Pregnant women’s attitudes to and experiences with a smartphone-based self-test for prediction of pre-eclampsia: a qualitative descriptive study

Ida Catharina Püschl,1,2 Mie Gaarskjær de Wolff,3,4 Lotte Broberg,5,6 Nick Macklon,7,8 Hanne Kristine Hegaard2,5

ABSTRACT

Objectives To explore attitudes to and experiences using a smartphone-based self-test for prediction of pre-eclampsia among pregnant women.

Design A qualitative, descriptive study.

Setting An obstetrical care unit at a university hospital in Denmark.

Participants Twenty women who had participated in the Salubre trial, a clinical trial testing the efficacy of a smartphone-based self-test for prediction of pre-eclampsia, were purposefully chosen for the study, using maximum variation sampling.

Data collection and analysis Data were collected by semistructured, individual, face-to-face interviews conducted from 4 October 2018 to 8 November 2018. Data were transcribed verbatim and analysed by means of thematic analysis.

Results Qualitative thematic analysis resulted in the identification of three main themes: Raising awareness, self-testing has the potential to be an integrated part of antenatal care, and women found it feasible to use. However, testing affected the participating women psychologically, leading to feelings of worry as well as safety. Therefore, if self-testing is implemented, it is important to take actions to handle adverse psychological side effects, including increasing knowledge on pre-eclampsia and having healthcare professionals ongoingly address the psychological state of women throughout pregnancy. In addition, it is essential to emphasise the importance of subjective bodily sensations during pregnancy, including fetal movements. Further studies on the experience of being labelled low risk versus high risk for pre-eclampsia are warranted since this was not investigated in this trial.

Conclusions The smartphone-based self-test for prediction of pre-eclampsia has potential to be integrated into antenatal care, and women found it feasible to use. However, testing affected the participating women psychologically, leading to feelings of worry as well as safety. Therefore, if self-testing is implemented, it is important to take actions to handle adverse psychological side effects, including increasing knowledge on pre-eclampsia and having healthcare professionals ongoingly address the psychological state of women throughout pregnancy. In addition, it is essential to emphasise the importance of subjective bodily sensations during pregnancy, including fetal movements. Further studies on the experience of being labelled low risk versus high risk for pre-eclampsia are warranted since this was not investigated in this trial.

INTRODUCTION

Pre-eclampsia (PE) remains a severe complication of pregnancy, affecting 2%–8% of all pregnancies.4 PE is associated with significant maternal and fetal morbidity and mortality and increased maternal long-term risk of cardiovascular and metabolic disease.3

According to the International Society for the Study of Hypertensive disorders in Pregnancy, PE is defined by de novo onset of hypertension after 20 weeks of gestation in combination with either proteinuria, intrauterine growth restriction or maternal organ dysfunction.4

PE can cause subjective symptoms, but since these are non-specific and the presence varies, women find it difficult to distinguish symptoms of PE from normal pregnancy, ultimately delaying help-seeking.5 In addition, mild PE can fulminate rapidly,2 making early identification of women at risk of developing PE of great clinical importance. However, prediction of PE is difficult.6 7

Angiogenic biomarkers have shown promise: the soluble fms-like tyrosine kinase 1/placental growth factor ratio might be a useful ‘rule out’ test for PE in the third trimester among women with suspected PE.8 9 In addition, angiogenic biomarkers in combination with maternal risk factors, mean arterial blood pressure and ultrasound of the uterine arteries have predictive value for preterm PE.10 11 This approach was recently recommended for universal first-trimester screening for preterm PE.12 However, the detection rates concerning late-onset and
term PE, which are significant contributors to maternal and fetal morbidity and mortality, are lower. Moreover, the combined prediction model is not applicable in low-resource settings, which are highly responsible for PE-related maternal and perinatal mortality.

