 (5.7)	
	Missing	1 (0.6)	0	1 (0.3)	
Use of Epidural analgesia (n. %)					0.13
	Yes	126 (72.4)	115 (64.6)	241 (68.5)	
	No	47 (27.0)	63 (35.4)	110 (31.3)	
	Missing	1 (0.6)	0	1 (0.3)	
Use of oxytocin (n. %)					0.006
	Yes	103 (59.2)	79 (44.4)	182 (51.7)	
	No	70 (40.2)	99 (55.6)	169 (48)	
	Missing	1 (0.6)	0	1 (0.3)	

**p value analysed with independent-samples* t*-tests and Levene's test of variances or chi-square test accordingly*

Overall, the CFA showed an acceptable fit. Goodness-of-fit statistics revealed that the CFI (0.839) and the TLI (0.820) are below what is considered acceptable, but the RMSEA (0.078) and SRMR (0.067) were within acceptable ranges—indicating that the three factors obtained from the SWE-ELEQ-PP can be validated. Reliability testing using Cronbach's α resulted in 0.79 for emotional well-being, 0.77 for emotional distress, 0.86 for perceptions of midwifery care and 0.88 for the total score.

However, the CFA indicated a poor fit of Q9. All factor loadings were between 0.31 and 0.80—except for Q9, with a factor loading of 0.19—and all factor loadings were statistically significant ($p \leq 0.001$): i.e., they were significantly contributing in terms of the definition of their respecting factors. The R^2 values were between 0.10 and 0.65, except Q9, which had an R^2 of 0.03. The overall R^2 was 0.99 (Table 4).

Table 4. Confirmatory Factor Analysis of the Swedish Version of the Early Labour Experience Questionnaire for Primiparous Women (SWE-ELEQ-PP) (N = 352).

	Cronbach's α	Std. factor loading	*p* value	R^2
Emotional well-being	0.79			
While you were in early labour at home did you feel:				
Q4: Happy?		0.45	< 0.001	0.21
Q1: Safe?		0.64	< 0.001	0.41
Q5: Excited?		0.31	< 0.001	0.10
Q8: Comfortable?		0.58	< 0.001	0.34
Q7: Relaxed?		0.67	< 0.001	0.45
Q2: Confident?		0.72	< 0.001	0.51
Q13: In control?		0.70	< 0.001	0.49
Emotional distress	0.77			
While you were in early labour at home did you feel:				
Q14: Confused?		0.56	< 0.001	0.31
Q3: Scared?		0.68	< 0.001	0.46
Q9: Tense?		0.19	0.001	0.03
Q11: Anxious?		0.71	< 0.001	0.51
Q6. Distressed?		0.71	< 0.001	0.51
Q12: Insecure?		0.72	< 0.001	0.52
Perceptions of midwifery care	0.86			
When you were at home in early labour, and had telephone contact or were on a visit before, did the midwife:				
Q15: …give you the information you wanted?		0.79	< 0.001	0.62
Q16: …reassured you when you needed it?		0.80	< 0.001	0.65
Q17: …spend enough time with you?		0.72	< 0.001	0.52
Q18: …listen carefully to what you had to say?		0.74	< 0.001	0.55
Q19: …treat your family and/or friends with respect?		0.50	< 0.001	0.25
Q20: …respect your wishes about going to the hospital?		0.61	< 0.001	0.38
Q21: …did you feel that you had confidence in the midwife?		0.74	< 0.001	0.55
Q22: …did the midwife and the doctor work as a team in providing your care?		0.46	< 0.001	0.21
Q23: …did you feel that the midwife always was at ease and calm with you?		0.36	< 0.001	0.13
Q24: …do you feel that the midwife treated you in a rude way?		0.36	< 0.001	0.13
Overall	0.88			0.99

Latent variable covariances

	Emotional well-being	Distress	Perceptions of midwifery care
Emotional well-being	1.00		
Distress	0.83	1.00	
Perceptions of midwifery care	0.37	0.38	1.00

Discussion

Overall results from the SWE-ELEQ-PP are unable to demonstrate that Latens.no improved early labour experience. However, when assessing the labour characteristics, we found that women in the post-intervention group presented at the labour ward with greater cervical dilatation than the pre-intervention group. Women in the post-intervention group also received less oxytocin during labour. Moreover, the number of telephone consultations increased significantly after the intervention was introduced. The CFA of the SWE-ELEQ-PP is within an acceptable fit, despite the poor fit of one item.

While this study was unable to show that introducing an online early labour educational intervention improved women's early labour experience when measured with the ELEQ, it might be argued that a null finding is positive, in light of recent research on pregnant women's mental health during COVID-19. Our pre-intervention cohort in this study was recruited pre-COVID-19, and our post-intervention cohort was recruited during the second wave in Norway. A systematic review of perinatal mental health outcomes during COVID-19 indicates an increase in depressive and anxiety symptoms in pregnant and postpartum women [25]; the authors suggest that perinatal women were faced with a heightened sense of unpredictability and uncertainty, increased stress and decreased practical and emotional support. All of the aforementioned factors may impact women's experience of early labour [26]. Additionally, COVID-19 has resulted in shifts in hospital guidelines, limiting the partner's presence at the hospital; this, in turn, may have resulted in unmet support expectations, with a subsequent negative experience for women.

Our results also show that women in the pre-intervention group scored significantly more positively on three of the questions related to midwifery care: whether the midwife listened carefully to what they had to say, treated their family and/or friends respectfully or treated them rudely. This may be explained by the fact that COVID-19 brought on changing care guidelines, possibly affecting how women in the post-intervention group perceived perinatal care. Alternatively, evidence suggests that when technology is used in healthcare services, the satisfaction of the therapeutic relationship between the healthcare professional and the individual may decrease [14]. Technology has the

potential to lessen social interaction, thus increasing feelings of anxiety, loneliness, and disconnection—this may also have played a part in reducing patient satisfaction in these three areas, following the introduction of Latens.no.

Participants with access to Latens.no felt significantly more relaxed while in early labour at home compared to participants in the pre-intervention group. This finding is somewhat surprising, given that other research shows an uptick in distress among pregnant women during COVID-19 [25, 27]. Although this only concerns a single item, it may indicate that digital support is a pragmatic but valuable supplement in improving women's experience of early labour care [18, 19].

The most striking result from this study is that women in the post-intervention group presented at the labour ward with more cervical dilatation and required less oxytocin. Women with access to Latens.no presented at the labour ward with a mean dilatation of 5.1 cm (SD ± 2.3) compared to 4.1 cm (SD ± 2.2) in the pre-intervention group ($p < 0.001$). The World Health Organization's recommendations from 2018 specify that women be considered in active labour when their cervix is 5 cm dilatated [1]. Hospital admittance is generally not recommended until active labour [2]. These findings indicate that participants with access to Latens.no had more timely admission to the labour ward. Several factors could explain this result. Firstly, it might indicate that women who received access to a suitable amount of trustworthy information at the appropriate time were better able to cope with early labour at home. This explanation is supported by a randomised trial of structured antenatal training sessions to improve the birth process, where women who received antenatal training arrived at the maternity ward in active labour more often than the reference group [12]. However, the result may also indicate that fear of being separated from their partner or contracting COVID-19 delayed access to the labour ward. It is also interesting to note that more participants in the pre-intervention cohort considered that they came to the hospital at the right time, although this finding was not statistically significant.

