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Maastricht University

Faculty of Medicine and Life Sciences
School for Life Sciences
Master of Biomedical Sciences

Master's thesis

Clinically validated digital apps and devices: do they have a future in gynecology?

Gitte Gaethofs

Thesis presented in fulfillment of the requirements for the degree of Master of Biomedical Sciences, specialization Clinical Molecular Sciences

SUPERVISOR :
Prof. dr. Wilfried GYSELAERS

MENTOR :
Mevrouw Pauline DREESEN
Mevrouw Hanne MARIEN

CO-SUPERVISOR :
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Acknowledgments

I was supposed to do an internship of eight months in order to graduate as a Biomedical Scientist at Hasselt University. I would like to thank Hasselt University and Ziekenhuis Oost-Limburg (ZOL, Genk) for giving me the opportunities, facilities and knowledge to perform my master thesis at the department of Gynecology and Obstetrics.

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List of abbreviations

3G	Third Generation
4G	Fourth Generation
Apps	Applications
BEATLE	Wearable tools for fetal wellbeing monitoring
BMI	Body mass index
cm	Centimeters
CRF	Case report form
CTG	Cardiotocography
ECG	Electrocardiography
EHG	Electrohysterography
EVA	Ervaringen van vrouwen omtrent het gebruik van digitale apps tijdens de zwangerschap
fHR	Fetal heart rate/foetaal hartritme
GA	Gestational age
GL	Gestationele leeftijd
IQR	Interquartile range
IUGR	Intrauterine growth restriction
mHealth	Mobile Health
MHU	Mobile health unit
MIC	Maternal intensive care
Min	Minutes
n	Sample size
P	P-value
PPROM	Preterm premature rupture of membranes
R	Correlation coefficient
R^2	Determination coefficient
SD	Standard deviation
SGA	Small for gestational age
SPSS	Statistical Package for Social Sciences
SR	Success rate
TMSi	Twente Medical Systems international
WiFi	Wireless Fidelity
ZOL	Ziekenhuis Oost-Limburg

Abstract

Introduction: Wearable devices and apps can assist women in monitoring their pregnancy. In the first study, the wearable tools for fetal wellbeing monitoring (BEATLE) study, fetal wellbeing (i.e. fetal heart rate, (fHR)) will be assessed by the Bloomlife sensor. However, the most optimal sensor position for high data quality of fHR detection in terms of accuracy and reliability remains unclear. We hypothesize that the data quality of fHR detection increases when placing the sensor on top of the fetus' back. The effect of gestational age (GA), Body mass index (BMI), and placental and fetal position on data quality is evaluated. In the second study (i.e. the experiences of women on the use of digital apps during pregnancy (EVA) study), the aim is to evaluate app usage, access to digital information, and needs and expectations during pregnancy. We hypothesize that women want to use apps during pregnancy for closer monitoring.

Subjects & methods: Forty subjects participated in the BEATLE study and were either assigned to group 1 (n=27) or group 2 (n=13). Group 1 consisted of patients who had participated only once. Subjects who participated more than one time were assigned to group 2. To test the first hypothesis, cardiotocography and the Bloomlife sensor were applied simultaneously to the pregnant woman's lower abdomen. The sensor was placed below the woman's belly button (i.e. position 1) and replaced to the top of the fetus' back (i.e. position 2) after 20 minutes. The entire population of the EVA study consisted of 94 subjects. To verify the second hypothesis, pregnant women or women who had recently given birth (i.e. women that are categorized as 'recently given birth', may not have given birth earlier than November 2017) were asked to fill in a questionnaire concerning the use of digital apps during pregnancy. A P-value <0.05 was considered a statistically significant difference.

Results: In group 1 and 2 of the BEATLE study, there are no statistically significant differences neither in the accuracy, nor in the reliability of fHR detection between sensor position 1 and 2. Furthermore, there are no statistically significant correlations between BMI and accuracy and/or reliability of fHR detection in both sensor positions. In group 2, there is a statistically significant correlation between accuracy and/or reliability of fHR detection of sensor position 2 and GA (P=0.046 and P=0.042) respectively. Additionally, in group 2, there is a statistically significant increase in the median accuracy of fHR detection in sensor position 1 compared to sensor position 2 in women with an anterior positioned placenta (P=0.049). Every woman of the EVA study, except one, is looking for pregnancy-related information, mostly to gain information about the development of their fetus. The three most important sources of information are the gynecologist, websites/internet forums and apps, with respectively 91.5%, 87.2% and 78.7% of the participants making use of them. Seventy-seven (81.9%) women have indicated that they have used/downloaded apps during their pregnancy. One very popular app used by almost 50% of the women, is 'Zwangerschap +'. Additionally, 70.1% of the surveyed women find it important that apps provide evidence-based information.

Discussion & conclusions: Placing the Bloomlife sensor above the fetus' back does not provide higher accuracy, nor reliability of fHR detection. Only GA has a statistically significant correlation with accuracy and/or reliability of fHR detection. Social media and mHealth apps are frequently used among pregnant women, essentially to acquire information about their fetus' development. In the future, evidence-based medical apps should be integrated into daily prenatal health care, encouraging patient engagement.

Samenvatting

Inleiding: Draagbare toestellen en apps kunnen vrouwen helpen bij het opvolgen van hun zwangerschap. In de eerste studie, draagbare toestellen voor het monitoren van foetaal welzijn (BEATLE), wordt het foetaal welzijn (i.e. foetaal hartritme (fHR)) gemeten met de Bloomlife sensor. De beste sensorpositie voor een hoge datakwaliteit van fHR detectie (i.e. accuraatheid en betrouwbaarheid) is echter nog niet gekend. Wij veronderstellen dat de datakwaliteit van de detectie van het fHR verbetert wanneer de sensor wordt verplaatst naar de foetus' rug. Tevens wordt de invloed van de gestationele leeftijd (GL), Body mass index (BMI), en placenta en foetus positie op de datakwaliteit geëvalueerd. Het doel van de tweede studie (i.e. ervaringen van vrouwen met het gebruik van digitale apps tijdens de zwangerschap (EVA) studie) is om het gebruik van apps, toegang tot digitale informatie, en behoeftes en verwachtingen tijdens de zwangerschap te beoordelen. Wij veronderstellen dat vrouwen apps willen gebruiken voor een nauwere zwangerschapsopvolging.

Patiënten & methoden: Veertig vrouwen namen deel aan de BEATLE studie en werden onderverdeeld in groep 1 (n=27) als ze één keer deelnamen en groep 2 indien ze meer dan één keer meededen (n=13). De eerste hypothese werd getest door de Bloomlife sensor simultaan met de cardiotocograaf te bevestigen op de vrouw haar onderbuik. De sensor werd geplaatst onder de vrouw haar navel (i.e. positie 1) en na 20 minuten verhangen naar de foetus' rug (i.e. positie 2). 94 personen namen deel aan de EVA studie. Om de tweede hypothese te testen moesten zwangere vrouwen en recent bevallen vrouwen (i.e. vrouwen die als 'pas bevallen' worden beschouwd, mogen niet voor november 2017 bevallen zijn) een vragenlijst over het gebruik van digitale apps tijdens de zwangerschap invullen. Een P-waarde <0.05 werd als een statistisch significant verschil beschouwd.

Resultaten: In groep 1 en 2 van de BEATLE studie zijn er geen significante verschillen in de accuraatheid, noch in de betrouwbaarheid van fHR detectie tussen positie 1 en 2. Bovendien zijn er geen significante correlaties tussen BMI en accuraatheid en/of betrouwbaarheid van fHR detectie in beide posities. In groep 2 is er een significante correlatie tussen accuraatheid en/of betrouwbaarheid van fHR detectie van sensor positie 2 en GL (P=0.046 en P=0.042) respectievelijk. Tevens is er in groep 2 een significante stijging in de accuraatheid van fHR detectie in sensor positie 1 in vergelijking met positie 2 in vrouwen waarbij de placenta vooraan ligt (P=0.049). Elke vrouw, op één na, zoekt informatie over de zwangerschap meestal om zich te informeren over de ontwikkeling van hun foetus. De gynaecoloog, websites/internetforums en apps zijn de drie belangrijkste informatiebronnen voor respectievelijk 91.5%, 87.2% en 78.7% van de ondervraagden. Zevenzeventig (81.9%) vrouwen hebben apps gebruikt/gedownload tijdens hun zwangerschap. Een populaire app is 'Zwangerschap +' die wordt gebruikt door 50% van de ondervraagden. Bovendien vindt 70.1% van de ondervraagde vrouwen het belangrijk dat apps wetenschappelijk onderbouwde informatie voorzien.

Discussie & conclusies: Het verplaatsen van de Bloomlife sensor naar de foetus' rug geeft geen betere accuraatheid, noch betrouwbaarheid in de detectie van het fHR. Er is enkel een statische significante correlatie tussen GL en accuraatheid en/of betrouwbaarheid in de detectie van het fHR. Sociale media en apps worden frequent gebruikt onder zwangere vrouwen, meestal om zich te informeren over de ontwikkeling van hun foetus. In de toekomst moeten wetenschappelijk onderbouwde medische apps geïntegreerd worden in de dagelijkse prenatale gezondheidzorg om een grotere betrokkenheid van de patiënt te realiseren.

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1. Introduction

Mobile Health (mHealth) is a rapidly developing area in healthcare wherein medical and public health practice is supported by mobile devices, such as mobile phones to which apps can be connected (1). Approximately 75% of the world population has access to mobile communication. Moreover, there are more than 97,000 health-related mobile applications (apps) available and around 1,000 new apps are published each month. Thus, the potential to perform telemonitoring exists (2). Remote monitoring or telemonitoring is defined as: "The use of telecommunication technologies to assist in the transmission of medical information and services between healthcare providers and patients" (3). Patients are performing measurements remotely in which the data is automatically sent via an app on their smartphone to the healthcare team (Figure 1). This way, the healthcare team can analyze the patients' data and provide them with appropriate feedback from a distance (1).

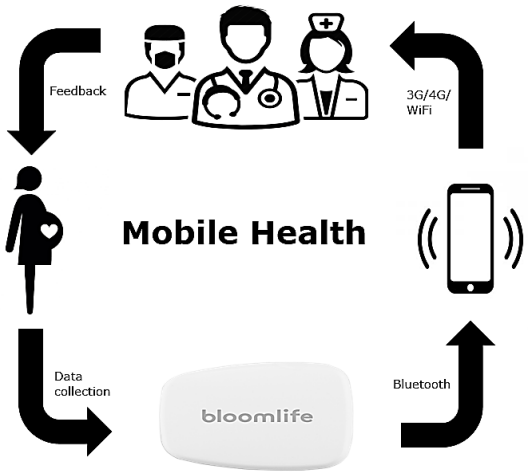

Figure 1. The principle of mHealth. Patient data is collected using a remote monitoring device from the patient's home. The remote monitoring device can transmit data to the patient's smartphone via Bluetooth. The data is then send to the healthcare team in the hospital via WiFi, 3G or 4G. The healthcare team provides the patient with feedback based on the received data. The Bloomlife sensor is used as an example of a remote monitoring device to explain to explain the principle of mHealth.

1.1 Remote monitoring in obstetrics

Lanssens et al. showed that remote monitoring of pregnancies at risk for gestational hypertensive disorders contributed to overall savings for both patients and the healthcare system due to a reduction of the use of healthcare resources, including maternal and neonatal admissions and medication usage (4).

1.1.1 Pregnancy apps

Pregnancy apps provide gestational age (GA) specific information throughout pregnancy (5). They offer a unique way of communicating with patients, both to collect information from them and to meet their needs (6).

There is a high level of interest in pregnancy apps among mobile device users. In June 2015, the 'I'm Expecting' app had between one and five million downloads from the Google Play store alone. Popular apps in the Apple App store in June 2015 were 'Period Diary' which is a fertility and ovulation tracker, 'My Pregnancy Today', 'Pregnancy & Baby – What to Expect' and 'Baby Names'. The bulk of

pregnancy apps are grouped into three main categories: entertainment, pregnancy and fetal monitoring and pregnancy information. The entertainment apps include games, shopping for pregnancy-related products, quizzes to test pregnancy knowledge, gender predictors and baby name generators. The second category allows to produce a repository of personal medical information such as weight and waist measurement, diet, water consumption, moods and medications. The last category offers a variety of information about pregnancy including details about fetal development and nutrition and exercise. Some information apps provide the possibility to connect with each other via online forums to share and compare personal stories and experiences (7).

Prof. dr. Inge Tency conducted a study whereby pregnant women were asked to fill in a questionnaire to investigate the multimedia and app usage during pregnancy. The questionnaire is divided into different topics concerning sociodemographic data and technology and app usage. In total, 60 pregnant women completed the questionnaire. The results have not been published yet.

1.1.2 Wearable devices for monitoring pregnant women

The evolution of digital technology made it possible to develop different home-based monitoring systems. Yuan et al. designed a fetal electrocardiography (ECG) device that collected fetal ECG signals in real time. The fetal ECG waveform and fetal heart rate (fHR) were displayed on a smartphone. Any detected abnormality was automatically uploaded to the cloud platform and subsequently further analyzed by the clinician. However, clinical studies have not been conducted yet (8).