Therefore, there remains a need for a cost-effective, easily applicable test for the prediction of PE to identify women at risk before the clinical onset of PE. The efficacy of a test aligned with these needs is being investigated in an ongoing clinical trial, the Salurate trial, examining a smartphone-based self-test for prediction of PE by monitoring the salivary uric acid levels using colourimetric test strips.

However, before implementing a smartphone-based self-test for the prediction of PE, it is important to examine the feasibility of such an approach to screening. For instance, it is important to explore how acceptable it would be for pregnant women to perform weekly self-tests for prediction of PE. Therefore, this qualitative study aims to explore pregnant women’s attitudes to and experiences with a smartphone-based self-test for prediction of PE.

**MATERIALS AND METHODS**

**Study design and setting**

The study is a qualitative descriptive study based on semi-structured, individual interviews analysed using thematic analysis. The study design and reporting of the results follow the Consolidated criteria for reporting qualitative research. The study is a substudy of a clinical trial, the Salurate trial (N=563), conducted at Zealand University Hospital, Roskilde, Denmark, from August 2016 to July 2018, where participants conducted a weekly self-test from 20 weeks of gestation until labour. The self-test was linked with a smartphone-app, used to take an image of the coloured test strip and to refer the image to a secure cloud-based database for storage. The images were not included in clinical monitoring. See figure 1 for picture of the Salurate test device and description of the testing procedure, including patient instruction.

**Sampling**

In accordance with qualitative research methodology and the intention to recruit information-rich cases, participants were purposefully chosen. To capture

---

**Testing procedure**

The Salurate smartphone-app guided the user through the sample procedure:

- The test was made first thing in the morning before eating, drinking, smoking, or brushing the teeth.
- The buccal swab was pressed onto the tongue for saliva collection
- Afterwards, it was pressed onto the test-strip, referring the saliva
- Test-strip changed from white to purple using a colorimetric technique
- The colour intensity depended on the level of salivary uric acid
- The test was placed on the cardboard box next to a colour reference scale consisting of blue-yellow-black-red areas for reference
- Using the app, a picture was taken of the test-strip, colour reference, and id number on the cardboard box
- The picture was sent through the app and stored in a secure database for later colour analysis

At recruitment, all participants conducted a self-test under supervision to make sure that they did it correctly.

Participants were informed about:

- in brief: definition, pathophysiology, symptoms and complications of PE
- that the study aimed to investigate if colour changes of the test strip could predict PE
- not to put any value into colour changes
- that they would not receive any individual test results and that the tests would not affect their perinatal health care programme

---

Figure 1 The Salurate test device and testing procedure.
a wide range of perspectives, a maximum variation sampling strategy was applied with the aim to include women with differences in baseline characteristics of maternal age, body mass index, parity and smoking, and with differences in degrees of compliance, and whether they had been diagnosed with PE or pregnancy-induced hypertension.

Recruitment
At enrolment, participants in the Salurate trial consented to be contacted after giving birth with information about the interview study. Using a maximum variation sampling strategy, 38 women were initially identified and were contacted by email in September or October 2018. By non-response to the email, up to two telephone calls were made. Nineteen women agreed to participate in the study; ten did not respond. Five were unable, though interested, and four refused to participate. One eligible woman was enrolled after contacting the research team, resulting in 20 participants.

Data collection
Interviews were conducted from 4 October 2018 to 8 November 2018 by ICP, female, the PhD fellow of the project. To ensure that interviews were conducted according to standards for qualitative methodology, the first two interviews were supervised by MGdW, who has extensive experience in interviewing. Four women had been recruited to the Salurate trial by ICP. Interviews were conducted face to face in the participants’ homes (n=11) or a private setting at the research facility (n=9), depending on the participants’ preference. In some cases, the baby and/or partner was present during the interview. If so, it was kindly mentioned that the partner could not participate.

The interviews were guided by a semistructured interview guide with open-ended questions to increase the procedure’s consistency and ensure the research question was covered, (online supplemental table S1). Field notes were made after the interviews.