Significantly fewer women received oxytocin in the group with access to Latens.no, with 103 participants (59.2%) using it in the pre-intervention group and 79 participants (44.4%) in the post-intervention group. This result agrees with findings in several other studies, which report significantly more use of oxytocin in women presenting at the labour ward in earlier stages of labour [8, 9]. As the use of oxytocin can be associated with several adverse effects, this is a positive finding.

The number of telephone consultations was significantly higher in the group with access to Latens.no—something that is likely explained by the intervention. In a previous publication from the PreCare study [19], we report that many women were reluctant to call the hospital despite wanting to talk to health professionals. Following this, we ensured that statements were abundant on Latens.no informing women that telephone calls are welcomed by the midwives. Given that women with access to Latens.no had timelier admission, this finding may support the hypothesis that women using the information on Latens.no were able to actively participate in care decisions. However, it might also be explained by the changing care guidelines due to COVID-19, leading to more questions and uncertainty.

Overall, the CFA of the Swedish version of the ELEQ for primiparous women demonstrates an acceptable fit. However, Q9 was found to be a poor fit ('While you were in labour at home did you feel tense?'). A possible explanation for this may be our translation of the word 'tense'. In Q9, the word 'tense' was translated to the Norwegian word *spent*. In Norwegian, one meaning of *spent* is 'tense', but another meaning is 'excited/expectant/eager/curious' when facing something unknown. Neither the developers of the ELEQ or the Swedish researchers preforming the exploratory factor analyses noted any issues with Q9 in their reliability testing [16, 17]. This might be because both the English word 'tense' and the Swedish word *spänd* primarily have negative connotations [28, 29], as opposed to the Norwegian word *spent*, which has both positive and negative connotations.

Strengths and limitations

The pre-intervention cohort in this study was recruited pre-COVID-19, and the post-intervention cohort was recruited during the pandemic's second wave in Norway. At the time of data collection

among the post-intervention-group, there was still limited research on COVID-19 and pregnancy, but there was no evidence that pregnant women were at a higher risk of developing COVID-19 than the general population [30]. Nevertheless, our participants were likely to have been affected by COVID-19 to some degree, which may have influenced the results.

The CFA of the SWE-ELEQ-PP indicates a poor fit of Q9 ('While you were in labour at home did you feel tense?'). Correspondingly, the model may be improved in this respect. However, factor loadings and covariances may be specific to our participants, and perhaps not generalizable. In addition, the purpose of this study was not to improve the questionnaire, but rather to test the underlying structure of the SWE-ELEQ-PP in a Norwegian setting.

Conclusions

Results from our study at Norway's largest delivery ward show that whilst digital support did not significantly improve women's experience with early labour, it was associated with timelier admission and reduced use of oxytocin. Digital media is already extensively used by pregnant women, and may very well influence experiences of early labour in addition to in-person interactions. Thus, we suggest further investigation into the use of technology in healthcare delivery to understand how it facilitates social support, well-being and outcomes related to giving birth. Finally, the CFA of the SWE-ELEQ-PP demonstrates an acceptable fit and we recommend its use, but the translation of Q9 should be carefully considered.

Abbreviations

ELEQ - The Early Labour Experience Questionnaire

NICE - National Institute for Health and Care Excellence

SWE-ELEQ-PP - The Swedish version of the ELEQ for primiparous women

Acknowledgments

We thank all the clinicians, especially Ina Dagsholm and Ingvild Nordhagen, at the admission ward for labouring and pregnant women at Oslo University Hospital for facilitating data collection, and for their input and advice.

Funding

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Appendices

Appendix 1 NSD approval no. 60109 (substudy 1)

Appendix 2 NSD approval no. 228701 (substudy 2)

Appendix 3 NSD approval no. 107878 (substudy 3)

Appendix 4 REK decision 2018/540 (substudy 1)

Appendix 5 REK decision 2018/1236 (substudy 3)

Appendix 6 PVO approval (substudy 3)

Appendix 7 Information letter and consent form, substudy 1

Appendix 8 Information letter and consent form, substudy 2

Appendix 9 Information letter and consent form, substudy 3

Appendix 10 Norwegian version of the ELEQ

Appendix 11 Pamphlet Latens.no

Enid Leren Myhre

3603 KONGSBERG

Vår dato: 04.05.2018 Vår ref: 60109 / 3 / LAR Deres dato: Deres ref:

Tilrådning fra NSD Personvernombudet for forskning § 7-27

Personvernombudet for forskning viser til meldeskjema mottatt 27.03.2018 for prosjektet:

60109	*The PreCare Study. Pre-admission early labour care: An electronic educational intervention to improve early labour care and women's preadmission early labour experience: A mixed-method study*
Behandlingsansvarlig	*Høgskolen i Sørøst-Norge, ved institusjonens øverste leder*
Daglig ansvarlig	*Enid Leren Myhre*

Vurdering

Etter gjennomgang av opplysningene i meldeskjemaet og øvrig dokumentasjon finner vi at prosjektet er unntatt konsesjonsplikt og at personopplysningene som blir samlet inn i dette prosjektet er regulert av § 7-27 i personopplysningsforskriften. På den neste siden er vår vurdering av prosjektopplegget slik det er meldt til oss. Du kan nå gå i gang med å behandle personopplysninger.

Vilkår for vår anbefaling

Vår anbefaling forutsetter at du gjennomfører prosjektet i tråd med:

- opplysningene gitt i meldeskjemaet og øvrig dokumentasjon
- vår prosjektvurdering, se side 2
- eventuell korrespondanse med oss

Meld fra hvis du gjør vesentlige endringer i prosjektet

Dersom prosjektet endrer seg, kan det være nødvendig å sende inn endringsmelding. På våre nettsider finner du svar på hvilke endringer du må melde, samt endringsskjema.

Opplysninger om prosjektet blir lagt ut på våre nettsider og i Meldingsarkivet

Vi har lagt ut opplysninger om prosjektet på nettsidene våre. Alle våre institusjoner har også tilgang til egne prosjekter i Meldingsarkivet.

Vi tar kontakt om status for behandling av personopplysninger ved prosjektslutt

Ved prosjektslutt 01.04.2021 vil vi ta kontakt for å avklare status for behandlingen av personopplysninger.

Se våre nettsider eller ta kontakt dersom du har spørsmål. Vi ønsker lykke til med prosjektet!

Dokumentet er elektronisk produsert og godkjent ved NSDs rutiner for elektronisk godkjenning.

Vennlig hilsen

Marianne Høgetveit Myhren

Lasse André Raa

Kontaktperson: Lasse André Raa tlf: 55 58 20 59 / Lasse.Raa@nsd.no
Vedlegg: Prosjektvurdering

Personvernombudet for forskning

Prosjektvurdering - Kommentar

Prosjektnr: 60109

ANDRE VURDERINGSINSTANSER
Prosjektet er fremlagt REK sør-øst, deres referanse 2018/540, og er vurdert å falle utenfor helseforskningslovens virkeområde. Det er dermed tilstrekkelig med personvernombudets tilrådning.

FORMÅL
Hensikten med studien er å utforske førstegangsfødendes behov for kunnskap og informasjon i tidlig fødsel før innleggelse på sykehus, for å sikre brukermedvirkning i utviklingen av en nettside med informasjon om tidlig fødsel.