Lai et al. developed a wearable system to monitor fetal movement patterns. This system consists of accelerometers and acoustic sensors. The wearable monitor has been validated with concurrent ultrasound on 44 pregnant women. They demonstrated that their system can detect and discriminate between different types of fetal movements which are general (movements of the whole body), startle (motions lasting about a second) and breathing movements. Maternal movements do not interfere with detection using an accelerometer to detect these movements. However, with the current monitor, it is not possible to predict the level of fetal activity. Nevertheless, this study contributes to further research toward a low-cost, wearable technology to monitor fetal movements (9).

An Israeli firm, the Nuvo Group, developed a pregnancy monitor. The PregSense is a wearable monitor that is designed to track fHR and maternal heart rate, fetal movements, and uterine contractions non-invasively. The wearable device is connected to an app that gives real-time data information about the mother's and the baby's health and can be shared with the doctor (10). A 200-patient trial is conducted to provide evidence of safety and compliance between PregSense and the standard of care, which is cardiotocography (CTG). A limitation of the clinical study of the Nuvo Group is that women should have a GA of 32 weeks or higher to take part in the study. Moreover, women with a body mass index (BMI) of ≥ 45 or ≤ 15 were excluded (11).

The Bloomlife sensor is a miniaturized, low-cost wearable device developed by Bloom Technologies. The aim is to develop a tool that can detect both uterine contractions, fHR and fetal movements remotely and non-invasively. We believe that the Bloomlife sensor monitors fetal wellbeing and uterine contractions objectively and accurately, thereby allowing to provide interventions in a more

timely and more efficient manner which in turn improves fetal outcomes and prolongs the gestational period respectively. A more detailed description of the Bloomlife device is provided in the section "Subjects and methods".

1.2 Preterm birth

Preterm birth is defined as birth before 37 weeks of gestation (12). Worldwide, 15 million babies are born preterm each year (13). In 2017, the frequency of preterm births in Flanders was approximately 7,8% (14). In 2007, the Institute of Medicine documented that the medical cost related to preterm birth in the United States alone was $16.9 billion per year (15).

1.2.1 Adverse effects of preterm birth

Preterm birth is the leading cause of neonatal death and the second cause of death in children below the age of five (12). Worldwide, one million babies die annually as a direct result of their prematurity (13). In Europe, 75% of all neonatal and 60% of all infant deaths occur in those born preterm (16). Preterm birth leads to the loss of months of fetal development, making the infant vulnerable to morbidities (17). Many of these morbidities are unique to the preterm population, such as reduced growth, cardiovascular, respiratory, gastrointestinal and metabolic problems, neurodevelopmental and cognitive dysfunction (15, 17).

1.2.2 Risk factors and causes

Premature birth, a syndrome with a variety of causes, can be divided into spontaneous and induced preterm birth. Preterm delivery can be induced by the care team due to maternal or fetal complications such as preeclampsia or intrauterine growth restriction (IUGR) respectively (12). Spontaneous preterm birth can be further divided into the spontaneous onset of labor and preterm premature rupture of membranes (PPROM) (18). Spontaneous preterm birth is a multifactorial process that emerges from the interaction of factors causing the uterus to shift from inactivity to active contractions, resulting in delivery before 37 completed weeks of gestation (18). However, half of all preterm births occur in women with no known clinical risk factors (19). Maternal history of preterm birth is a strong risk factor for spontaneous preterm birth but, young or advanced age, short inter-pregnancy intervals and, low maternal BMI, increase also the chance of delivering preterm. There are also some lifestyle factors that strengthen the risk for a preterm delivery including stress, smoking, excessive physical work and alcohol consumption (18). However, it is important to emphasize that risk is not equivalent to causation (20).

1.2.3 Diagnosis

The diagnosis of preterm labor is mostly based on the occurrence of regular uterine contractions (≥ 4 every 20 min or ≥ 8 in 60 min) accompanied by a change in cervical dilatation (≥ 3 cm). The criteria for diagnosing preterm labor lack precision because the underlying etiology of preterm labor is not completely understood. Symptoms such as severe uterine contractions, pelvic pressure, increased vaginal discharge, and low back pain are correlated with preterm labor. However, these symptoms also occur in women with normal pregnancies, making the diagnosis of preterm labor even more difficult. Problems in diagnosing preterm labor often result in overdiagnosis in up to 40% of women with symptoms of preterm labor. Moreover, less than 10% of the women that are diagnosed with preterm labor give birth within seven days of presentation (20).

1.2.4 Prevention

Preventing preterm labor will prolong pregnancy and allow further intrauterine growth, resulting in improved neonatal outcomes (21).

The morbidity and mortality of preterm birth can be reduced by primary, secondary, or tertiary interventions. Primary prevention e.g. nutritional supplements and cessation of smoking is directed to all women before or during their pregnancy with the aim to prevent and reduce risk. The aim of a secondary intervention is to eliminate or reduce risk in women with known risk factors e.g. a previous preterm birth and multiple gestation. Tertiary prevention is initiated when preterm contractions are started and aims at preventing delivery or improving outcomes for preterm infants. Tocolytic drugs, antibiotics, and antenatal corticosteroids are examples of tertiary interventions (22).

1.2.5 Uterine monitoring

The occurrence of regular uterine contractions is often used to predict preterm labor (20). Differentiating true and false labor is often a challenge despite the availability of tocodynamometry and electrohysterography (EHG), which both detect uterine contractions. Uterine contractions are the result of the electrical activity within the uterus. Therefore, measuring the uterine electrical activity can be used to monitor and analyze the contractility of the uterus (20).

✓ *Tocodynamometry*

External tocodynamometry is currently the method of choice, being non-invasive and simple to apply (23). It measures the frequency and approximate duration of contractions, but not their intensity. However, signal dropout is common, necessitating repositioning. Tocodynamometry also often fails in obese women (24).

✓ *Electrohysterography*

EHG is a non-invasive technique that records the electrical activity of the uterus through electrodes placed on the woman's abdomen (23). Uterine electrical activity is infrequently and insufficiently coordinated early in pregnancy, whereas it becomes more intense and synchronized later in pregnancy. EHG identifies women and especially obese women in true labor better than any other method presently used in clinics (20). However, clinicians are not familiar with the interpretation and analysis of the results yet, restricting its clinical application (25).

1.3 Fetal wellbeing

It is important to recognize timely and subsequently manage appropriately high-risk pregnancies, such as pregnancies in which the fetus appears with IUGR (26). In addition to IUGR, there are other factors that pose a risk to fetal wellbeing. These factors are already listed under the section "1.2.2 Risk factors and causes". Fetal wellbeing can be evaluated by different methods, including fetal movement counting and fHR monitoring (27).

1.3.1 Fetal health related problems

Worldwide, there are 3.2 million stillbirths at 28 weeks of gestation or more every year. IUGR and small for gestational age (SGA) (i.e. birthweight below 10^{th} centile) are the main risk factors for stillbirth (28).

IUGR is a main cause of diverse morbidities and mortalities for the fetal and neonatal population. It is described as the rate of fetal growth that is lower than normal for the growth potential of that fetus (29). Short-term consequences of IUGR include thermal, metabolic, and hematological disorders. Long-term effects are increased risk of developing metabolic syndrome and cardiovascular disease, systolic hypertension, obesity, insulin resistance, and diabetes type II (30).

1.3.2 Fetal wellbeing monitoring

Fetal monitoring is employed to examine fetal wellbeing. Monitoring of fetuses provide early detection and treatment of pregnancy complications, subsequently, allowing further maturation of the unborn baby. Fetal wellbeing is assessed throughout pregnancy, labor, and birth and evaluated by different factors such as fetal growth, movement, and cardiac function (27).

- ✓ *Cardiotocography*

CTG records the fHR and the contractions of the uterus simultaneously (31). The fHR and the uterine activity are obtained via an ultrasound transducer and a pressure-sensitive transducer respectively, both placed on the abdomen of the pregnant woman. Baseline fHR, variability, accelerations and decelerations are routinely assessed (26). CTG is often used in antenatal monitoring despite its major drawbacks including a high false positive rate causing unnecessary interventions, insufficient CTG interpretation standards, and poor inter- and intra-observer agreement in assessing fHR patterns (32).

- ✓ *Ultrasound*

Ultrasound is used to estimate the GA and to screen for anomalies. Additionally, fetal ultrasound measurements are commonly used to monitor fetal growth and movement. However, ultrasound is expensive and trained personnel is required (33).

- ✓ *Fetal movement counting*

The fetus' condition is also evaluated by the number of fetal movements counted by the mother (34). The advantage of the count-to-ten method is that it can be performed several times a day. It is the most commonly used technique where the woman is advised to record the time she needs to feel ten fetal movements. If it takes more than two hours to note ten fetal movements, they should seek medical care (35). A reduced number of fetal movements is correlated with a range of adverse pregnancy and birth outcomes such as fetal growth restriction and stillbirth (34). However, many factors different from worsening fetal condition can influence the perception of fetal movement including maternal activity, obesity, GA, and placental location (35). The average sensitivity of maternal perception of fetal movements is only 30%, constituting a major drawback of this method (36).

1.4 Prenatal management: facing problems

Pregnant women who are at increased risk for pregnancy complications are more often hospitalized and experience more stress, which in turn influences the growth of the fetus. This intensified monitoring and follow-up causes high healthcare costs. One way to reduce costs is by increasing the efficiency within healthcare organizations to reduce the number of face-to-face consultations and days spent in the hospital. Another way to reduce hospital costs is by detecting pregnant women at

risk at an early stage. Another drawback of the present healthcare system are the time gaps between consultations because the first signs of complications may not be picked up in time (37).

The currently used methods to assess fetal wellbeing and uterine contractions are limited in time and frequency and represent only a snapshot. Moreover, fHR and uterine contraction measurements can only be performed in hospital settings. At present, there is no tool to monitor fetal wellbeing objectively and accurately in a home environment. Wearable devices and apps can aid women to monitor their pregnancy remotely, hence reducing time gaps between consultations. They allow urgent care remotely and closer pregnancy monitoring (38).

1.5 Objectives and hypotheses

We believe that the Bloomlife sensor monitors fetal wellbeing objectively and accurately, thereby allowing to provide interventions in a more timely and more efficient manner which in turn improves fetal outcomes. Next to this, we think that women are willing to use digital apps for closer pregnancy monitoring. Keeping this in mind, two studies are being conducted during this internship.

In the first study, the wearable tools for fetal wellbeing monitoring (BEATLE) study, we aim to investigate if the data quality (i.e. accuracy and reliability) of fHR detection increases when the Bloomlife sensor is placed above the fetus' back compared to the regular position (i.e. below the belly button). The hypothesis is that the accuracy increases and the reliability of fHR detection improves when placing the sensor above the fetus' back.

Information obtained from the BEATLE study will contribute to a better understanding of the use of the Bloomlife sensor for fHR monitoring.

The second study, the experiences of women on the use of digital apps during pregnancy (EVA) study, aims to evaluate the applicability of digital apps during pregnancy. The following hypothesis can be formulated: "Pregnant women use digital apps to monitor their own and fetus' health."

By asking pregnant women and new moms to fill in a questionnaire related to the use of digital apps during pregnancy, insight is gained into the use of digital apps, their impact on pregnancy experiences and how expecting parents acquire new insights (Appendix, pages 39 – 47). In case of pregnancy, early and regular follow-up by a doctor or a midwife is recommended. The care team must pay sufficient attention to the questions of the pregnant woman and her partner, so that future parents take more responsibility and make informed decisions. In the future the implementation of clinically validated digital apps in gynecology can lead to more efficient support during pregnancy in the field of administration, knowledge, and home monitoring.

2. Subjects and methods

Both studies complied with the Declaration of Helsinki, and written informed consent was obtained from all participants. The protocol and other study related documents were approved by the local institutional ethics committee. Both studies are part of the Mobile Health Unit (MHU) and were conducted at the department of Gynecology at ZOL in Genk.

2.1 BEATLE study – Patch position testing

The BEATLE study aims to develop a new generation of the Bloomlife sensor which allows continuous fetal wellbeing monitoring (i.e. fHR and fetal movement). In our study, the CTG was used as the standard device to measure fHR and will be used as the reference for the measurement of fHR with the Bloomlife sensor.

In phase one of the study, data is collected using the Twente Medical Systems international (TMSi) (TMSi B.V., Overijssel, The Netherlands) and CTG to develop algorithms for fHR and fetal movement detection and to determine the optimal electrode positions for the patch. In phase two, data is collected with the Bloomlife sensor and CTG on the one hand and with the Bloomlife sensor and ultrasound on the other hand. The aim of phase two is to evaluate the algorithms developed in phase one and to subsequently adapt and improve the software of the sensor. As a subpart of phase two, the position of the patch of the Bloomlife sensor is placed above the fetus' back to investigate if the data quality (i.e. accuracy and reliability) of fHR detection increases compared to the regular position (i.e. below the belly button). The latter part will be executed during my internship.

The accuracy and reliability of fHR detection are assessed for both groups for two sensor positions, namely, the regular sensor position (i.e. below the belly button) and the new sensor position (i.e. above the fetus' back) (Figure 2).