To enhance credibility, the interviewer encouraged participants to speak freely and elaborate on statements during the interview, and it was emphasised that there were no right or wrong answers. Aligning with this, the interviewer would let the participants elaborate on topics not directly relevant to the objective of the study without interrupting. All participants were asked the same opening question: ‘How did you experience participating in the Salurate trial?’ After the first and the second interview, the interview guide was evaluated, and no adjustments were made. Informational redundancy appeared during the last interviews, implying that data saturation was reached. Interviews lasted from 21 to 84 min (average duration was 35 min), reflecting an expected variation of personal wordiness, and of the elaboration of topics not directly relevant to the objective of the study. All interviews were audiorecorded.

Data analysis
Data were analysed by thematic analysis described by Braun and Clarke following six phases:
1. Familiarising with data, including verbatim transcription of interviews, 2 by ICP and 18 by two research assistants. ICP read and reread the material, writing down initial ideas on meanings and patterns, while MGdW, LB and HKH read up to six interviews, covering all data.
2. Generating initial codes using the software program NVivo V.12, QRS international. Two interviews were double-coded by LB and ICP. The initial coding tree was discussed and revised by ICP, MGdW, LB and HKH.
3. Searching for themes, which implied organising the codes into possible themes, discussed by ICP, MGdW, LB and HKH until agreement was reached.
4. Reviewing themes, including moving back and forth between themes, codes and quotes. ICP, MGdW, LB and HKH discussed and changed the themes until the whole data set was covered and no themes were overlapping.
5. Defining and naming themes, including describing what each theme represented, using quotes to keep the descriptions close to the original material. Names and descriptions were discussed until thematic saturation was reached.
6. Producing the report, including writing down the analysis. In these two last steps, all coauthors discussed the findings and presentations of the results several times.

Patient and public involvement
No patients were involved in the design of this study, but the project was carried out to gain insights into patient attitudes.

RESULTS
Participant characteristics are presented in table 1. The average time from giving birth to conducting the interview was 7 months (6 weeks to 10 months).

Themes
Thematic analysis identified three main themes, comprised six subthemes. The main themes were raising awareness, self-testing has the potential to be an integrated part of pregnancy and trusting in technology (table 2).

Raising awareness
Impact of new knowledge
The women explained how the information they had received about PE when recruited to the Salurate trial had affected them and described various thoughts and actions. Some women told that receiving information about PE had made them seek additional knowledge in different ways, including searching the internet, seeking other people’s experiences and rereading the information leaflet about the study.
Afterwards, I went home and researched on what PE was exactly [Participant 3].

Some women described that seeking additional information made them aware of the severity of PE. One woman told how seeking other people’s experiences with PE had affected her:

“It can really make people sad if they have gotten it (PE red.). It is something one does not control. Someone in my mothers’ group is seeing a psychologist because of this… I really started to worry a lot about ‘could I be one of the percentages that develop this?’ [Participant 12].

Others told that seeking information about what symptoms of PE to be aware of made them feel safer.

In contrast to seeking additional information, some women explained that they had decided not to give possible complications to pregnancy, including PE, attention as long as it was not relevant for them. As one of the women figuratively described it: ‘I will cross that bridge when I come to it’ [Participant 19].

A woman elaborated on this view, explaining that reading about the symptoms would make her worry, feeling that she had the symptoms herself.

Opposed to the above-mentioned strategies, a few women described how receiving information about PE had not affected them since they did not have the mental capacity to consider PE a possibility due to other physical or psychological pregnancy complications.

### The colour of the test strip: reflections and reactions

Women described how they had been aware of the colour of the test strip and wondered if it had changed during pregnancy. Some women tried to evaluate whether the colour was the same as in their previous samples. If not, they expressed an experience of distress:

“You walk around and think to yourself, ‘well, is this because I am starting to develop something (PE, red.)?’” [Participant 16].