UTVALG
Utvalget vil bestå av førstegangsfødende kvinner som nylig har født barn.

INFORMASJON OG SAMTYKKE
Dere har opplyst i meldeskjema at utvalget vil motta skriftlig informasjon om prosjektet, og samtykke skriftlig til å delta. Vår vurdering er at informasjonsskrivet til utvalget er godt utformet.

SENSITIVE OPPLYSNINGER
Personvernombudet tar høyde for at vil behandles sensitive opplysninger om helseforhold i prosjektet. Det bør utøves særlig forsiktighet ved behandling av sensitive personopplysninger, både når det gjelder etiske problemstillinger, innhenting av data og informasjonssikkerhet underveis.

DATASIKKERHET
Personvernombudet forutsetter at dere behandler alle data i tråd med Høgskolen i Sørøst-Norge sine retningslinjer for datahåndtering og informasjonssikkerhet.

PROSJEKTSLUTT
Prosjektslutt er oppgitt til 01.04.2021. Det fremgår av meldeskjema/informasjonsskriv at dere vil anonymisere datamaterialet ved prosjektslutt. Anonymisering innebærer vanligvis å:
- slette direkte identifiserbare opplysninger som navn, fødselsnummer, koblingsnøkkel
- slette eller omskrive/gruppere indirekte identifiserbare opplysninger som bosted/arbeidssted, alder, kjønn
- slette lydopptak

For en utdypende beskrivelse av anonymisering av personopplysninger, se Datatilsynets veileder: https://www.datatilsynet.no/globalassets/global/regelverk-skjema/veiledere/anonymisering-veileder-041115.pdf

NSD NORSK SENTER FOR FORSKNINGSDATA

Vurdering

Referansenummer

228701

Prosjekttittel

The PreCare Study Pre-admission early labour care: An electronic educational intervention to improve early labour care and women's preadmission early labour experience

Behandlingsansvarlig institusjon

Universitetet i Sørøst-Norge / Fakultet for helse- og sosialvitenskap / Institutt for sykepleie- og helsevitenskap

Prosjektansvarlig (vitenskapelig ansatt/veileder eller stipendiat)

Enid Leren Myhre, enid.myhre@usn.no, tlf: 91698469

Type prosjekt

Forskerprosjekt

Prosjektperiode

10.02.2020 - 01.04.2021

Vurdering (2)

18.02.2020 - Vurdert

NSD har vurdert endringen registrert 17.02.2020.

Det er vår vurdering at behandlingen av personopplysninger i prosjektet vil være i samsvar med personvernlovgivningen så fremt den gjennomføres i tråd med det som er dokumentert i meldeskjemaet med vedlegg den 18.02.2020. Behandlingen kan fortsette.

OPPFØLGING AV PROSJEKTET
NSD vil følge opp ved planlagt avslutning for å avklare om behandlingen av personopplysningene er avsluttet.

Lykke til med prosjektet!

Kontaktperson hos NSD: Marita Ådnanes Helleland
Tlf. Personverntjenester: 55 58 21 17 (tast 1)

04.02.2020 - Vurdert

BAKGRUNN
Behandlingen av personopplysninger ble opprinnelig meldt inn til NSD 27.03.2018 (NSD sin ref: 60109) og vurdert under personopplysningsloven som var gjeldende på det tidspunktet.

31.01.2020 meldte prosjektleder inn en endring av prosjektet (ny metode for datainnsamling).

Det er vår vurdering at behandlingen/hele prosjektet vil være i samsvar med den gjeldende personvernlovgivningen, så fremt den gjennomføres i tråd med det som er dokumentert i meldeskjemaet 04.02.2020 med vedlegg, samt i meldingsdialogen mellom innmelder og NSD. Behandlingen kan fortsette.

MELD VESENTLIGE ENDRINGER
Dersom det skjer vesentlige endringer i behandlingen av personopplysninger, kan det være nødvendig å melde dette til NSD ved å oppdatere meldeskjemaet. Før du melder inn en endring, oppfordrer vi deg til å lese om hvilke type endringer det er nødvendig å melde:
https://nsd.no/personvernombud/meld_prosjekt/meld_endringer.html
Du må vente på svar fra NSD før endringen gjennomføres.

TYPE OPPLYSNINGER OG VARIGHET
Prosjektet vil behandle særlige kategorier av personopplysninger om helse og alminnelige kategorier av personopplysninger frem til 01.04.2021.

LOVLIG GRUNNLAG
Prosjektet vil innhente samtykke fra de registrerte til behandlingen av personopplysninger. Vår vurdering er at prosjektet legger opp til et samtykke i samsvar med kravene i art. 4 nr. 11 og art. 7, ved at det er en frivillig, spesifikk, informert og utvetydig bekreftelse, som kan dokumenteres, og som den registrerte kan trekke tilbake.

Lovlig grunnlag for behandlingen vil dermed være den registrertes uttrykkelige samtykke, jf. personvernforordningen art. 6 nr. 1 bokstav a, jf. art. 9 nr. 2 bokstav a, jf. personopplysningsloven § 10, jf. § 9 (2).

PERSONVERNPRINSIPPER
NSD vurderer at den planlagte behandlingen av personopplysninger vil følge prinsippene i personvernforordningen om:

- lovlighet, rettferdighet og åpenhet (art. 5.1 a), ved at de registrerte får tilfredsstillende informasjon om og samtykker til behandlingen
- formålsbegrensning (art. 5.1 b), ved at personopplysninger samles inn for spesifikke, uttrykkelig angitte og berettigede formål, og ikke viderebehandles til nye uforenlige formål
- dataminimering (art. 5.1 c), ved at det kun behandles opplysninger som er adekvate, relevante og nødvendige for formålet med prosjektet
- lagringsbegrensning (art. 5.1 e), ved at personopplysningene ikke lagres lengre enn nødvendig for å oppfylle formålet

DE REGISTRERTES RETTIGHETER
Så lenge de registrerte kan identifiseres i datamaterialet vil de ha følgende rettigheter: åpenhet (art. 12), informasjon (art. 13), innsyn (art. 15), retting (art. 16), sletting (art. 17), begrensning (art. 18), underretning (art. 19), dataportabilitet (art. 20).

NSD vurderer at informasjonen som de registrerte vil motta oppfyller lovens krav til form og innhold, jf. art. 12.1 og art. 13.

Vi minner om at hvis en registrert tar kontakt om sine rettigheter, har behandlingsansvarlig institusjon plikt til å svare innen en måned.

FØLG DIN INSTITUSJONS RETNINGSLINJER
NSD legger til grunn at behandlingen oppfyller kravene i personvernforordningen om riktighet (art. 5.1 d), integritet og konfidensialitet (art. 5.1. f) og sikkerhet (art. 32).

For å forsikre dere om at kravene oppfylles, må dere følge interne retningslinjer og eventuelt rådføre dere med behandlingsansvarlig institusjon.

OPPFØLGING AV PROSJEKTET
NSD vil følge opp ved planlagt avslutning for å avklare om behandlingen av personopplysningene er avsluttet.

Lykke til med prosjektet!