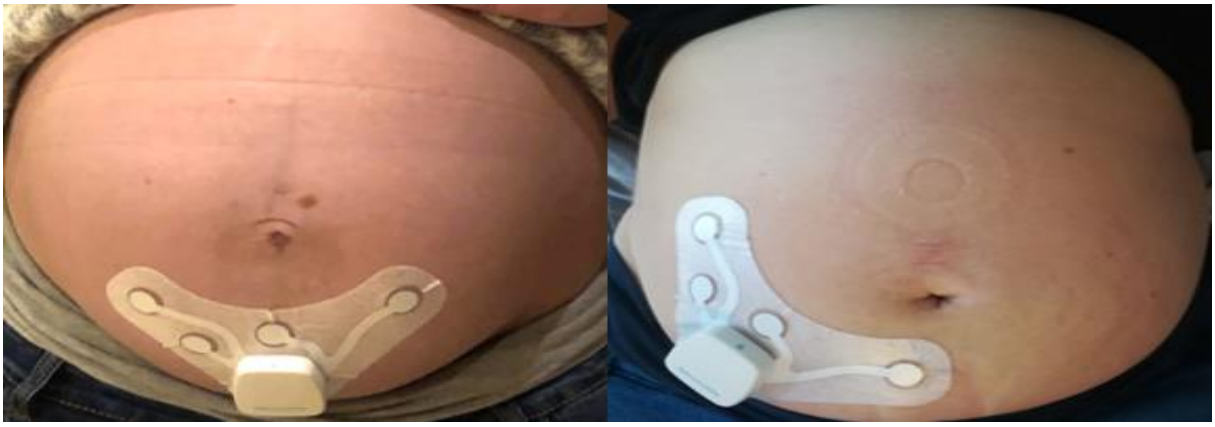

Figure 2. Regular position of the Bloomlife sensor (left) and new position of the Bloomlife sensor (right).

Hereafter, regular sensor position and new sensor position are named as sensor position 1 and sensor position 2 respectively.

2.2 EVA study – Questionnaire

The aim is to assess the opinion of (pregnant) women about the use of digital apps during pregnancy based on a questionnaire to provide optimal guidance considering her personal experiences and expectations.

2.3 Study population

Hereafter, the inclusion and exclusion criteria of the BEATLE and EVA study are specified.

2.3.1 BEATLE study – Patch position testing

Women were eligible to participate in the BEATLE study if they were eighteen years or older, had a GA of at least twenty weeks, had a singleton pregnancy and spoke Dutch. They could not participate in the study if they had a multiple pregnancy, an implanted pacemaker or another implanted electrical device and/or a silicone allergy.

2.3.2 EVA study – Questionnaire

To fill out the EVA study questionnaire, women had to be pregnant or had recently given birth (i.e. women that are categorized as 'recently given birth', may not have given birth earlier than November 2017). Moreover, they must been eighteen years or older and must be able to read and understand Dutch.

2.4 Study procedure

Following sections stated the executed protocols of the BEATLE and EVA study.

2.4.1 BEATLE study – Patch position testing

The Bloomlife sensor (Bloom Technologies, California, USA) measures electrophysiological signals and acceleration. It is attached to the user's lower abdomen using a five-electrode medical grade adhesive patch (Figure 3). The sensor can be used to track the electrical activity of the uterus (EHG) and the maternal heart rate and fHR (ECG) by measuring tree-lead electrophysiological signals, allowing to monitor the frequency and duration of contractions. Moreover, it is also able to record fetal movement (actimetry) by measuring tree-axis acceleration (39). A great advantage of the Bloomlife device is that it only records electrical waves from the body and does not generate any energy inside the body, making it a safe and non-invasive pregnancy monitoring tool. Moreover, it is a portable, low-cost and easy to use device for continuous monitoring during pregnancy.

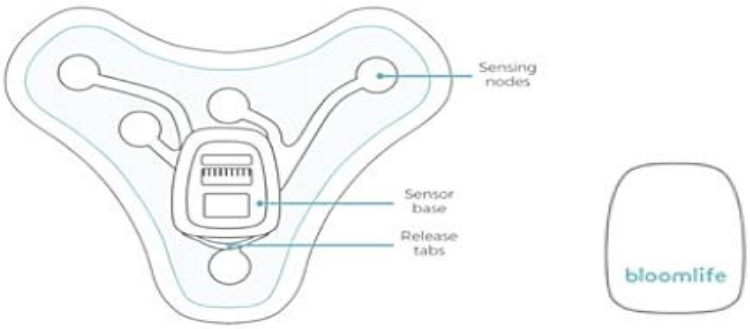

Figure 3. The Bloomlife sensor (right) and adhesive patch (left).

Pregnant women hospitalized at the maternal intensive care (MIC) unit, who met the inclusion and exclusion criteria, were informed about the study and enrolled if they agreed to participate. Pregnant women who were not hospitalized were informed about the study through a phone call. The investigator asked if they had time and were willing to participate in the study before or after their next prenatal consultation or ultrasound. If they agreed, a study visit was scheduled.

During the study visit, the subjects were asked to lie down on a hospital bed. The CTG probes and the Bloomlife sensor (Bloom Technologies, California, USA) were applied simultaneously to the woman's abdomen and the pulse oximeter was placed on top of the finger. After twenty minutes the position of the sensor was changed. The total duration of the measurement was 40 minutes. After the measurements, the participants received a gift voucher of 25 euros as compensation for their time and expenses related to the study visit.

Information about current and past pregnancies, personal and clinical information were recorded in the Case Report Form (CRF).

2.4.2 EVA study – Questionnaire

Pregnant women or women who had recently given birth were asked to fill in the questionnaire concerning the use of digital apps during pregnancy anonymously in the waiting room of the Gynecology department. Afterwards, these questionnaires were deposited in an enclosed box. Additionally, a call will be made via social media (e.g. Facebook) to fill in the questionnaire digitally via Qualtrics.

The aim was to include as many as participants as possible within the foreseen period (April 2019 to June 2019).

2.5 Data analysis

All data were analyzed with Statistical Package for Social Sciences Version 25.0 (SPSS Inc, Chicago, Illinois, USA).

2.5.1 BEATLE study – Patch position testing

Continuous variables (BMI, GA, age, birth weight, length, head circumference, accuracy, reliability) were presented as mean and standard deviation (SD) or median and interquartile range (IQR) when the normality test failed. Normality of the data was determined by the Shapiro-Wilk statistic. Categorical variables such as placental and fetal position, educational level, etc. were presented as absolute number and percentage (n - %). Independent two-sided test or a Mann-Whitney test were performed to compare continuous variables between two groups, while categorical data were compared using Chi-square test. The Wilcoxon signed-rank test was used to compare accuracy and reliability of fHR detection between the regular sensor position and new sensor position. The Wilcoxon signed-rank test was also used to compare variables between two groups. Spearman's rank-order correlation was used to assess possible correlations between non-normally distributed continuous variables. The Kruskal Wallis test was used to compare discrete variables between > 2 groups. All analyses were two-sided and a p-value <0.05 was considered statistically significant. Data were analyzed with SPSS Version 25.0 (SPSS Inc, Chicago, Illinois, USA).

2.5.2 EVA study – Questionnaire

Year of birth, a continuous variable, was presented as median and IQR because the normality test failed. Normality of the data was assessed by the Shapiro-Wilk statistic. Categorical variables (educational level, marital status) were shown as absolute number and percentage (n - %). Data were analyzed with SPSS Version 25.0 (SPSS Inc, Chicago, Illinois, USA).

3. Results

The results of the BEATLE and EVA study are discussed in the following sections.

3.1 Characteristics of the BEATLE subjects

The entire population of the BEATLE study consisted of 40 pregnant women. In total, 74 measurements are performed, meaning that some subjects are measured more than once (Figure 4). The study population is divided into two groups, depending on the number of study measurements performed. Group 1 (n=27) consisted of patients who have participated only once. Subjects who participated more than one time are assigned to group 2 (n=13). In total, 7 subjects did not deliver at ZOL due to a temporary transfer from another hospital to ZOL. Consequently, no postpartum data are available for these patients.

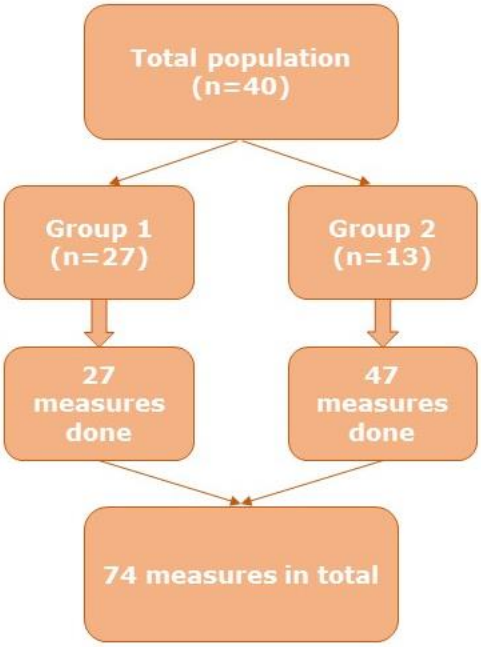

Figure 4. Overview of the total study population and total measurements of the BEATLE study. n: sample size.

Patient's and fetus' baseline characteristics are summarized in Table 1. The median GA at inclusion in group 1 and group 2 is 35.64 (IQR 10.07) and 35.76 (IQR 4.62) respectively. The mean GA at delivery in group 1 and group 2 is 38.98 ± 1.43 and 39.71 ± 2.38 respectively and is statistically significant different between group 1 and group 2 (P=0.023). The occurrence of proteinuria is significant different between group 1 and group 2 (P=0.016). There are also statistically significant differences observed with respect to fetal characteristics. Birth weight and length of the fetus are statistically significant different between group 1 and group 2 (P=0.004 and P=0.045) respectively. Considering the total population, there is only one woman who have had a previous preterm delivery. In group 1, 74.1% of the included women never smoked, 3.7% continued smoking during pregnancy and 22.2% stopped smoking. In group 2, 92.3% of the included women never smoked, no one continued smoking during pregnancy and 7.7% have ever smoked but have already stopped at inclusion or even before inclusion. The vast majority of group 1 (48.1%) completed secondary education. No statistically significant differences between group 1 and group 2 are observed with respect to socio-demographic characteristics.

Table 1. Patient's and fetus' baseline characteristics of group 1 (n=27) and group 2 (n=13) of the BEATLE study.

Variable	Group 1 (n=27)	Group 2 (n=13)	P-value†
Socio-Demographics			
Age, years	29.00 ± 4.21	30.33 ± 6.81	0.144
BMI (kg/m²)			
Before pregnancy	24.84 ± 4.69	25.50 ± 3.42	0.599
During pregnancy	27.84 ± 4.20	29.41 ± 3.35	0.739
Educational level – n (%)			0.445
Secondary education	13 (48.1)	4 (30.8)	
Bachelor	9 (33.3)	6 (46.2)	
Master	4 (14.8)	1 (7.7)	
PhD	1 (3.7)	1 (7.7)	
Unknown	0 (0.0)	1 (7.7)	
Pregnancy characteristics			
GA, weeks			
At inclusion	35.64 (IQR 10.07)	35.76 (IQR 4.62)	0.272
At delivery	38.98 ± 1.43	39.71 ± 2.38	**0.023***
Placental position – n (%)			0.493
Posterior	10 (37.0)	6 (46.2)	
Anterior	13 (48.1)	4 (30.8)	
Lateral	2 (7.4)	2 (15.4)	
Fundal	1 (3.7)	0 (0.0)	
Previa	1 (3.7)	0 (0.0)	
Unknown	0 (0.0)	1 (7.7)	
Fetal position – n (%)			0.369
Head	22 (81.5)	12 (92.3)	
Breech	5 (18.5)	1 (7.7)	
GPA – n (%)			
Gravida			0.919
Primigravida	15 (55.6)	7 (53.8)	
Multigravida	12 (44.4)	6 (46.2)	
Para			0.570
0	18 (66.7)	10 (76.9)	
1	8 (29.6)	2 (15.4)	
2	1 (3.7)	1 (7.7)	
Abortus/Miscarriages			0.941
0	19 (70.4)	9 (69.2)	
1	8 (29.6)	4 (30.8)	
Risk factors – n (%)			
Smoking			0.386
Yes	1 (3.7)	0 (0.0)	
Never	20 (74.1)	12 (92.3)	
Quit	6 (22.2)	1 (7.7)	

Previous preterm births			0.482
Yes	1 (3.7)	0 (0.0)	
No	26 (96.3)	13 (100.0)	
Diabetes			0.412
Yes	1 (3.7)	2 (15.4)	
No	23 (85.2)	10 (76.9)	
Unknown	3 (11.1)	1 (7.7)	
Hypertension			0.702
Yes	3 (11.1)	2 (15.4)	
No	24 (88.9)	11 (84.6)	
Proteinuria			**0.016***
Yes	1 (3.7)	5 (38.5)	
No	23 (85.2)	7 (53.8)	
Unknown	3 (11.1)	1 (7.7)	
Bleeding			0.736
Yes	5 (18.5)	3 (23.1)	
No	22 (81.5)	10 (76.9)	
Renal diseases			0.144
Yes	0 (0.0)	1 (7.7)	
No	27 (100.0)	12 (92.3)	
Fetal characteristics			
Gender – n (%)			0.564
Girl	14 (51.9)	8 (61.5)	
Boy	13 (48.1)	5 (38.5)	
Birth weight (g)	3165.25 ± 574.52	3398.33 ± 362.50	**0.004***
Length (cm)	50.50 (IQR 2.40)	49.33 (IQR 2.08)	**0.045***
Head circumference (cm)	33.53 (IQR 1.20)	34.00 (IQR 1.00)	0.284
Apgar after 1 min – n (%)			0.357
6 – 7	3 (11.1)	3 (23.1)	
8 – 9	19 (70.4)	5 (38.5)	
Unknown	5 (18.5)	5 (38.5)	
Apgar after 5 min – n (%)			0.190
8 – 10	21 (77.8)	8 (61.6)	
Unknown	6 (22.2)	5 (38.5)	

Data are presented as mean ± standard deviation (SD) for parametric continuous variables and as median and interquartile range (IQR) for non-parametric continuous variables. Categorical variables are presented as number of patients and percentage. n: sample size. A P-value <0.05 was considered a statistically significant difference (*). *Apgar* appearance pulse grimace activity respiration; *BEATLE* wearable tools for fetal wellbeing monitoring; *BMI* body mass index; *GA* gestational age; *GPA* gravida para abortus; *PhD* Doctor of Philosophy. † comparison between group 1 and group 2.