A few women described that this feeling of distress was something they just had to endure. Others explained that they had come up with alternative reasons for a colour change, including increasing gestational age, hormonal changes or gestational diabetes mellitus (GDM). Some women added that if testing were a part of the antenatal healthcare programme, they would have acted on a change of the test-strip colour.

Different strategies for taking action were mentioned: contacting healthcare professionals, contacting the research team, searching online for more information, being more aware of symptoms and measuring their blood pressure.

However, most women perceived the colour to be the same throughout pregnancy and were reassured by this:

“It was a good thing. It was a proof that everything was still fine” [Participant 13].
Self-testing has the potential to be an integrated part of pregnancy
Feasible, but it has to work

Most women found the test feasible, but some disturbing elements concerning testing were mentioned.

Most women found the test to be straightforward to use—as one woman said: ‘It was easy, simple, and it did not put any demands on me’ [Participant 1]. It was described as convenient that testing did not have to fit into someone else’s schedule—it could be done at home, and it did not need to be delivered anywhere. Yet, some women with small children said that they found the requirement of testing first thing in the morning stressful.

The women had different experiences with the physical part of testing. Several women emphasised they found it favourable that the test was non-invasive and not painful, contrasting with, for example, blood glucose measurements for GDM. Most women found the taste and the smell of the test-strip neutral, increasing the feasibility of the test, but women who suffered from nausea told that they were discomforted by the taste and the smell of the test strip and described it as something they had to overcome when testing.

The women also elaborated on the functional aspect of testing. Most women described that the app was easy to use, and they liked how it guided them through testing systematically. In addition, they told that the reminder function had made it easy to remember to perform the test. Nonetheless, some women experienced technical issues, including problems with the reminder function. Other women experienced that the app never approved the first picture they took. They had to retake it at least once every time they tested, which was disturbing and negatively affected compliance.

Self-testing led to feelings of increased responsibility

Women reflected on the experience of self-testing. Some women found it positive to be responsible for testing. As one woman said:

This was something to take control of. I mean, there are so many areas where you are not in charge of what happens. But with this, it was like, well, I am the one in charge of this [Participant 18].

In addition, some women explained that they felt more in control and less concerned when testing at home in a secure setting away from healthcare workers. Some women described that testing had become a habit in their pregnancy, comparable to taking vitamin pills. One woman elaborated that to her, this habit was something that brought her closer to meeting the child as a countdown to the due date.

Contrarily, some women said they had not liked to be in charge of testing. They described they had doubted their ability to perform the test correctly and had worried about affecting the results falsely, ultimately turning the negative feelings inward. They said they would have liked to have had more support in the testing procedure, for example, as a frequently asked questions (FAQ) in the app. As one woman said:

If it were already there, I would use the information, but I do not want to ask the question myself. I think it is the thought of feeling stupid by asking questions [Participant 17].

Trusting in technology
Validating bodily sensations

Several women described how they sometimes had worried if they could rely on bodily sensations. Nulliparous women, in particular, described worries regarding fetal movements and whether the frequency and pattern of fetal movements were sufficient. These women said that testing provided peace of mind and reassurance that the baby was healthy, confirming their bodily sensations of normal pregnancy. As one woman described:

When you are pregnant, you are so uncertain if anything is wrong… Now I have not felt her (the baby red.) for three hours. Is there something wrong? If you can do this (testing red.) and get 100 % piece at mind… I would do it several times a day [Participant 12].

A few women suffered from migraines, and during attacks, they were more aware of whether or not the test-strip colour changed since they knew headache could be a sign of PE. They described how they had used the fact that the colour of the test strip had not changed to confirm that the headache was due to migraine and not PE.