Kontaktperson hos NSD: Marita Ådnanes Helleland
Tlf. Personverntjenester: 55 58 21 17 (tast 1)

NSD NORSK SENTER FOR FORSKNINGSDATA

Vurdering

Referansenummer

107878

Prosjekttittel

The PreCare Project, Pre-admission early labour care: An electronic educational intervention to improve early labour care and women's pre-admission early labour experience: A mixed-method study

Behandlingsansvarlig institusjon

Universitetet i Sørøst-Norge / Fakultet for helse- og sosialvitenskap / Institutt for helse-, sosial- og velferdsfag

Prosjektansvarlig (vitenskapelig ansatt/veileder eller stipendiat)

Enid Leren Myhre, enid.myhre@usn.no, tlf: 91698469

Type prosjekt

Forskerprosjekt

Prosjektperiode

02.04.2018 - 01.04.2023

Vurdering (2)

27.04.2021 - Vurdert

NSD har vurdert endringen registrert 21.04.2021.

Vi har nå registrert 01.04.2023 som ny sluttdato for behandling av personopplysninger.

Vi gjør oppmerksom på at ytterligere forlengelse ikke kan påregnes uten at utvalget informeres om forlengelsen.

NSD vil følge opp underveis (hvert annet år) og ved ny planlagt avslutning for å avklare om behandlingen av personopplysningene er avsluttet/pågår i tråd med den behandlingen som er dokumentert.

Lykke til videre med prosjektet!

03.04.2019 - Vurdert

BAKGRUNN
Prosjektet er fremlagt for REK, og vurdert til å falle utenfor virkeområdet til helseforskningsloven § 2.

Det er vår vurdering at behandlingen av personopplysninger i prosjektet vil være i samsvar med personvernlovgivningen så fremt den gjennomføres i tråd med det som er dokumentert i meldeskjemaet med vedlegg den 3.4.2019, samt i meldingsdialogen mellom innmelder og NSD. Behandlingen kan starte.

MELD ENDRINGER
Dersom behandlingen av personopplysninger endrer seg, kan det være nødvendig å melde dette til NSD ved å oppdatere meldeskjemaet. På våre nettsider informerer vi om hvilke endringer som må meldes. Vent på svar før endringen gjennomføres.

TYPE OPPLYSNINGER OG VARIGHET
Prosjektet vil behandle særlige kategorier av personopplysninger om helseopplysninger, samt alminnelige personopplysninger, frem til 01.04.2021. Datamaterialet vil deretter anonymiseres, og slettes senest fem år etter prosjektslutt.

LOVLIG GRUNNLAG
Prosjektet vil innhente samtykke fra de registrerte til behandlingen av personopplysninger. Vår vurdering er at prosjektet legger opp til et samtykke i samsvar med kravene i art. 4 nr. 11 og art. 7, ved at det er en uttrykkelig, frivillig, spesifikk, informert og utvetydig bekreftelse, som kan dokumenteres, og som den registrerte kan trekke tilbake.

Lovlig grunnlag for behandlingen vil dermed være den registrertes uttrykkelige samtykke, jf. personvernforordningen art. 6 nr. 1 a), jf. art. 9 nr. 2 bokstav a, jf. personopplysningsloven § 10, jf. § 9 (2).

PERSONVERNPRINSIPPER
NSD vurderer at den planlagte behandlingen av personopplysninger vil følge prinsippene i personvernforordningen:

- om lovlighet, rettferdighet og åpenhet (art. 5.1 a), ved at de registrerte får tilfredsstillende informasjon om og samtykker til behandlingen
- formålsbegrensning (art. 5.1 b), ved at personopplysninger samles inn for spesifikke, uttrykkelig angitte og berettigede formål, og ikke viderebehandles til nye uforenlige formål
- dataminimering (art. 5.1 c), ved at det kun behandles opplysninger som er adekvate, relevante og nødvendige for formålet med prosjektet
- lagringsbegrensning (art. 5.1 e), ved at personopplysningene ikke lagres lengre enn nødvendig for å oppfylle formålet

DE REGISTRERTES RETTIGHETER
Så lenge de registrerte kan identifiseres i datamaterialet vil de ha følgende rettigheter: åpenhet (art. 12), informasjon (art. 13), innsyn (art. 15), retting (art. 16), sletting (art. 17), begrensning (art. 18), underretning (art. 19), dataportabilitet (art. 20).

NSD vurderer at informasjonen som de registrerte vil motta oppfyller lovens krav til form og innhold, jf. art. 12.1 og art. 13.

Vi minner om at hvis en registrert tar kontakt om sine rettigheter, har behandlingsansvarlig institusjon plikt til å svare innen en måned.

FØLG DIN INSTITUSJONS RETNINGSLINJER
NSD legger til grunn at behandlingen oppfyller kravene i personvernforordningen om riktighet (art. 5.1 d), integritet og konfidensialitet (art. 5.1. f) og sikkerhet (art. 32).

For å forsikre dere om at kravene oppfylles, må dere følge interne retningslinjer og eventuelt rådføre dere med behandlingsansvarlig institusjon.

OPPFØLGING AV PROSJEKTET
NSD vil følge opp ved planlagt avslutning for å avklare om behandlingen av personopplysningene er avsluttet.

Lykke til med prosjektet!

Kontaktperson hos NSD: Pernille Ekornrud Grøndal
Tlf. Personverntjenester: 55 58 21 17 (tast 1)

enidleren@hotmail.com

Fra: post@helseforskning.etikkom.no
Sendt: tirsdag 13. mars 2018 12:55
Til: enidleren@hotmail.com
Emne: Sv: REK sør-øst 2018/540 Informasjon og omsorg i tidlig fødsel

Hei.

Vi viser til fremleggingsvurdering for prosjektet, «Informasjon og omsorg i tidlig fødsel», mottatt 08.03.2018.

I skjema og vedlagt prosjektbeskrivelse fremkommer det at formålet med studien er å

forbedre omsorgen i tidlig fødsel og kvinners opplevelse av tidlig fødsel gjennom å utvikle og teste en elektronisk informasjonsintervensjon.

I henhold til helseforskningslovens § 4 forstås medisinsk og helsefaglig forskning som virksomhet som utføres med vitenskapelig metodikk for å skaffe til veie ny kunnskap om helse og sykdom. Vi forstår det som at det her ikke er ny kunnskap om helse eller sykdom i seg selv som er formålet, men opplevelsen av fødselens tidlige fase sett ut fra informasjon man fikk på forhånd og underveis.

Prosjektet faller dermed utenfor bestemmelsene i helseforskningsloven, jf. helseforskningslovens § 4. Prosjektet er ikke fremleggelsespliktig for REK.