3.2 BEATLE study – Group 1

In total, 27 subjects participated one time in the study and are assigned to group 1 of the BEATLE study.

3.2.1 Comparison of accuracy and reliability of fetal heart rate detection between sensor position 1 and sensor position 2

Accuracy is described as how well a measuring instrument determines the variable it is measuring. The median accuracy of fHR detection of sensor position 1 and sensor position 2 is 22.0% (IQR 48.0%) and 15.0% (IQR 60.0%) respectively. Reliability can be interpreted as the overall consistency of a measure. A measurement is considered reliable if it produces the same results when the measurement is repeated. The median reliability of fHR detection of sensor position 1 and sensor position 2 is 16.0% (IQR 43.0%) and 18.0% (IQR 66.0%) respectively.

The median differences in accuracy and reliability of fHR detection are not statistically significant between sensor position 1 and sensor position 2 for study group 1 (P=0.393 and P=0.394) respectively (Figure 5).

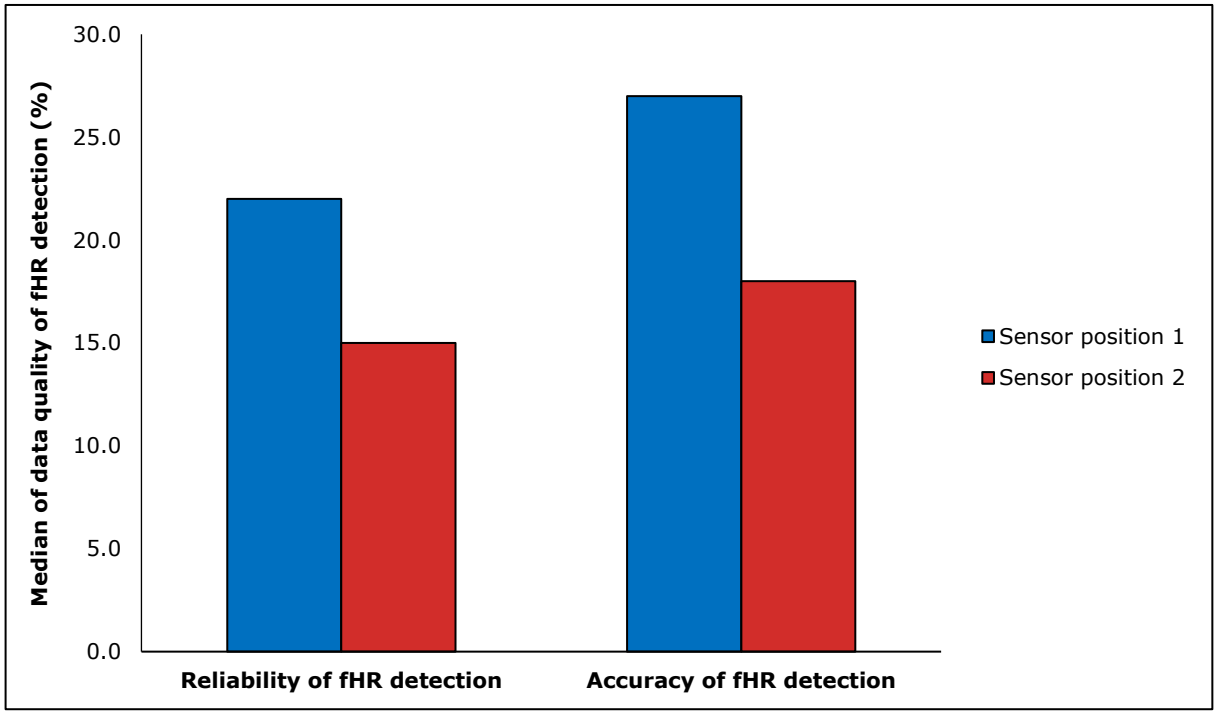

Figure 5. The Bloomlife sensor's accuracy and reliability of fetal heart rate detection of sensor position 1 and sensor position 2 represented for study group 1. No statistically significant differences in the median accuracy or reliability are observed between sensor position 1 and sensor position 2. A P-value <0.05 is considered a statistically significant difference. *fHR* fetal heart rate.

3.2.2 Correlations

Different variables are tested for a possible correlation with the accuracy and/or reliability of fHR detection of sensor position 1 and sensor position 2. Both GA and BMI show no statistically significant correlation with accuracy and reliability of fHR detection of sensor position 1 (Appendix, Table 3). The same applies to sensor position 2 (Appendix, Table 4).

3.2.3 Data quality – Accuracy and reliability of fetal heart rate detection

The effect of placental and fetal position on data quality (i.e. accuracy and reliability) of both sensor positions is evaluated.

✓ *Effect of placental position on accuracy and reliability of fetal heart rate detection*

The median accuracy of fHR detection of sensor position 1 is not statistically significant different between the various placental positions: posterior, anterior and fundal (P=0.301) (Figure 6). The same applies for the median accuracy of fHR detection of sensor position 2 (P=0.495) (Figure 6). Furthermore, there are no statistically significant differences in the median accuracy of fHR detection between sensor position 1 and sensor position 2 among the different placenta positions (Appendix, Table 5).

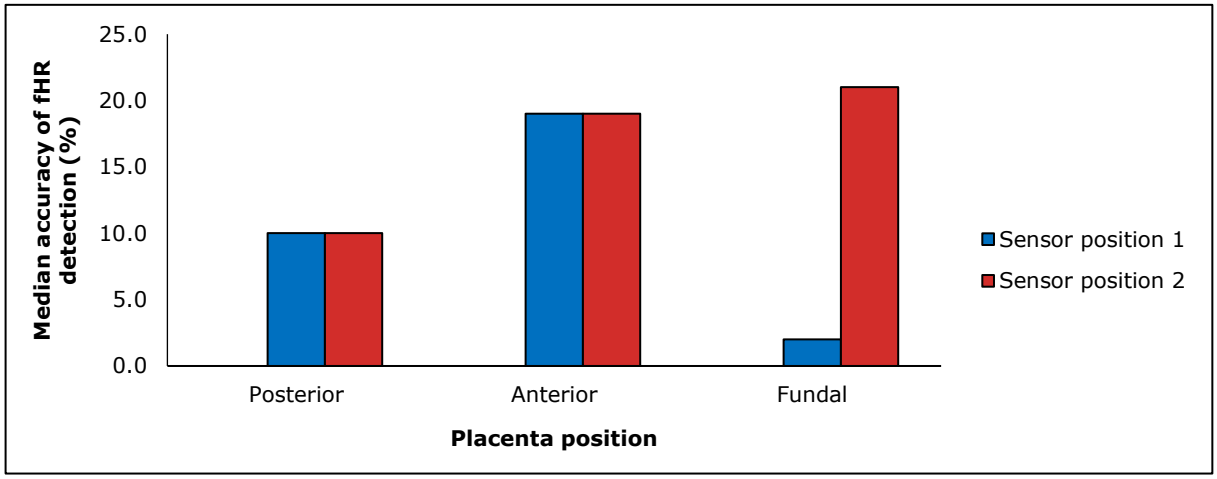

Figure 6. Median accuracy of fetal heart rate detection of sensor position 1 and 2 for different placental positions (i.e. posterior, anterior and fundal) represented for study group 1. A P-value <0.05 is considered a statistically significant difference. *fHR* fetal heart rate.

The median reliability of fHR detection of sensor position 1 is not statistically significantly different for the various placental positions (P=0.441) (Figure 7). The same is applicable for the median reliability of fHR detection of sensor position 2 (P=0.499) (Figure 7). There are also no statistically significant differences in the median reliability of fHR detection between sensor position 1 and sensor position 2 among the three different placenta positions (Appendix, Table 5).

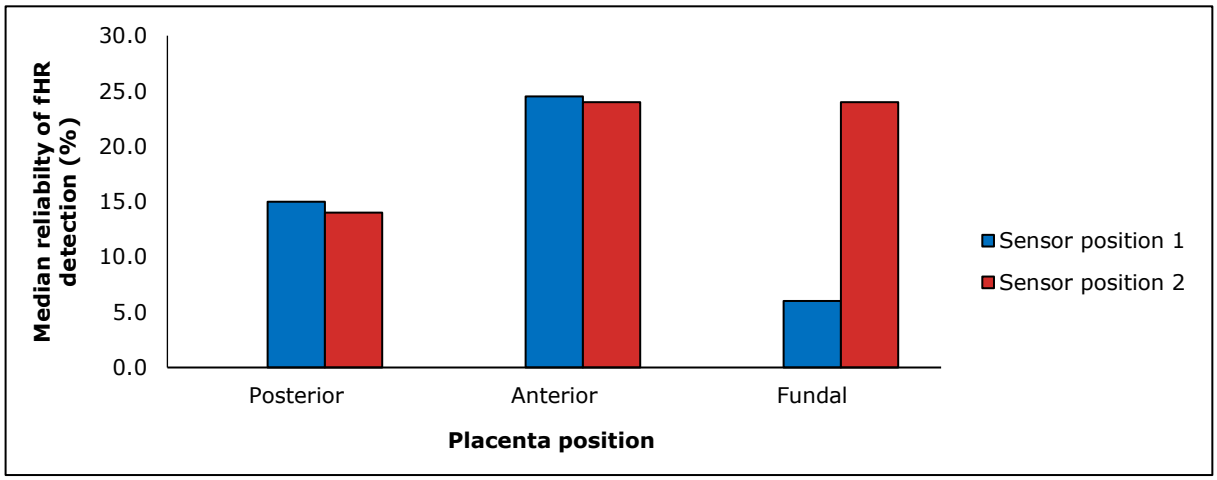

Figure 7. Median reliability of fetal heart rate detection of sensor position 1 and 2 between three different placental positions (i.e. posterior, anterior, fundal) represented for study group 1. A P-value <0.05 is considered a statistically significant difference. *fHR* fetal heart rate.

✓ *Effect of fetal position on accuracy and reliability of fetal heart rate detection*

The accuracy of fHR detection of sensor position 1 is compared between two fetal positions: head and breech. This is likewise performed to detect differences in accuracy of fHR detection of sensor position 2 between the two fetal positions. The median accuracy of fHR detection of sensor position 1 is not statistically significant different between head and breech (P=0.827) (Figure 8). The median accuracy of fHR detection of sensor position 2 is also not statistically significant different between head and breech (P=0.850) (Figure 8). There are also no statistically significant differences in the median accuracy of fHR detection between sensor position 1 and sensor position 2 among the two tested fetal positions (Appendix, Table 6).

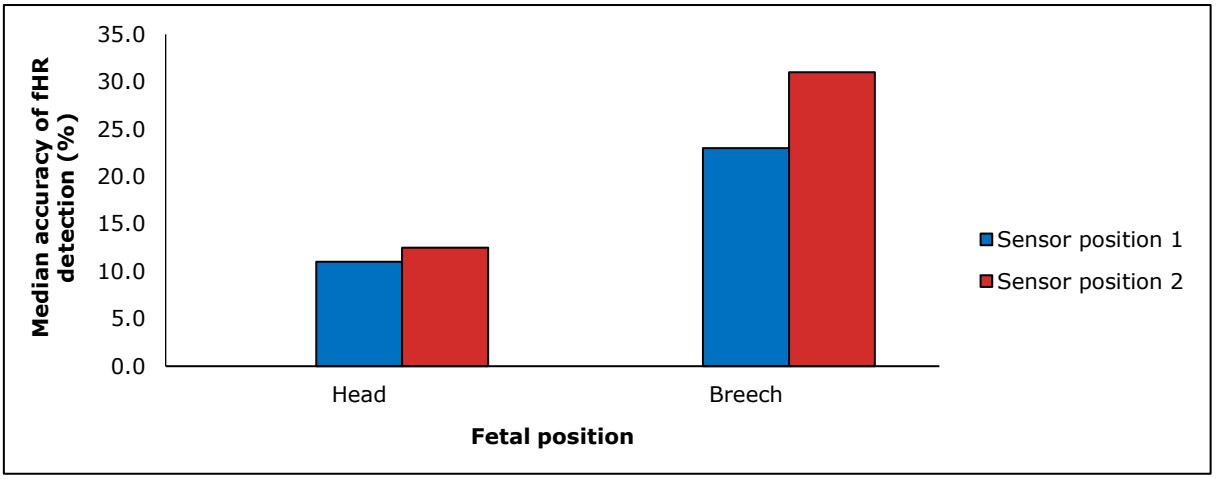

Figure 8. Median accuracy of fetal heart rate detection of sensor position 1 and 2 in two fetal positions (i.e. head and breech) represented for study group 1. A P-value <0.05 is considered a statistically significant difference. *fHR* fetal heart rate.