Some women described how they had perceived the test as a backup if healthcare professionals did not pick up on something. They reflected on how healthcare workers are just human beings who can have an off day and overlook something. In this light, they found it safe to have a technological solution as a backup. A few women, who had previously experienced developing PE, described how they felt secure using the self-test in addition to their doctor’s and midwife’s appointments. They told how it made them feel they had a supporting tool if they developed subtle PE symptoms, not yet detectable on clinical parameters. One woman explained:

I feel it would support my intuition in case I get sick … and I would be able to put my foot down and say: ‘the test shows this and this, shouldn’t we see if there is something that can be done?’ [Participant 14].

The healthcare system takes care of me in a new way

The women described how testing had made them feel safe. The women explained how they, in general, felt that the more tests, the better. All women said they would use the test in a subsequent pregnancy if it were a part of the perinatal healthcare programme. They said that monitoring throughout pregnancy made them feel comforted that everything was okay.
Most women described that even though they did not perceive themselves at high risk of developing PE, they thought of PE as something that could happen to everyone. They explained that PE could be dangerous to both mother and child but were unsure how to describe the disease further.

Most women thought that early detection would allow healthcare workers to take action and prescribe antihypertensive medication or increase antepartum surveillance to ensure that PE did not evolve.

Several women had the impression that the research team would have picked up on an abnormal test: ‘I felt more secure because if something happened, they would let me know’ [Participant 15].

Some women described home monitoring as a gesture from the healthcare system in times with cut downs on maternity care. As one woman puts it:

You would indicate to the pregnant woman: ‘We are watching you, we are making sure you are safe. Even though we take these things (maternity care red.) away from you…we are still here for you’ [Participant 6].

Women, who had developed PE in this or a previous pregnancy, stressed the importance of early detection in feeling informed. The acute onset of PE and confusion about what it meant had been traumatic and was perceived as essential to avoid. In addition, they thought that getting an early warning sign would have made them more conscious about taking care of themselves and relaxing. They said it would have made them feel that they had done their best to take care, regardless of the effect.

DISCUSSION

This study, exploring pregnant women’s attitudes to and experiences with using a smartphone-based self-test to predict PE, found that self-testing had a psychological impact on women, causing feelings of worry as well as safety. Women perceived the test to be a feasible intervention and they were positively set toward self-testing.

A key finding was that using the app for weekly screening for PE increased worries about PE, which were magnified if the test-stripe colour was perceived as changing. This is consistent with previous studies suggesting that screening can lead to anxiety.25-29 Our findings indicated that the women perceived PE as a threat to themselves and their unborn child even though they were unsure about how to define PE further. This is consistent with both earlier and more recent studies, finding that women typically have inadequate knowledge of PE.30-32 A previous study has reported that poor knowledge of PE is associated with higher anxiety levels in women at high risk of PE.33 However, our findings regarding this are mixed, indicating that depending on the personality and coping strategy of the women, more information could either make them feel safer or more worried.

Women coped differently with the worries they experienced by using active as well as passive coping strategies,34 supporting previous findings on women’s reactions to being at risk of developing PE.35 Women who coped passively with their worries, for example, by trying to avoid information about PE, might be less likely to reach out for support in case of worries or ambiguities,34 leaving them in need of more attention from the healthcare workers if self-testing is implemented.

Contrarily, we found that all participating women perceived testing as risk-reducing, increasing safety for themselves and the unborn child, confirming existing literature on self-monitoring in pregnancy.36 According to Lupton and Scamell, pregnancy and childbirth are experienced within the frame of the risk-society, where pregnancy implies potential risks for the mother and fetus, leading to elevated awareness on risks throughout pregnancy.37-38 Aligning with this, the women in this study found that the more tests, the better, and that using the app for weekly monitoring made them feel safe. Further, existing literature suggests that pregnant women turn ‘probable risks’ into ‘possible risks’, meaning that when informed about a potential risk, women will consider it a possibility, regardless of how low the probability is to experience it.39 In accordance with this, the women in this study found weekly monitoring relevant and welcomed it, even though most of the women did not perceive themselves at high risk of developing PE. These findings indicate that understanding the experience of potential risks is central when exploring the experience of self-monitoring in pregnancy.