Komiteen antar for øvrig at prosjektet kommer inn under de interne regler for behandling av opplysninger som gjelder ved ansvarlig virksomhet. Søker bør derfor ta kontakt med enten forskerstøtteavdeling eller personvernombud for å avklare hvilke retningslinjer som er gjeldende**. Vi gjør videre oppmerksom på at konklusjonen er å anse som veiledende, jfr. forvaltningsloven § 11.**

Dersom dere likevel ønsker å søke REK vil søknaden bli behandlet i komitémøte, og det vil bli fattet et enkeltvedtak etter forvaltningsloven.

mvh
Henriette Snilsberg
REK sør-øst

-------Original melding--------

> **Emne:** Informasjon og omsorg i tidlig fødsel
> **Fra:**
> **Dato:** 08.03.2018 20:29:45
> **Til:** enidleren@hotmail.com
> **Kopi:**

> Prosjektbeskrivelse REK.pdf
> Informasjonsskriv REK.pdf

REK
REGIONALE KOMITEER FOR MEDISINSK OG HELSEFAGLIG FORSKNINGSETIKK

Region:	Saksbehandler:	Telefon:	Vår dato:	Vår referanse:
REK sør-øst	Ingrid Dønåsen	22845523	20.09.2018	2018/1236 REK sør-øst B
			Deres dato:	Deres referanse:
			12.06.2018	

Vår referanse må oppgis ved alle henvendelser

Enid Leren Myhre
Universitetet i Sørøst-Norge

2018/1236 Utvikling og evaluering av en informasjonsintervensjon om tidlig fødsel

Vi viser til søknad om forhåndsgodkjenning av ovennevnte forskningsprosjekt. Søknaden ble behandlet av Regional komité for medisinsk og helsefaglig forskningsetikk (REK sør-øst) i møtet 22.08.2018. Vurderingen er gjort med hjemmel i helseforskningsloven § 10.

Forskningsansvarlig: Universitetet i Sørøst-Norge
Prosjektleder: Enid Leren Myhre

Prosjektleders prosjektbeskrivelse
Formålet med prosjektet er å forbedre omsorgen i tidlig fødsel og kvinners opplevelse av tidlig fødsel gjennom å utvikle og teste en elektronisk informasjonsintervensjon. Prosjektet vil bestå av tre delstudier: Del 1: Kvalitativ studie. Utforsker kvinners behov i tidlig fødsel (denne studien er vurdert av REK, ref. punkt 1.10). Del 2: Kvantitativ studie. Sammenligner kvinners opplevelse av tidlig fødsel i to grupper, en før og en etter introduksjon av en elektronisk informasjonsside (intervensjonen). Data samles ved hjelp av et spørreskjema utfylt mens kvinner er på barselavdelingen. Del 3: Kvantitativ studie. Undersøker hvilken effekt intervensjonen har på bruk av helsetjenesten og fødselsutfall. Dataene hentes fra journalsystemet Partus om bruk av oksytocin, epidural, operative forløsninger, antall konsultasjoner før innleggelse og antall fødsler før ankomst på sykehuset for samme gruppen før og etter intervensjonen som i del 2.

Komiteens vurdering
Komiteen anser at prosjektets overordnede formål er å undersøke om en informasjonsside på nett påvirker kvinners opplevelse av tidlig fødsel og tilfredshet med helseomsorg, og at dette ikke fremskaffer ny kunnskap om helse og sykdom som sådan.

Det kreves ikke godkjenning fra REK for å gjennomføre prosjektet. Prosjektet kommer inn under de interne regler som gjelder ved forskningsansvarlig virksomhet.

Komiteen gjør oppmerksom på at det faktum at et prosjekt blir vurdert av REK til å være utenfor helseforskningslovens virkeområde ikke er til hinder for at resultater fra prosjektet kan publiseres.

Vedtak
Prosjektet faller utenfor helseforskningslovens virkeområde, jf. § 2 og § 4 bokstav a). Det kreves ikke godkjenning fra REK for å gjennomføre prosjektet.

Klageadgang
REKs vedtak kan påklages, jf. forvaltningslovens § 28 flg. Eventuell klage sendes til REK sør-øst B. Klagefristen er tre uker fra du mottar dette brevet. Dersom vedtaket opprettholdes av REK sør-øst B, sendes klagen videre til Den nasjonale forskningsetiske komité for medisin og helsefag for endelig vurdering.

Komiteens avgjørelse var enstemmig.

Med vennlig hilsen

Ragnhild Emblem
Professor, dr. med.
leder REK sør-øst B

Ingrid Dønåsen
Rådgiver

Kopi til:milu@oslomet.no

Universitetet i Sørøst-Norge: postmottak@usn.no

Fra: OUSHF PB Personvern
Sendt: 25. juni 2018 13:57
Til: Enid Myhre; Marte Myhre Reigstad
Emne: SV: Skjema for behandling av helseforskningsdata

Hei!

Takk for tilbakemelding.

Vi har ingen innvendinger til prosjektet gitt:
- REK godkjenner prosjektet.
- Rekruttering gjøres av personell med lovlig tilgang til journal, jf. http://ehandboken.ous-hf.no/document/12640?preview=true
- Kodeliste over pasienter ved OUS oppbevares ved OUS i Medinsight.
- Utlevering gjøres ved personlig overlevering, og avidentifiserte opplysninger lagres på godkjent lagringsområde ved USN for sensitive helse- og personopplysninger.
- Nettsiden er kun en informasjonskanal og ikke en løsning der deltakerne deler eller skriver inn data.

Ønsker dere lykke til med prosjektet!

mvh
Annika Mortensen
Personvernrådgiver
Avdeling for informasjonssikkerhet og personvern | Stab pasientsikkerhet og kvalitet
Oslo universitetssykehus HF
Telefonnummer: 22 11 80 80
Besøk: Kirkeveien 166 (Ullevål sykehus)
www.oslo-universitetssykehus.no\personvern

Forespørsel om deltakelse i forskningsprosjektet *"The Pre-Care Study"*

Bakgrunn og formål
«The Pre-Care study» er en studie som har som formål å bedre førstegangsfødende kvinners opplevelse av den tidlige fasen av fødselen. Med den tidlige fasen av fødselen mener vi tiden etter at man har startet med rier, men før man blir lagt inn på sykehuset. Formålet med studien er å utforske hvilke erfaringer førstegangsfødende kvinner har i den tidlige fasen av fødselen, og hvilke behov for kunnskap og informasjon kvinnene har i tidlig fødsel før innleggelse på sykehus.

Prosjektet er en del av «The Pre-Care Study», som er en doktorgradsstudie ved Høgskolen i Sørøst-Norge.

Vi ønsker å snakke med deg som nylig har født ditt første barn og som hadde en naturlig start på fødselen. Vi ønsker kun å snakke med deg som hadde rier hjemme en stund før du dro til sykehuset. Det er ingen tidsbegrensning på hvor lenge du var hjemme, det viktigste er at du selv føler at du tilbrakte en del av fødselen i hjemmet.

Hva innebærer deltakelse i studien?
Deltagelsen i studien vil innebære at du sier deg villig til å delta på et fokusgruppeintervju. Et fokusgruppeintervju foregår ved at flere personer intervjues samtidig, i dette tilfellet 6-8 kvinner. Intervjuet vil vare i ca. 60 -90 minutter. Spørsmålene vil omhandle tiden du tilbragte hjemme med rier, før du ble innlagt på sykehuset. Det vil bli gjort lydopptak av hele intervjuet, og i tillegg vil det være en sekretær tilstede som gjør notater.

Hva skjer med informasjonen om deg?
Alle personopplysninger vil bli behandlet konfidensielt. Personlige data og opplysninger vil bli anonymisert. Lydopptak og notater vil være trygt oppbevart så lange arbeidet foregår, og kun doktorgradsstudenten og veilederne vil ha tilgang til data. Deltagerne vil ikke kunne gjenkjennes i en publikasjon.

Prosjektet skal etter planen avsluttes april 2021. Lydopptak og notater vil da bli slettet.

Frivillig deltakelse
Det er frivillig å delta i studien, og du kan trekke ditt samtykke frem til analysearbeidet påbegynnes uten å oppgi noen grunn. Dersom du trekker deg, vil alle opplysninger om deg bli slettet.