Median reliability of fHR detection of sensor position 1 is not statistically significantly different between head and breech position (P=0.574). There is also no statistically significant difference in the median reliability of fHR detection of sensor position 2 between the two observed fetal positions (P=0.614) (Figure 9). Moreover, there are no statistically significant differences in the median reliability of fHR detection between sensor position 1 and sensor position 2 among the two different tested fetal positions (Appendix, Table 6).

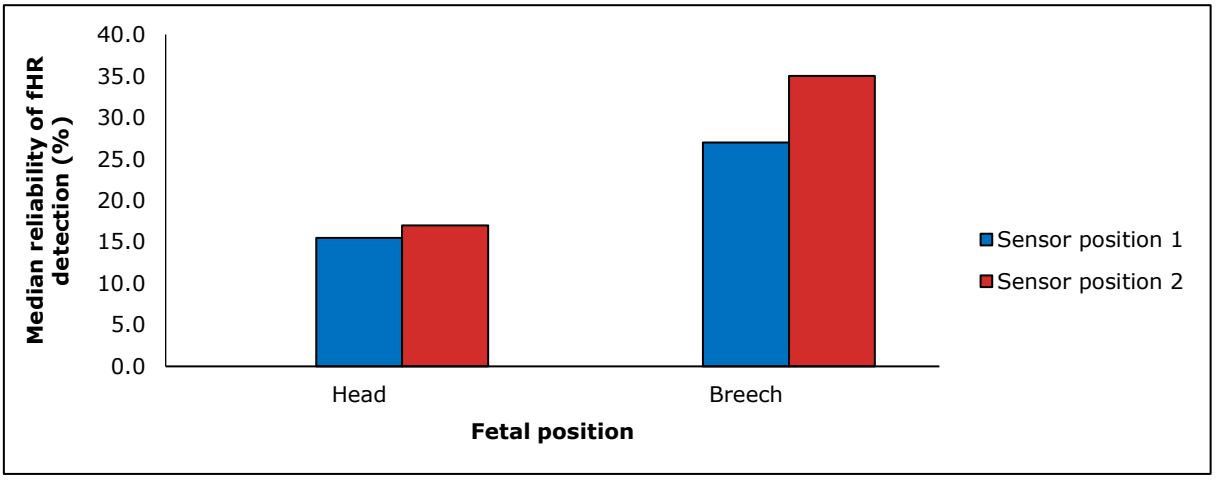

Figure 9. Median reliability of fetal heart rate detection of sensor position 1 and 2 in two fetal positions (i.e. head and breech) represented for study group 1. A P-value <0.05 is considered a statistically significant difference. *fHR* fetal heart rate.

3.3 BEATLE study – Group 2

Group 2 of the BEATLE study included 13 subjects. In this group, a total of 47 measurements are performed with an average of four per woman.

3.3.1 Comparison of accuracy and reliability of fetal heart rate detection between sensor position 1 and sensor position 2

The median accuracy of fHR detection of sensor position 1 and sensor position 2 is 37.0% (IQR 53.0%) and 17.0% (IQR 50.0%) respectively. The median reliability of fHR detection of sensor position 1 and sensor position 2 is 45.0% (IQR 61.0%) and 20.0% (IQR 57.0%) respectively.

It is investigated whether a higher data quality of fHR detection (i.e. accuracy and reliability) is achieved for sensor position 2. There is a tendency towards a median decrease in accuracy of fHR detection when comparing sensor position 2 to sensor position 1, however, this difference is not statistically significant (P=0.053). The median difference in reliability of fHR detection is also not statistically significant when sensor position 2 is compared to sensor position 1 (P=0.085) (Figure 10).

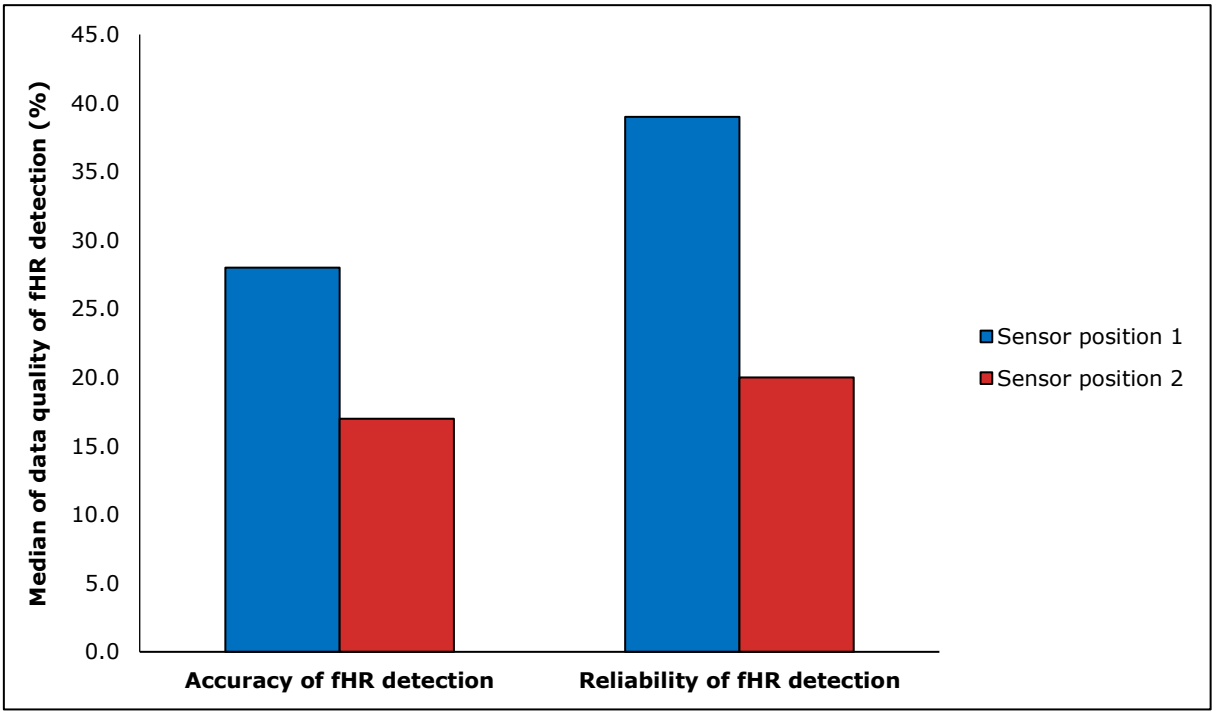

Figure 10. The Bloomlife sensor's accuracy and reliability of fetal heart rate detection in sensor position 1 and sensor position 2 represented for study group 2. No statistically significant differences in the median accuracy or reliability are observed between sensor position 1 and sensor position 2. A P-value <0.05 is considered a statistically significant difference. *fHR* fetal heart rate.

3.3.2 Correlations

GA and BMI are both tested for a possible correlation with the accuracy and reliability of fHR detection of sensor position 1 and sensor position 2. GA and BMI both show no statistically significant correlation with accuracy and reliability of fHR detection of sensor position 1 (Appendix, Table 7). In addition, BMI also shows no statistically significant correlation with accuracy and reliability of fHR detection of sensor position 2 (Appendix, Table 8). However, a statistically significant correlation is found between GA and accuracy (P=0.046, R= -0.374) (Figure 11) and GA and reliability of fHR detection of sensor position 2 (P=0.042, R= -0.380) (Figure 12).

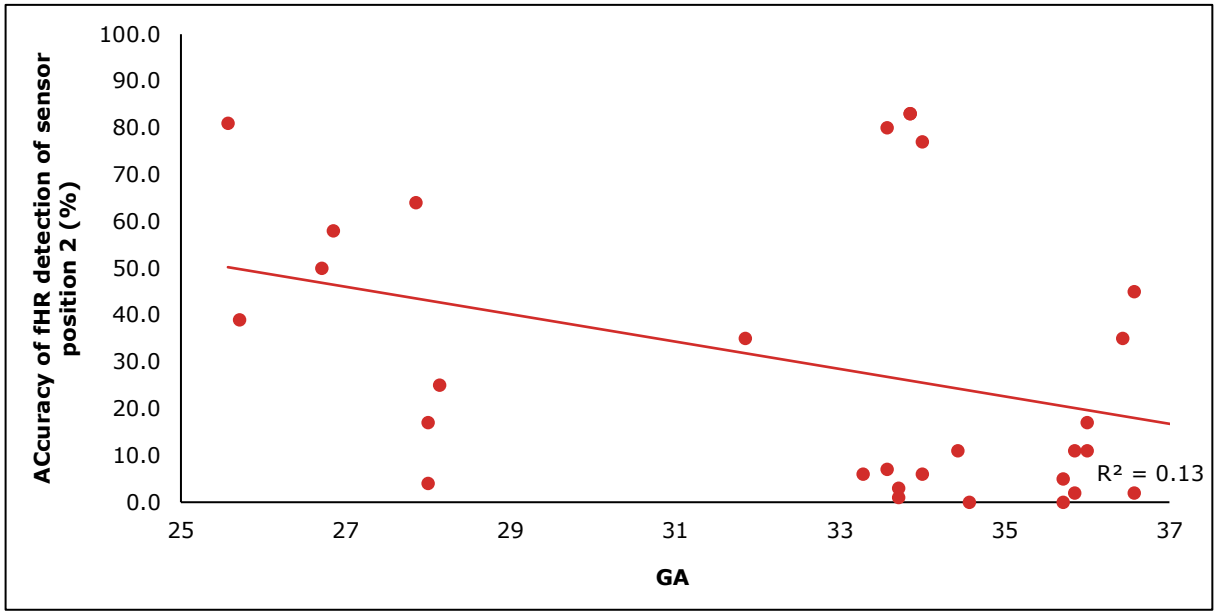

Figure 11. Correlation between the accuracy of fetal heart rate detection of sensor position 2 and GA for study group 2. R²: determination coefficient. *fHR* fetal heart rate; *GA* gestational age.

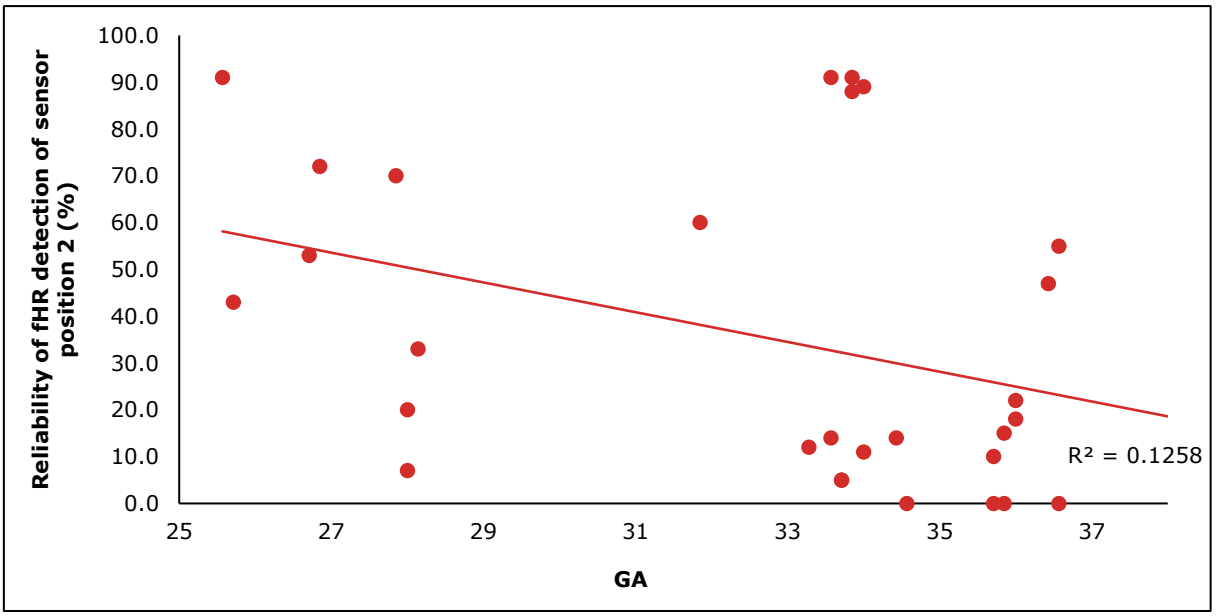

Figure 12. Correlation between the reliability of fetal heart rate detection of sensor position 2 and GA for study group 2. R²: determination coefficient. *fHR* fetal heart rate; *GA* gestational age.

3.3.3 Data quality – Accuracy and reliability of fetal heart rate detection

The performances of the Bloomlife sensor are evaluated based on accuracy and reliability of fHR detection.

✓ *Effect of placental position on accuracy and reliability of fetal heart rate detection*

A P-value of 0.128 shows that the median accuracy of fHR detection of sensor position 1 does not statistically significantly differ between the various tested placental positions (i.e. posterior, anterior and lateral), while there tends to be a difference in the median accuracy of fHR detection between distinct placental positions for sensor position 2, however, this difference is not statistically significant (P=0.068) (Figure 13). Further, there is a statistically significant difference in the median accuracy of fHR detection between sensor position 1 and sensor position 2 when the placenta is located anteriorly (P=0.049) (Figure 13). This is not the case when the placenta is located posteriorly and laterally (P=0.345 and P=0.109) respectively.