Women who had developed PE, described the experience as a traumatic event. They specified that self-testing made them feel secure because they hoped to avoid a last-minute diagnosis of PE, confirming and extending previous findings that self-testing might positively affect this subgroup of women.36 40-41

Another important finding was that women perceived the test an objective measurement of health, and some women found it to be more reliable than subjective bodily sensations including fetal movements, headache and bodily unease. This is supported in findings on self-monitoring for diabetes mellitus and hypertension42 and aligning with existing literature that some women with high risk of PE pay less attention to fetal movement when offered frequent ultrasound scans.43 This is important in terms of ensuring that women still engage in and react to bodily unease and fetal movements while self-testing.

A central finding was that the women found the test feasible and welcomed telemedicine to improve antenatal health, which is supported by previous studies.36 44-45 Most women found themselves capable of accomplishing self-testing and welcomed it, while others were insecure if they managed to test correctly. This feeling was amplified by external factors such as technical issues and lack of communication with the research team, leading to negative emotions. This is in accordance with the literature, showing that telemedicine can empower pregnant
Strengths and limitations

A strength to this study is the diversity of participants, making it possible to uncover different perspectives as well as shared patterns which increased transferability. In alignment, the variation concerning parity was a strength, ensuring that the data reflected different experiences with pregnancy and childbirth. Accordingly, it was a strength that women with and without a hypertensive pregnancy complication were equally included in the study population, ensuring diversity on how this reflected the experience of self-testing. Also, the steps taken to ensure trustworthiness is a strength; credibility and confirmability were enhanced by analysing data using robust qualitative methodology including researcher triangulation and by encouraging women to speak freely while dependability was increased by consistency of the opening question, the use of double-coding and by providing a detailed methodology description. It was a strength that the partner, in some cases, was present to take care of the baby during the interview, which allowed the women to engage in the interview without distraction. However, we do not know if it caused the women to omit anything, thereby reducing the credibility of the findings.

A limitation of the study was that many women did not reply to our invitation to the interview study, decreasing transferability of our findings. A potential limitation of the study is that the difference in duration time from the delivery until the interviews were conducted ranged from 6 weeks to 10 months. However, women’s memories of pregnancy-related events and childbirth have shown to be valid several years after the delivery, why we believe that conducting all interviews within the first year postpartum minimised the risk of recall bias. Another limitation is that since the interviews were performed in Danish, ethnic minorities not fluent in Danish were not included, decreasing transferability to populations with different characteristics. Further, a minimum of 10 years of education is mandatory in Denmark, decreasing the transferability of our findings to less educated populations. Since diagnoses of anxiety and depression have been associated with levels of worry in pregnancy, it is a potential limitation that this information was not possible to include in the maximum variation sampling strategy due to data unavailability. In addition, the experience of self-testing was evaluated during the ongoing Salurate trial, possibly decreasing transferability to testing as a part of an antenatal care programme. Also, we solely investigated the experience of women who accepted to participate in the clinical trial, possibly decreasing transferability.

Clinical implications and future research

Globally, as well as nationally, there is a growing demand for telemedical solutions, and recently the COVID-19 pandemic has helped recognise the significance of inventing and implementing digital health solutions. Therefore, exploring the experience of using telemedicine to self-test for a potential severe disease provides insights that are more broadly applicable to these rapidly developing technologies. This study provides new insights into women’s attitudes to and experiences with a smartphone-based self-test to predict PE. Being non-invasive and feasible, this was found to be an attractive test in principle. However, if self-testing is to be implemented, this study identifies important areas to focus on to handle levels of worry. First, the finding that women coped differently is important for healthcare workers to identify different needs for support for each pregnant woman, including adjusting the information level. Second, as worries may be reduced by providing an increased support to pregnant women, adding an FAQ and a chat function to the app could be beneficial.