Dersom du ønsker å delta eller har spørsmål til studien, ta kontakt med Enid Leren Myhre på telefon 916 98 469.

Studien er anbefalt av Personvernombudet for forskning, NSD - Norsk senter for forskningsdata AS.

Samtykke til deltakelse i studien
Jeg har mottatt informasjon om studien, og er villig til å delta

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(Signert av prosjektdeltaker, dato)

FORESPØRSEL OM DELTAKELSE I FORSKNINGSPROSJEKTET THE PRECARE PROJECT

Dette er et spørsmål til deg om å delta i en forskningsprosjekt for å bedre kvinners tilgang til informasjon i og om den tidlige fasen av fødselen. Som en del av et doktorgradsprosjekt på Universitetet i Sørøst-Norge (USN) ønsker vi å utvikle og teste en nettside med råd og informasjon til kvinner i tidlig fødsel, og undersøke om tilgang til nettsiden kan bidra til at kvinnene får en bedre opplevelse av denne fasen av fødselen.

Vi ønsker å snakke med deg som nylig har født ditt første barn og som hadde en naturlig start på fødselen. Vi ønsker kun å snakke med deg som hadde rier hjemme en stund før du dro til sykehuset. Det er ingen tidsbegrensning på hvor lenge du var hjemme, det viktigste er at du selv føler at du tilbrakte en del av fødselen hjemme.

I tillegg ønsker vi å snakke med partnere eller andre støttepersoner som har vært tilstede med en kvinne som var hjemme med rier.

HVA INNEBÆRER PROSJEKTET?

Det overordnede formålet med doktorgradsprosjektet er å forbedre tilgang til informasjon i den tidlige fasen av fødsel og dermed kvinners opplevelse av tidlig fødsel gjennom å utvikle og teste en elektronisk nettside

Hvis du velger å delta i prosjektet, innebærer det at du sier deg villig til å fortelle oss hva slags informasjonsbehov du opplevde i den tidlige fasen av fødselen. Deretter vil du få spørsmål om brukervennligheten og innholdet på en prototyp nettside. Du vil også få ulike spørsmål om nettsiden slik at vi ser om det er enkelt å finne frem til informasjon. Du vil da bli bedt om å «tenke og snakke høyt» slik at vi kan følge med på hvordan du finner veien gjennom nettsiden. Intervjuet vil vare i ca. 45 minutter. Det vil bli gjort lydopptak av hele intervjuet.

MULIGE FORDELER OG ULEMPER

Tilbakemeldinger fra kvinner som har mottatt fødselsomsorg viser manglende tilfredshet med omsorgen gitt i tidlig fødsel før innleggelse på sykehus. Disse funnene er i samsvar med forskningen på feltet. Vår hypotese er at implementering av en elektronisk informasjonsintervensjon vil styrke fødende kvinner og gjøre dem mer kvalifiserte til å involveres i avgjørelser vedrørende den tidlige fasen av fødselen. Deltagelse i studien vil ikke påvirke ditt behandlingsforløp, men ved å delta i studien har du muligheten til å hjelpe andre ved å bidra til at nettsiden blir bedre.

DITT PERSONVERN – HVORDAN VI OPPBEVARER OG BRUKER DINE OPPLYSNINGER

Alle personopplysninger vil bli behandlet konfidensielt. Personlige data og opplysninger vil bli anonymisert. Lydopptak og notater vil være trygt oppbevart så lange arbeidet foregår, og kun doktorgradsstudenten og veilederne vil ha tilgang til data. Deltagerne vil ikke kunne gjenkjennes i en publikasjon.

Prosjektet skal etter planen avsluttes april 2021. Lydopptak og notater vil da bli slettet.

FRIVILLIG DELTAKELSE OG MULIGHET FOR Å TREKKE DITT SAMTYKKE

Dersom du ønsker å delta, undertegner du denne samtykkeerklæringen. Det er frivillig å delta i studien. Frem til analysearbeidet påbegynnes kan du når som helst og uten å oppgi noen grunn trekke ditt samtykke ved å kontakte Enid Leren Myhre, på epost: enid.myhre@usn.no eller telefon: 916 98 469. Dersom du trekker deg, vil alle opplysninger om deg bli slettet.

DINE RETTIGHETER

Så lenge du kan identifiseres i datamaterialet, har du rett til innsyn i hvilke personopplysninger som er registrert om deg, å få rettet personopplysninger om deg, få slettet personopplysninger om deg, få utlevert en kopi av dine personopplysninger (dataportabilitet), og å sende klage til personvernombudet eller Datatilsynet om behandlingen av dine personopplysninger. Vi behandler opplysninger om deg basert på ditt samtykke.

Hvis du har spørsmål til studien, eller ønsker å benytte deg av dine rettigheter, ta kontakt med:

- Universitetet i Sørøst-Norge ved Enid Leren Myhre, på epost: enid.myhre@usn.no eller telefon: 916 98 469
- Paal Are Solberg, personvernombud ved Universitetet i Sørøst-Norge, på epost: personvernombud@usn.no eller telefon: 35 57 50 53
- NSD – Norsk senter for forskningsdata AS, på epost: personverntjenester@nsd.no eller telefon: 55 58 21 17.

GODKJENNING

På oppdrag fra Universitetet i Sørøst-Norge har NSD – Norsk senter for forskningsdata AS vurdert at behandlingen av personopplysninger i dette prosjektet er i samsvar med personvernregelverket.

DELTAGERE I FORSKNINGSTEAMET

Enid Leren Myhre (Stipendiat, ansvarlig for den daglige driften av prosjektet), Mirjam Lukasse (Professor, prosjektleder), Marte Myhre Reigstad (gynekolog), Bente Dahl (førsteamanuensis, prosjektmedarbeider) og Lisa Garnweidner-Holme (førsteamanuensis, prosjektmedarbeider).

SAMTYKKE TIL DELTAKELSE I PROSJEKTET

Jeg har mottatt og forstått informasjon om The PreCare Project, og har fått anledning til å stille spørsmål.
Jeg samtykker til at mine opplysninger behandles frem til prosjektet er avsluttet, 1. april 2021

Sted og dato

Deltakers signatur

Deltakers navn med trykte bokstaver

FORESPØRSEL OM DELTAKELSE I FORSKNINGSPROSJEKTET THE PRECARE PROJECT

Dette er et spørsmål til deg om å delta i en forskningsprosjekt for å bedre kvinners tilgang til informasjon i og om den tidlige fasen av fødselen. Som en del av et doktorgradsprosjekt på Universitetet i Sørøst-Norge (USN) ønsker vi å utvikle og teste en nettside med råd og informasjon til kvinner i tidlig fødsel, og undersøke om tilgang til nettsiden kan bidra til at kvinnene får en bedre opplevelse av denne fasen av fødselen.

Vi ønsker å snakke med deg som er gravid med ditt første barn, som er frisk med et normalt svangerskap, og som ikke har noen grunn til å bli lagt inn på sykehus med en gang riene starter.

I tillegg ønsker vi å snakke med partnere eller andre støttepersoner som planlegger å være tilstede hjemme med en kvinne som har rier for første gang.

HVA INNEBÆRER PROSJEKTET?