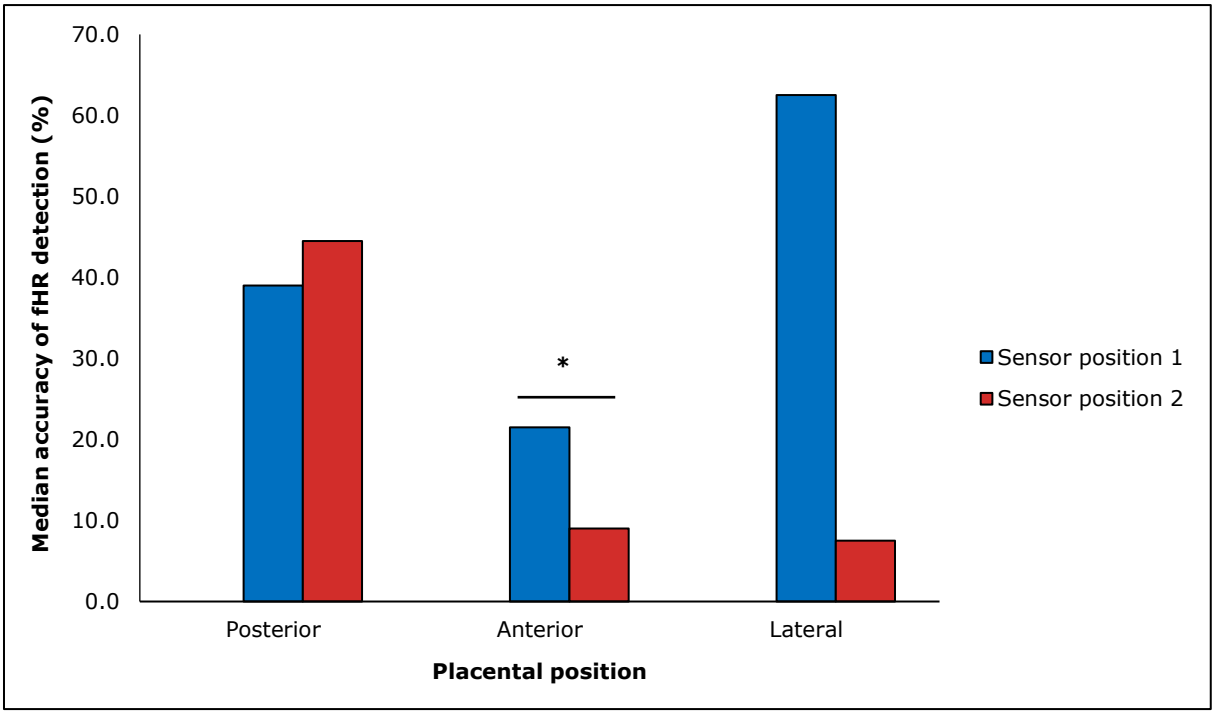

Figure 13. Median accuracy of fetal heart rate detection of sensor position 1 and 2 between different placenta positions (i.e. posterior, anterior, lateral) represented for study group 2. A P-value <0.05 is considered a statistically significant difference (*). *fHR* fetal heart rate.

There is no statistically significant difference in the median reliability of fHR detection of sensor position 1 between different placental positions (P=0.071) (Figure 14). For sensor position 2, there tends to be a difference in the median reliability of fHR detection between various placental positions, but the difference is not statistically significant (P=0.058) (Figure 14). Additionally, there are no statistically significant differences in the median reliability of fHR detection between sensor position 1 and sensor position 2 among the three different placenta positions (Appendix, Table 9).

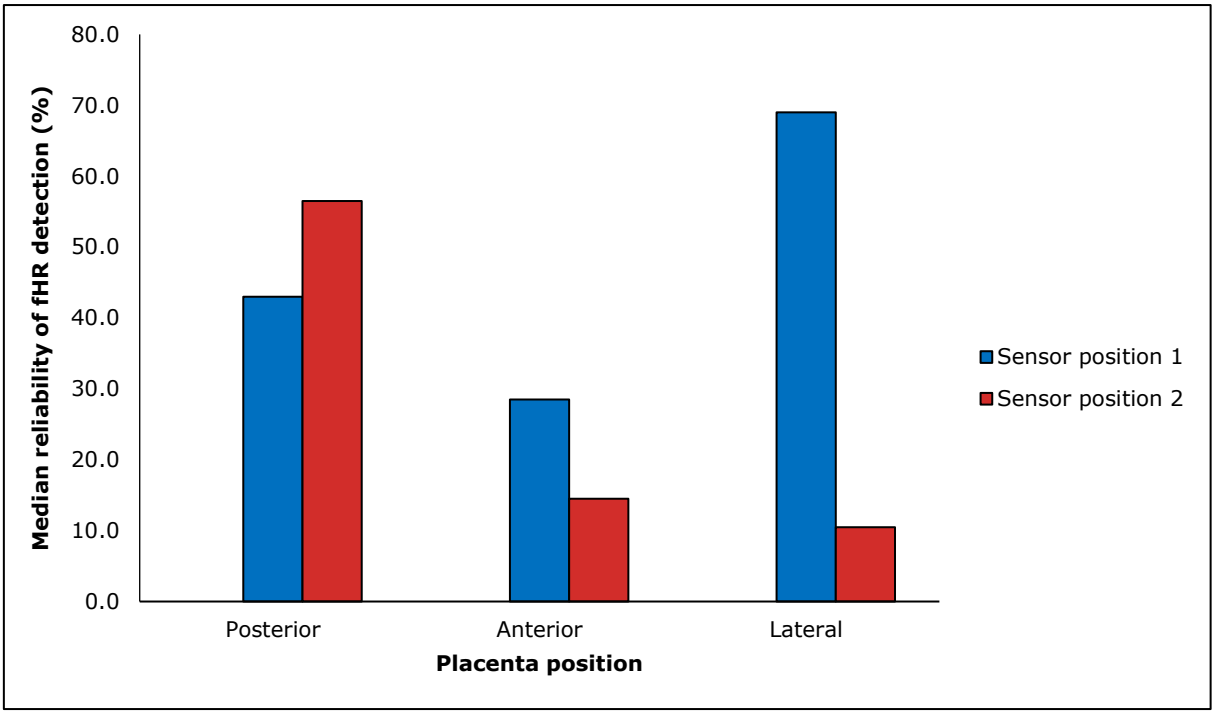

Figure 14. Median reliability of fetal heart rate detection of sensor position 1 and 2 among various placenta positions represented for study group 2. A P-value <0.05 is considered a statistically significant difference. *fHR* fetal heart rate.

✓ *Effect of fetal position on accuracy and reliability of fetal heart rate detection*

Median accuracy of fHR detection of sensor position 1 is not statistically significant different between head and breech fetal position (P=1.000). The same applies to sensor position 2 (P=0.143) (Figure 15). Nevertheless, there is a statistically significant increase in the median accuracy of fHR detection in sensor position 1 compared to sensor position 2 when the fetus is headed downwards (P=0.016) (Figure 15). There was no statistically significant difference in the median accuracy of fHR detection between sensor position 1 and sensor position 2 when the fetus is in breech (P=0.180) (Figure 15).

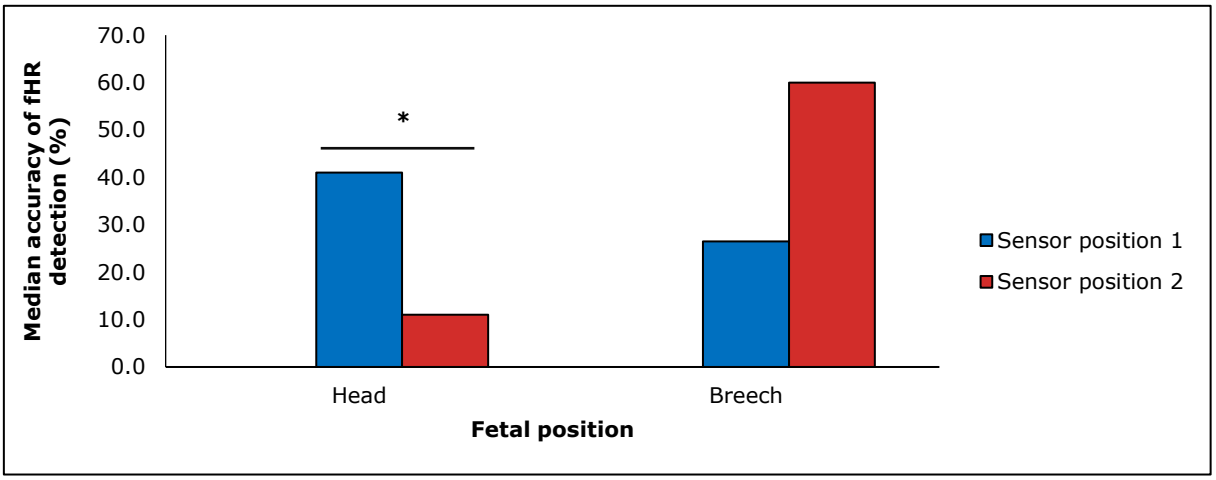

Figure 15. Median accuracy of fetal heart rate detection of sensor position 1 and 2 for head and breech fetal position represented for group 2. A P-value <0.05 is considered a statistically significant difference (*). *fHR* fetal heart rate.

There are no statistically significant differences in the median reliability of fHR detection of sensor position 1, neither in the median reliability of fHR detection of sensor position 2 between the two fetal positions (P=0.874 and P=0.168) respectively (Figure 16). Nevertheless, there is a statistically significant increase in the median reliability of fHR detection in sensor position 1 compared to sensor position 2 when the fetus is headed downwards (P=0.030), but there is not when the fetus is in breech (P=0.180) (Figure 16).

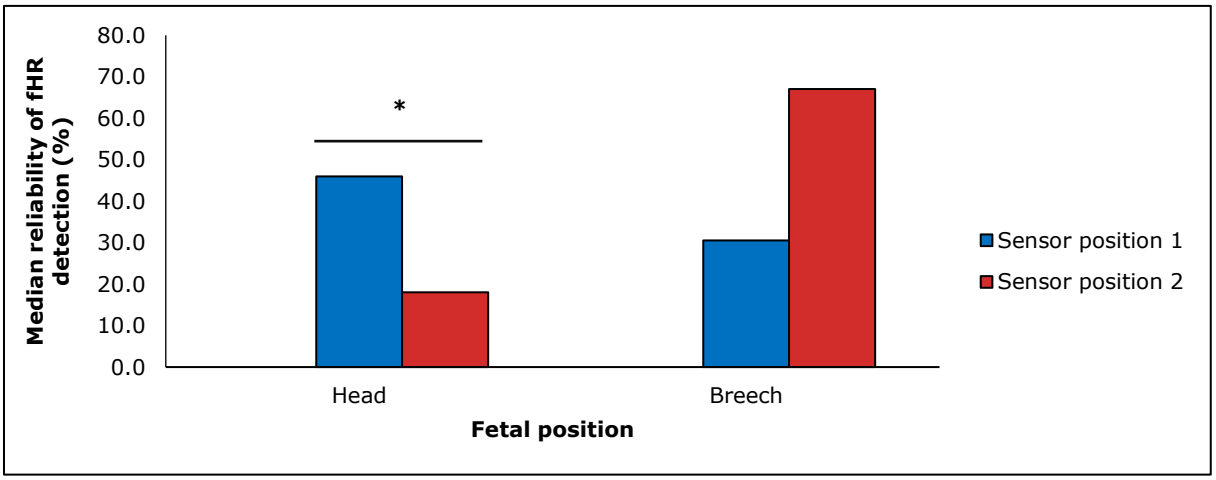

Figure 16. Median reliability of fetal heart rate detection of sensor position 1 and 2 for head and breech fetal position represented for group 2. A P-value <0.05 is considered a statistically significant difference (*). *fHR* fetal heart rate.

3.4 Characteristics of the EVA subjects

Ninety-nine women have completed the questionnaire regarding the use of digital apps during pregnancy. Fifty-five questionnaires are filled in after distributing them on Facebook and 44 questionnaires are completed at the waiting room of the gynecology department at ZOL. In total, five questionnaires are excluded for data analysis. Three of them were completed by women who had not recently given birth (i.e. women that are categorized as 'recently given birth', may not have given birth earlier than November 2017). For two other questionnaires it is not clear whether they are completed by women who are currently pregnant or had recently given birth. Consequently, 94 questionnaires are analyzed. Patient's baseline characteristics are presented in Table 2.

Table 2. Baseline characteristics of the EVA study subjects (n=94).

Socio-Demographics	EVA subjects (n=94)
Year of birth	1989.00 ± 4.00
Pregnant – n (%)	
Yes	64 (68.1)
Recently given birth (2017-2019)	30 (31.9)
Educational level – n (%)	
Primary education	1 (1.1)
Secondary education	20 (21.3)
Higher education or university degree	73 (77.7)
Marital status – n (%)	
Married	49 (52.1)
Legally cohabiting with partner	29 (30.9)
Unmarried	7 (7.4)
Single	2 (2.1)
Other	7 (7.4)

Data are presented as median and interquartile range (IQR) for non-parametric continuous variables. Categorical variables are presented as number of patients and percentage. n: sample size. *EVA* experiences of women on the use of digital apps during pregnancy.