In addition, since some women perceived the test as superior to subjective bodily sensations, it is essential to repeatedly communicate throughout pregnancy the importance of acknowledging physical sensations.

For women already at high risk of PE, our findings suggest that this subgroup might benefit psychologically from self-testing. Further, to increase user satisfaction and compliance, identification of technical issues are of great importance.

CONCLUSION

Our study suggests that using a smartphone-based self-test to predict PE affects women on a psychological level, leading to feelings of worry as well as safety, why healthcare workers should address and work with levels of worry if self-testing is implemented. Further, this study found, that self-testing is welcomed by pregnant women and that they found the test feasible, though some women might benefit from enhanced support from the healthcare workers to experience testing as accomplishable. With digital health on the rise, this study contributes with relevant findings on patient’s attitudes to self-testing for potential severe disease. Future studies investigating the experience of being labelled low risk versus high risk of PE are warranted.

Author affiliations

1Department of Gyneacology and Obstetrics, Zealand University Hospital, Roskilde, Denmark
2Department of Gynecology and Obstetrics and ReproHealth Consortium, Zealand University Hospital Koge, Koge, Denmark
3Department of Obstetrics, Copenhagen University Hospital, Rigshospitalet, Kobenhavn, Denmark
4Department of Obstetrics, Copenhagen University Hospital, Rigshospitalet, Kobenhavn, Denmark
5Department of Obstetrics, Hvidovre Hospital, Hvidovre, Denmark
6Department of Obstetrics, Copenhagen University Hospital, Rigshospitalet, Kobenhavn, Denmark
7London Womens Clinic, London, UK
8Department of Gynecology and Obstetrics and ReproHealth Consortium, Zealand University Hospital Koge, Koge, Denmark
Acknowledgements The authors want to acknowledge the women who agreed to participate in the study and thank them for sharing thoughts and experiences related to a personal and emotional area as pregnancy and childbirth.

Contributors ICP, MGdW, LB, NM and HKH designed the study. ICP, MGdW and HKH participated in the data collection. ICP, MGdW, LB and HKH analysed the data. All authors were involved in data interpretation. ICP drafted the manuscript with closely supervision from the coauthors. HKH is the guarantor of the study. All authors read and approved the final manuscript for publication.

Funding Morgan Innovation and Technology partly sponsored the Salurlate trial.

Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants and the study was approved by the Danish Data Protection Agency (REG-084-2018). The study protocol was presented to the Research Ethics Committee of Region Zealand, who had no objection to performance of the study (J.nr. 18-000080). Participants gave informed consent to participate in the study before taking part.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available on reasonable request. Original data are available on request by emailing the first author, who will delete any personal identification information.

Supplemental material This content has been supplied by the author(s). It has not been vetted by BMJ Publishing Group Limited (BMJ) and may not have been peer-reviewed. Any opinions or recommendations discussed are solely those of the author(s) and are not endorsed by BMJ. BMJ disclaims all liability and responsibility arising from any reliance placed on the content. Where the content includes any translated material, BMJ does not warrant the accuracy and reliability of the translations (including but not limited to local regulations, clinical guidelines, terminology, drug names and drug dosages), and is not responsible for any error and/or omissions arising from translation and adaptation or otherwise.

Open access This is an open access article distributed in accordance with the Creative Commons Attribution Non Commercial (CC BY-NC 4.0) license, which permits others to distribute, remix, adapt, build upon this work non-commercially, and license their derivative works on different terms, provided the original work is properly cited, appropriate credit is given, any changes made indicated, and the use is non-commercial. See: http://creativecommons.org/licenses/by-nc/4.0/.

ORCID iD Ida Catharina Püschl http://orcid.org/0000-0002-9670-0348


Precautionary Culture and the Rise of Possibilistic Risk Assessment (researchgate.net)
Thank you for engaging in this interview study.