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Sted og dato

Deltakers signatur

Deltakers navn med trykte bokstaver

Universitetet i Sørøst-Norge

precare

FORESPØRSEL OM DELTAKELSE I FORSKNINGSPROSJEKTET THE PRECARE PROJECT

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HVA INNEBÆRER PROSJEKTET?

Det overordnede formålet med doktorgradsprosjektet er å forbedre omsorgen i tidlig fødsel og kvinners opplevelse av tidlig fødsel gjennom å utvikle og teste en elektronisk informasjonsintervensjon (nettsiden). I tillegg ønsker vi å undersøke om tilgang til nettsiden har en effekt på bruk av helsetjenesten og på fødselsutfall. Utvalget vårt vil bestå av kvinner som har født sitt første barn og som var hjemme med rier.

Hvis du velger å delta i prosjektet, innebærer det at du fyller ut et spørreskjema. Det vil ta deg ca. 15 minutter. Spørreskjemaet inneholder spørsmål om hvordan du hadde det da du var hjemme med rier.

I tillegg ber vi om tillatelse til å innhente følgende opplysninger om deg fra pasientjournal: Røyking i svangerskapet, pre-gravid BMI, bruk av medikamenter i fødsel, forløsningsmetode, antall konsultasjoner før innleggelse (i forbindelse med fødsel), antall cm ved innleggelse, tid fra første telefonkontakt til innleggelse, fødested (utenfor eller på sykehuset).

MULIGE FORDELER OG ULEMPER

Tilbakemeldinger fra kvinner som har mottatt fødselsomsorg viser manglende tilfredshet med omsorgen gitt i tidlig fødsel før innleggelse på sykehus. Disse funnene er i samsvar med forskningen på feltet. Vår hypotese er at implementering av en elektronisk informasjonsintervensjon vil styrke fødende kvinner og gjøre dem mer kvalifiserte til å involveres i avgjørelser vedrørende den tidlige fasen av fødselen. Deltagelse i studien vil ikke påvirke ditt behandlingsforløp, men ved å delta i studien har du muligheten til å hjelpe andre ved å bidra til mer kunnskap om dette feltet.

DITT PERSONVERN – HVORDAN VI OPPBEVARER OG BRUKER DINE OPPLYSNINGER

Informasjonen som registreres om deg skal kun brukes slik som beskrevet i hensikten med studien. Vi behandler opplysningene konfidensielt og i samsvar med personvernregelverket. Kun deltagerne i forskningstemaet vil ha tilgang til opplysningene. Alle opplysningene vil bli behandlet uten navn og fødselsnummer eller andre direkte gjenkjennbare opplysninger. En kode knytter deg til dine opplysninger gjennom en navneliste. Denne kodenøkkelen/ navnelisten vil bli lagret i et elektonisk registerverktøy ved OUS, adskilt fra andre data. Kun stipendiaten og lokal prosjektleder ved OUS har tilgang til kodenøkkelen og navnelisten. Ingen som jobber på Føde-gyn mottaket, føden eller barsel vil ha tilgang til det du svarer i spørreskjemaet. Du vil ikke kunne gjenkjennes i publikasjoner.

Ved å delta i prosjektet samtykker du også til at svarene dine, samt avidentifiserte journalopplysninger, utleveres til USN som er ansvarlig for prosjektet. På USN vil dette bli lagret på en sikker forskningsserver. Koden som knytter deg til dine personidentifiserende opplysninger vil ikke bli utlevert. Informasjon om deg vil bli anonymisert senest i 2021. Dette betyr at direkte personopplysninger (kodenøkkel og navneliste) slettes, og øvrig datamateriale bearbeides slik at indirekte identifisering ikke er mulig. Alt datamateriale slettes senest fem år etter prosjektslutt.

FRIVILLIG DELTAKELSE OG MULIGHET FOR Å TREKKE DITT SAMTYKKE

Det er frivillig å delta i prosjektet. Dersom du ønsker å delta, undertegner du denne samtykkeerklæringen. Du kan når som helst og uten å oppgi noen grunn trekke ditt samtykke ved å kontakte Enid Leren Myhre, på epost: enid.myhre@usn.no eller telefon: 916 98 469. Dersom du velger å trekke deg vil alle opplysninger om deg vil bli anonymisert. Dette vil ikke få konsekvenser for din videre behandling.

DINE RETTIGHETER

Så lenge du kan identifiseres i datamaterialet, har du rett til innsyn i hvilke personopplysninger som er registrert om deg, å få rettet personopplysninger om deg, få slettet personopplysninger om deg, få utlevert en kopi av dine personopplysninger (dataportabilitet), og å sende klage til personvernombudet eller Datatilsynet om behandlingen av dine personopplysninger. Vi behandler opplysninger om deg basert på ditt samtykke.

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- NSD – Norsk senter for forskningsdata AS, på epost: personverntjenester@nsd.no eller telefon: 55 58 21 17.

GODKJENNING

Prosjektet er godkjent av Regional komite for medisinsk og helsefaglig forskningsetikk, saksnummer 2018/1236 REK sør-øst B. Prosjektet er i tillegg godkjent av personvernombudet ved Oslo Universitetssykehus (OUS) og ledelsen av Kvinneklinikken ved OUS. På oppdrag fra Universitetet i Sørøst-Norge har NSD – Norsk senter for forskningsdata AS vurdert at behandlingen av personopplysninger i dette prosjektet er i samsvar med personvernregelverket.

DELTAGERE I FORSKNINGSTEAMET

Enid Leren Myhre (Stipendiat, ansvarlig for den daglige driften av prosjektet), Mirjam Lukasse (Professor, prosjektleder), Marte Myhre Reigstad (gynekolog, lokal prosjektleder på OUS) og Bente Dahl (førsteamanuensis, prosjektmedarbeider).

SAMTYKKE TIL DELTAKELSE I PROSJEKTET

Jeg har mottatt og forstått informasjon om The PreCare Project, og har fått anledning til å stille spørsmål. Jeg samtykker til:

- ☐ *Å delta ved å besvare spørreskjemaet*
- ☐ *At vi innhenter og registrerer følgende opplysninger om deg fra pasientjournal: Røyking i svangerskapet, pre-gravid BMI, bruk av medikamenter i fødsel, forløsningsmetode, antall konsultasjoner før innleggelse (i forbindelse med fødsel), tid fra første telefonkontakt til innleggelse, antall cm ved innleggelse, fødested (utenfor eller på sykehuset).*

Jeg samtykker til at mine opplysninger behandles frem til prosjektet er avsluttet, ca. april 2021

Sted og dato

Deltakers signatur

Deltakers navn med trykte bokstaver

Erfaringer i tidlig fødsel

Vennligst besvar disse spørsmålene utfra dine opplevelser i tidlig fødsel før du ble lagt inn på fødeavdelingen. Det er fint om du forsøker å svare på alle spørsmål, selv om det er mange. Sett et kryss ved det svaralternativet som stemmer best for deg.

Da du var hjemme med rier følte du deg:

1.Trygg?