3.5 EVA study – Questionnaire

Data is analyzed for 94 study subjects.

3.5.1 Internet user experience

Every woman who completed the questionnaire reported to have a smartphone: 97.9% use their smartphone on a daily base and 93.6% use different kind of apps.

3.5.2 Sources of information

It is questioned which source of information pregnant women find the most important one to gather information about pregnancy-related topics (Figure 17). The three most important sources are the gynecologist (91.5%) followed by websites/internet forums (87.2%) and apps (78.7%). Only one woman did not search for any information. Three women also make use of other sources of information including a delivery session, a lactation expert and a physiotherapist.

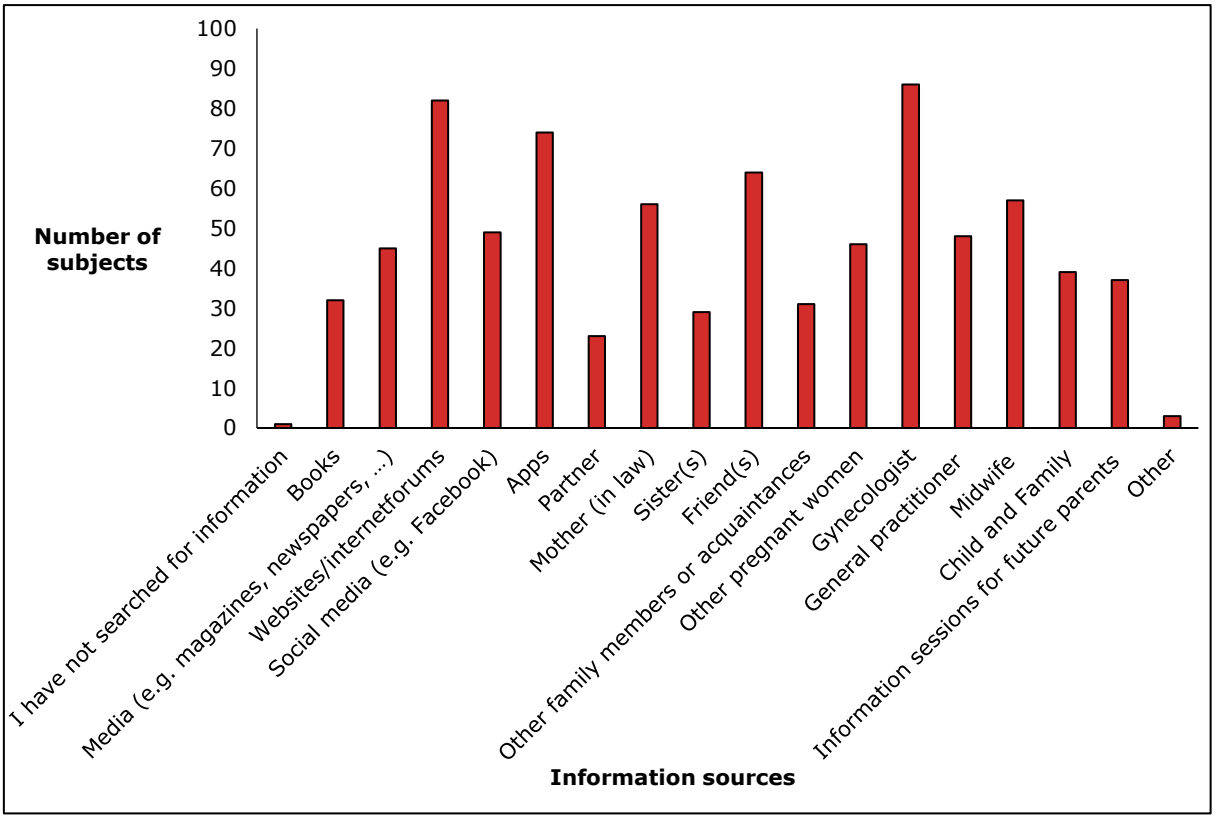

Figure 17. Patient's pregnancy-related sources of information. Other sources of information are a delivery session, a lactation expert and a physiotherapist.

One of the study goals is to learn more about the type of information pregnant women are looking for (Figure 18). Pregnant women are most interested in the following topics: the development of the baby (91.5%), discomfort/complaints during pregnancy (85.1%) and health during pregnancy (e.g. lifestyle, food, etc.) (81.9%).

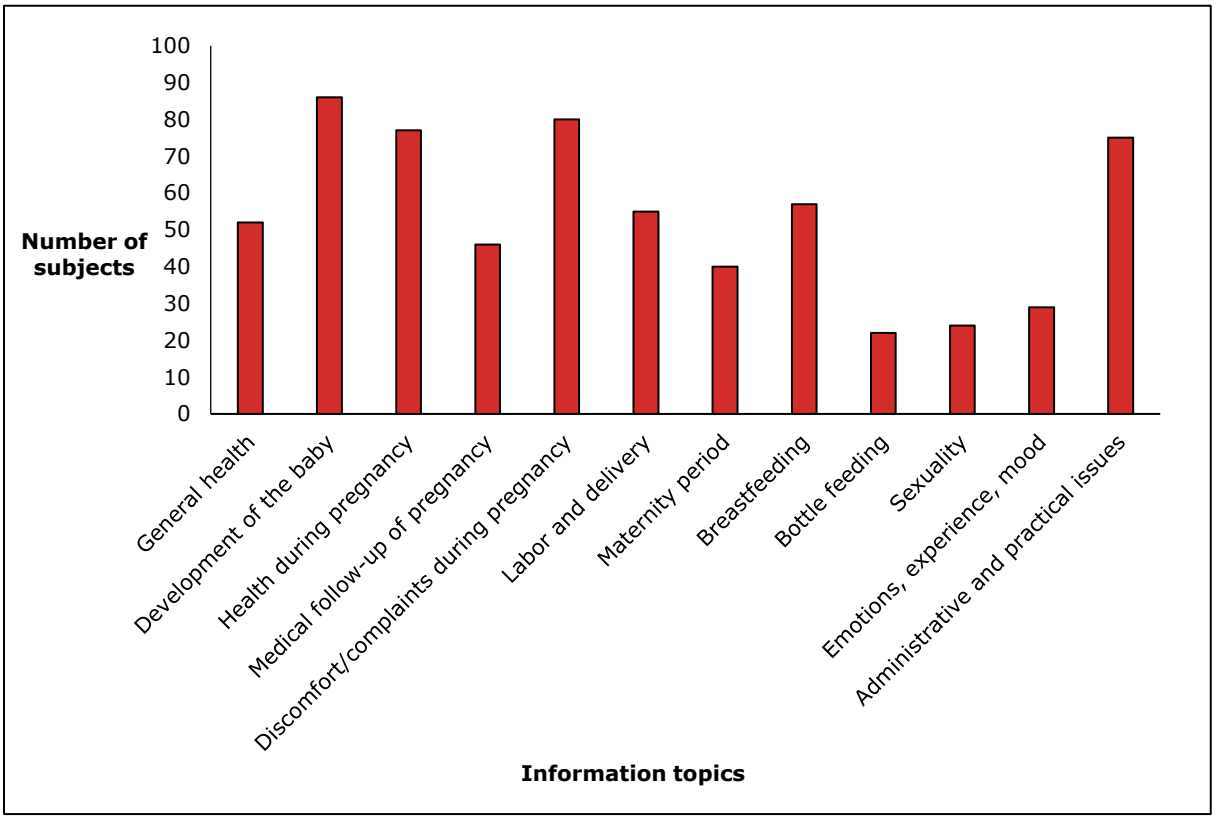

Figure 18. Information topics sought by pregnant women.

3.5.3 App usage

Seventy-seven (81.9%) women have indicated that they have used/downloaded apps during their pregnancy. Of these 77 women, 56%, 28%, 9%, 3% and 1% downloaded 1 app, 2 apps, 3 apps, 4 apps and 6 apps respectively. Two women did not describe which or how many apps they downloaded (Figure 19). One very popular app is 'Zwangerschap +', used by 50% of the women. The app store is the most important source for women to find an appropriate app. Other ways women get to know apps are via the health insurance and a fashion shop for pregnancy (Figure 20). One woman has downloaded an app for online shopping, as a reward she received a discount in the shop. The x-axis represents the number of answers instead of the number of subjects since women can give multiple answers to the asked question.

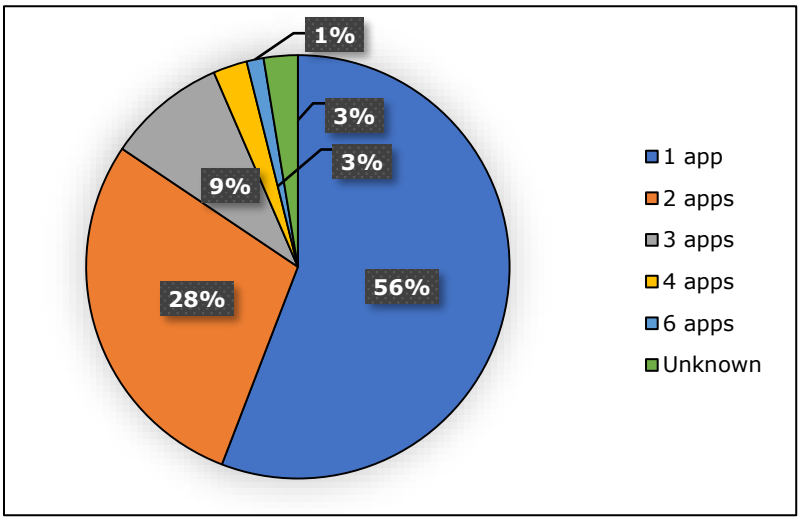

Figure 19. Average number of apps downloaded by EVA study subjects.

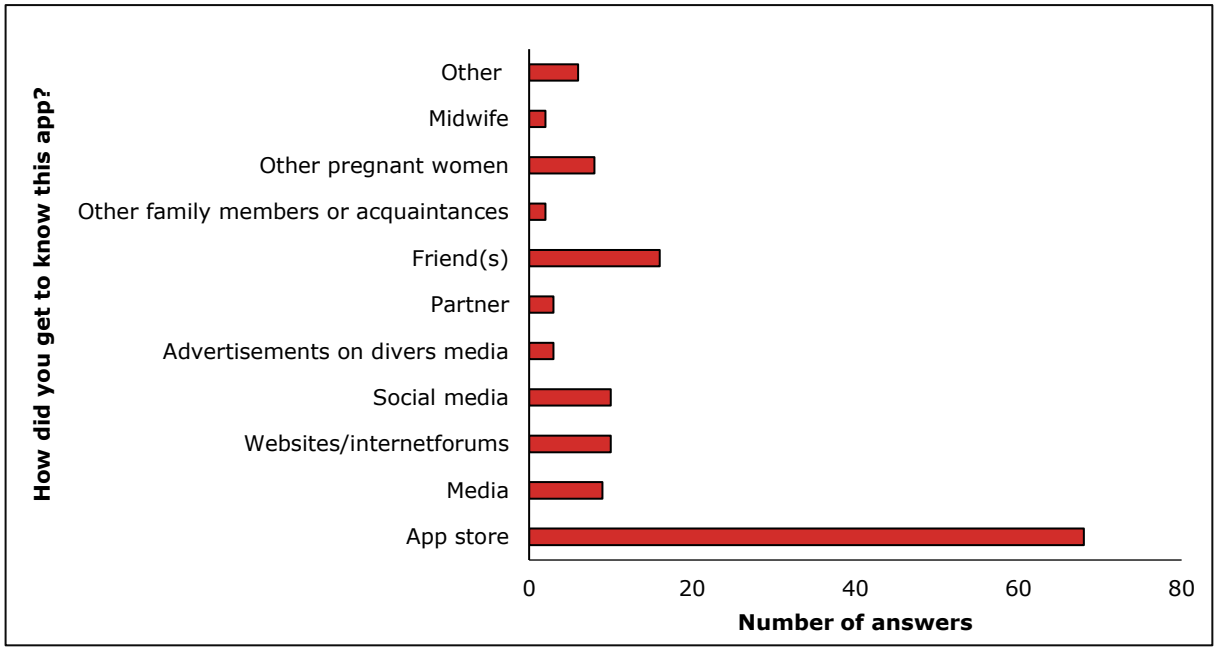

Figure 20. Patient's most important ways to get in touch with pregnancy-related apps. Other ways EVA study subjects get to know apps are via the health insurance and a fashion shop for pregnancy.

It has also been investigated for what reason or based on what need a pregnant woman downloads certain apps (Figure 21). In total, we received 107 answers because women can select more than one reason for downloading an app. Therefore, the numbers on the x-axis do not represent the number of subjects, rather the number of times this option has been indicated. Pregnant women choose to download a certain app in the first place because the app provides information, tips and advice about pregnancy on a daily/weekly basis via push messages (64.5%). Another important reason is that the app has implemented a calendar in which the growth and development of the baby/pregnancy can be monitored (63.6%).