**Intro to the conversation:** I would like to know how you experienced participating in the Salurate trial, and also how you experienced being pregnant, including eventual thoughts and worries. I would also like to hear how you experienced the presence or absence of disease during pregnancy, both on a general level and in relation to the trial you have participated in.

There are no right or wrong answers, so just speak freely and in your own words. If you have any questions for me related to health or the self-test, I will be happy to answer them after the interview to the best extent.

**Recording of the interviews:** If it is all right with you, I would like to audio-record the interview for my following work on this project? We will store it according to the safety procedures.

**Anonymity:** Before we start, I would like to mention again that what you tell during this interview is anonymous.

Do you have any questions before we start?

<table>
<thead>
<tr>
<th>CONTEXT</th>
<th>QUESTIONS</th>
</tr>
</thead>
</table>
| **The trial** | How did you experience participating in the Salurate trial? (If short answer, like "easy"). Could you try to elaborate on what was easy/why it was easy?)
|             | Could you tell me in your own words (just as if you were to explain it to a friend) what the trial was about?
|             | Try to describe what happened after you attended the mid-pregnancy scan, where I told you about the project, and you agreed to participate in the trial. |
| **Pre-eclampsia** | Could you try to explain to me in your own words what pre-eclampsia is? (just as if you were to explain it to a friend)
|             | Were you familiar with pre-eclampsia before being introduced to this trial? (If yes, how?)
|             | What were your thoughts on pre-eclampsia following the introduction to this trial?
|             | Did you subsequently seek information about pre-eclampsia?
<p>|             | Did you ever consider, whether you were at risk of developing pre-eclampsia yourself? |</p>
<table>
<thead>
<tr>
<th>General worries in the pregnancy</th>
<th>The interviewer asks about emotional aspects of being pregnant, focusing on worries</th>
<th>What might one possibly worry about when being pregnant? Do you recall any moments during your pregnancy where you were uncertain if what you felt in your body was normal? - (Can you elaborate on this?) - (Did it initiate any thoughts?) - (Do you recall if it made you worry about yourself and/or the baby?)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Self-testing</td>
<td>The interviewer asks the informant's experience with and thoughts about self-testing and tries to uncover the informant's thoughts about being at risk of developing pre-eclampsia</td>
<td>Try to describe how it was to do something every week related to the pregnancy. Did you think about the colours of the test? - (If yes: can you elaborate on how it made you feel?) Did you think about whether we had received the test, and if you had tested correctly? Do you think that the experience of testing changed during the pregnancy? Did the thoughts about testing change during the pregnancy, as you recall? Is it important to you, whether a positive test would lead to a specific treatment or to increased surveillance? Try to describe how you think you would experience it to be categorised as being at high risk of developing pre-eclampsia, and then not developing it.</td>
</tr>
<tr>
<td>Feasibility</td>
<td>The interviewer seeks to uncover the user experience and feasibility of the test</td>
<td>Try to describe how it was to use the test. Is there anything that you think could be improved concerning the test and the smartphone-app? - (If yes, in what ways?) How would you have liked it if the smartphone app contained a feature for communication with a health care worker? - (This could be in relation to any concerns about the test results, or it could be in relation to performance of the test) - (If yes, in what way would you prefer to communicate? A chat function, a text message, a phone call, or something else?)</td>
</tr>
<tr>
<td>Future potential</td>
<td>The interviewer asks about the future potential of the test</td>
<td>Do you think that you would want to use this test in a subsequent pregnancy if it was available?</td>
</tr>
</tbody>
</table>
The interviewer is summing-up and finishes the interview. However, I would like to ask if there is anything you would like to add? Maybe something that I did not ask about or something that you thought would have been smarter? Or is there anything that you thought about during the interview and did not have the chance to mention?

Thank you so much for your time and participation. It has been very helpful.

Before we finish, can I have your background information – your marital status, educational level, occupation, and weekly working hours?

Can I contact you later if there is anything I have forgotten to ask about?

Again, thank you so much for this.