○ Ja, absolutt ○ Ja, til en viss grad ○ Verken eller ○ Ikke så veldig ○ Ikke i det hele tatt

2. Selvsikker?

○ Ja, absolutt ○ Ja, til en viss grad ○ Verken eller ○ Ikke så veldig ○ Ikke i det hele tatt

3. Redd?

○ Ja, absolutt ○ Ja, til en viss grad ○ Verken eller ○ Ikke så veldig ○ Ikke i det hele tatt

4. Glad?

○ Ja, absolutt ○ Ja, til en viss grad ○ Verken eller ○ Ikke så veldig ○ Ikke i det hele tatt

5. Forventningsfull?

○ Ja, absolutt ○ Ja, til en viss grad ○ Verken eller ○ Ikke så veldig ○ Ikke i det hele tatt

6. Urolig?

○ Ja, absolutt ○ Ja, til en viss grad ○ Verken eller ○ Ikke så veldig ○ Ikke i det hele tatt

7. Rolig?

○ Ja, absolutt ○ Ja, til en viss grad ○ Verken eller ○ Ikke så veldig ○ Ikke i det hele tatt

8. Komfortabel?

○ Ja, absolutt ○ Ja, til en viss grad ○ Verken eller ○ Ikke så veldig ○ Ikke i det hele tatt

9. Spent?

○ Ja, absolutt ○ Ja, til en viss grad ○ Verken eller ○ Ikke så veldig ○ Ikke i det hele tatt

10. At du hadde støtte rundt deg?

○ Ja, absolutt ○ Ja, til en viss grad ○ Verken eller ○ Ikke så veldig ○ Ikke i det hele tatt

11. Bekymret?

○ Ja, absolutt ○ Ja, til en viss grad ○ Verken eller ○ Ikke så veldig ○ Ikke i det hele tatt

12. Usikker?

○ Ja, absolutt ○ Ja, til en viss grad ○ Verken eller ○ Ikke så veldig ○ Ikke i det hele tatt

13. At du hadde kontroll?

○ Ja, absolutt ○ Ja, til en viss grad ○ Verken eller ○ Ikke så veldig ○ Ikke i det hele tatt

14. Forvirret?

○ Ja, absolutt ○ Ja, til en viss grad ○ Verken eller ○ Ikke så veldig ○ Ikke i det hele tatt

Da du var hjemme i tidlig fødsel og hadde telefonkontakt med jordmor på sykehuset, eller var på kontroll på sykehuset, opplevde du at jordmor:

15. Ga deg den informasjonen du trengte?

○ Ja, absolutt ○ Ja, til en viss grad ○ Verken eller ○ Ikke så veldig ○ Ikke i det hele tatt

16. Beroliget deg når du trengte det?

○ Ja, absolutt ○ Ja, til en viss grad ○ Verken eller ○ Ikke så veldig ○ Ikke i det hele tatt

17. Ga deg den tiden du trengte?

○ Ja, absolutt ○ Ja, til en viss grad ○ Verken eller ○ Ikke så veldig ○ Ikke i det hele tatt

18. Lyttet nøye til det du hadde å si?

○ Ja, absolutt ○ Ja, til en viss grad ○ Verken eller ○ Ikke så veldig ○ Ikke i det hele tatt

19. Behandlet din familie og/eller dine venner med respekt?

○ Ja, absolutt ○ Ja, til en viss grad ○ Verken eller ○ Ikke så veldig ○ Ikke i det hele tatt

20. Respekterte dine ønsker om å dra til sykehuset?

○ Ja, absolutt ○ Ja, til en viss grad ○ Verken eller ○ Ikke så veldig ○ Ikke i det hele tatt

21. Følte du tillit til jordmor da du var hjemme i tidlig fødsel?

○ Ja, absolutt ○ Ja, til en viss grad ○ Verken eller ○ Ikke så veldig ○ Ikke i det hele tatt

22. Samarbeidet jordmødrene om din omsorg da du var hjemme i tidlig fødsel?

○ Ja, absolutt ○ Ja, til en viss grad ○ Verken eller ○ Ikke så veldig ○ Ikke i det hele tatt ○ Vet ikke

23. Følte du at jordmor alltid var rolig og fattet med deg da du var hjemme i tidlig fødsel?

○ Ja, absolutt ○ Ja, til en viss grad ○ Verken eller ○ Ikke så veldig ○ Ikke i det hele tatt

24. Følte du at jordmor behandlet deg på en uhøflig måte da du var hjemme i tidlig fødsel?

○ Ja, absolutt ○ Ja, til en viss grad ○ Verken eller ○ Ikke så veldig ○ Ikke i det hele tatt

25. Føler du at du reiste til sykehuset på riktig tidspunkt?

○ Ja, absolutt ○ Ja, til en viss grad ○ Verken eller ○ Ikke så veldig ○ Ikke i det hele tatt

Tilleggsspørsmål:

Alder:

Sivilstatus:

- ○ Gift
- ○ Samboer
- ○ Ugift/enslig
- ○ Annet

Lengde på utdanning:

- ○ Grunnskole
- ○ Videregående
- ○ Høyere utdanning

Familiens totale inntektsnivå:

- ○ 0- 400 000
- ○ 400 000- 700 000
- ○ 700 000- 1 000 000
- ○ Mer enn 1 000 000

Er du yrkesaktiv?

- ○ Ja
- ○ Nei

Er din partner yrkesaktiv?

- ○ Ja
- ○ Nei
- ○ Jeg har ikke partner

Er du født i Norge?

- ○ Ja
- ○ Nei
- ○ Hvis nei, hvor gammel var du da du kom til Norge:

Morsmål:

- ○ Norsk
- ○ Annet:

Har du noen flere kommentarer/ vil du si mer om din opplevelse av tidlig fødsel?

Bruk gjerne baksiden av spørreskjemaet om du har mer på hjertet enn det som får plass her.

Takk for at du hjelper oss å lære mer om omsorgen for kvinner i tidlig fødsel!

FINN SVAR PÅ DET DU LURER PÅ

LATENS.NO

En nettside med råd og informasjon om den første fasen av fødselen. Innholdet på nettsiden er først og fremst rettet mot førstegangsfødende.

latens.no

LATENS.NO

OM LATENS.NO

Latens.no er en informasjonsside på nett utviklet i The PreCare Project, et doktorgradsprosjekt på Universitetet i Sørøst-Norge

Vi har snakket med kvinner som nylig har født sitt første barn, og spurt de om hvilken informasjon de savnet og hva de hadde nytte av da de var hjemme med rier. På bakgrunn av svarene har vi laget en nettside med råd og informasjon som du har direkte tilgang til når du er hjemme med rier.

HVA ER EGENTLIG FORSKJELLEN PÅ KYNNERE OG RIER? OG NÅR SKAL JEG RINGE SYKEHUSET?

Å VÆRE HJEMME MED RIER

Vi vet at mange førstegangsfødende er usikre og har mange spørsmål når riene starter. Jordmødrene på sykehuset er aldri mer enn en telefonsamtale unna, og latens.no ønsker på ingen måte å erstatte samtalene med jordmor. Det latens.no ønsker å tilby er muligheten til å finne råd og informasjon du kanskje ikke visste at du lurte på, og i tillegg muligheten til å lese det i fred og ro hjemme, så mange ganger som du trenger det.

RÅD

På latens.no kan du finne råd om ulike ting du kan gjøre for å få det bedre hjemme.

INFORMASJON

I tillegg vil du finne informsjon om hva som skjer med kroppen i latensfasen. .

INFO TIL PARTNER

Latens.no inneholder også informasjon som kan være nyttig for den du eventuelt har sammen med deg hjemme

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Dissertation for the degree of PhD

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Enid Myhre

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