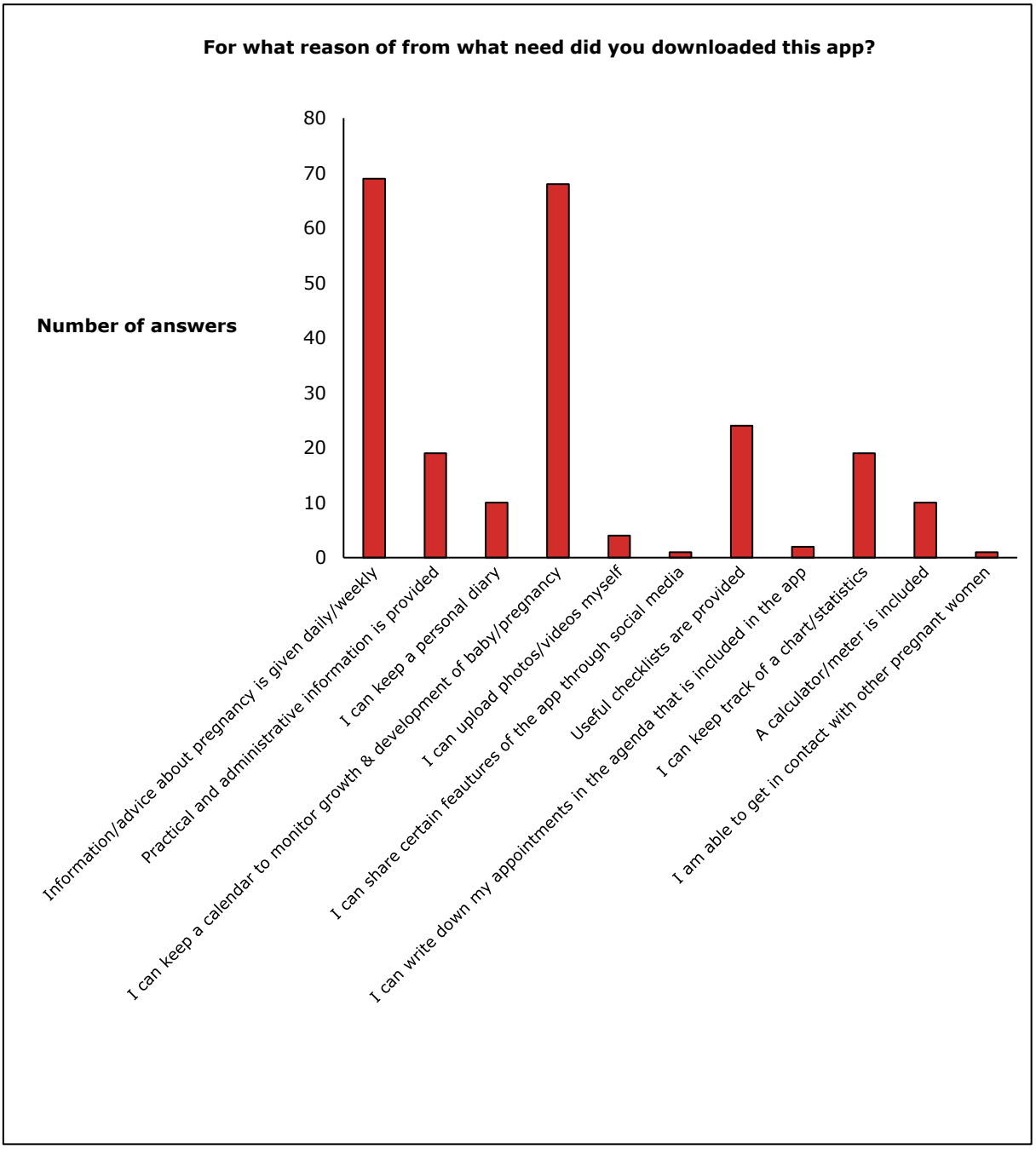

Figure 21. Patient's reasons for downloading certain pregnancy-related apps.

In the future, women should be able to detect both uterine contractions, fHR and fetal movements remotely and non-invasively with the Bloomlife sensor which can be connected to a smartphone via Bluetooth. Therefore, we want to investigate whether the EVA study subjects are willing to use such a device that can be connected to an app. 52.6% (n=40) and 50.0% (n=38) report that they would use an app to monitor the fHR and fetal movements and uterine contractions respectively, even when they are not at an increased risk of developing pregnancy complications (Figure 22).

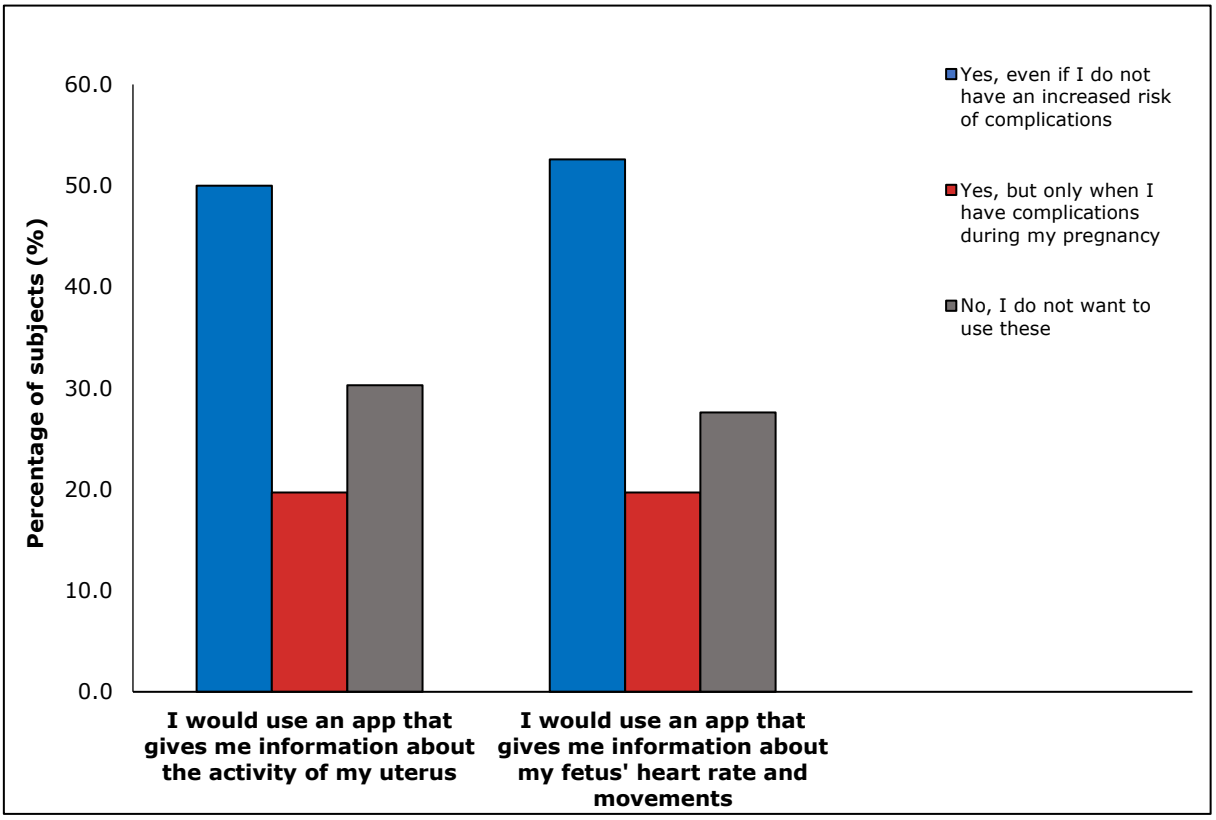

Figure 22. Patient's opinion regarding the use of an app for fetal heart rate detection, fetal movement and uterine contractions.

3.5.4 Privacy and data quality

On a secure platform, pregnant women can communicate electronically with other people where the exchange of data is performed safely. We want to investigate whether pregnant women are interested in using such a platform and what they would like to use it for (Figure 23). The EVA study subjects had to rate each question on a ten-point Likert scale ranging from "not interested" (score of 0) to "very interested" (score of 10). 58.9% of the women are not interested in using a secure platform to communicate with other (pregnant) women via video chat. 38.9% of the study subjects express their disinterest in using such a platform to ask questions to their healthcare provider via video chat. However, about one-quarter of the study subjects do want to use a safe platform to ask questions to their healthcare provider via e-mail. Moreover, a quarter of the study subjects are interested in using a secure platform to exchange data with their healthcare provider. They also want to use a safe platform to obtain additional information specific to their situation via an online folder. 70.1% of the study subjects find it important that apps provide evidence-based information.

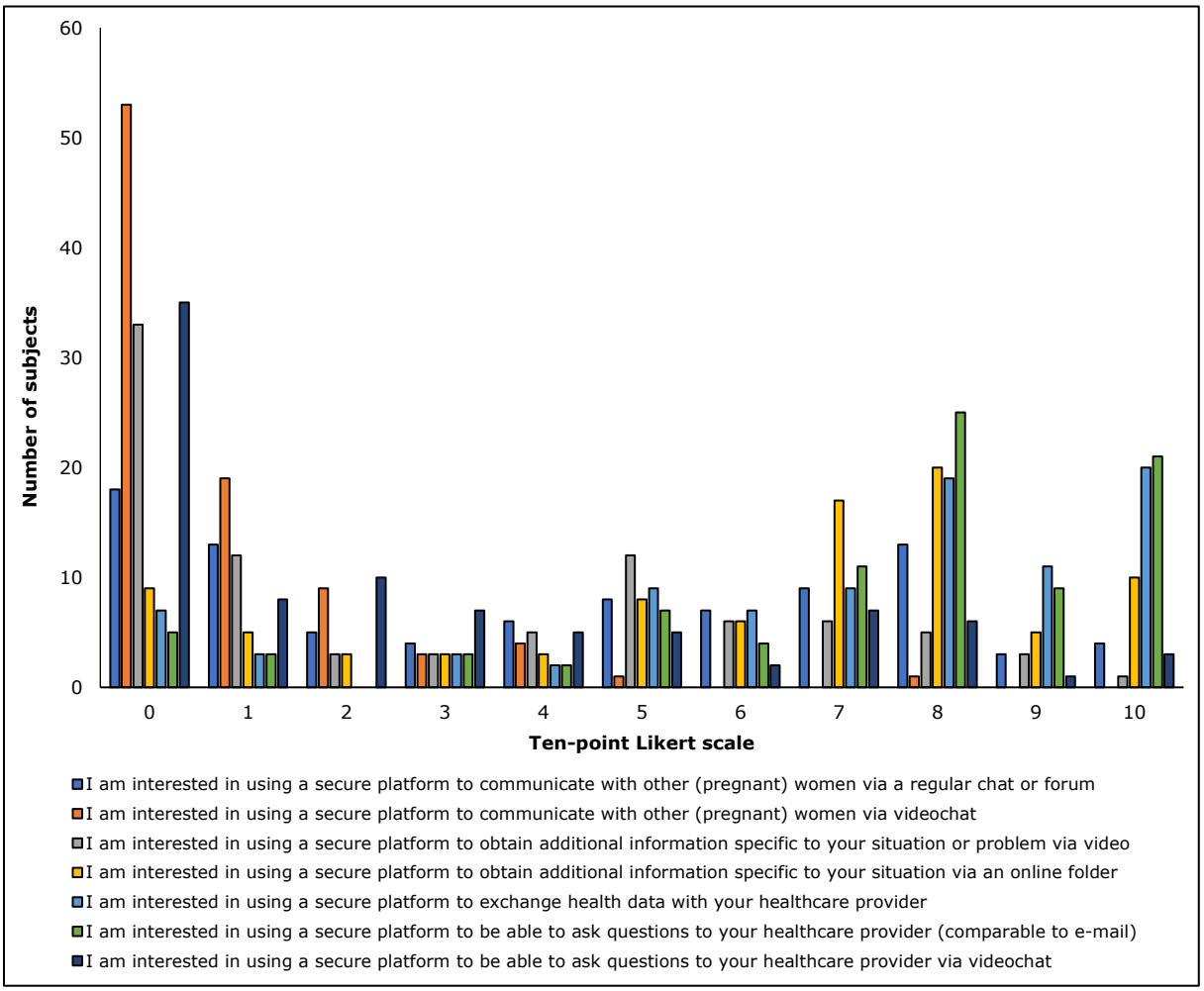

Figure 23. Patient's attitude regarding the use of a secure platform. The statements must be judged from 0 to 10. 0: not interested; 10: very interested.

4. Discussion

The BEATLE study aims to investigate whether the data quality (i.e. accuracy and reliability) of fHR detection increases when the Bloomlife sensor is placed above the fetus' back compared to the regular position (i.e. below the belly button). The EVA study investigates the applicability of digital apps during pregnancy.

4.1 Fetal heart rate detection

The ability of the Bloomlife sensor to detect fHR is assessed in terms of accuracy and reliability.

4.1.1 Missing data

For some subjects, there is only data from the regular sensor position available. One reason for these missing data could be the lack of space on the belly of the mother to replace the sensor to the new position (i.e. above fetus' back).

4.1.2 Accuracy and reliability of fetal heart rate detection

The low median accuracy and reliability of fHR detection of both sensor positions (<50.0%) may be due to the high percentage of measurements performed with anteriorly located placentas in group 1 (48.1%) and group 2 (51.1%). FHR is less well captured when the placenta is located anteriorly compared to posteriorly (40). Moreover, one-third of all the measurements are done in women with a GA between 28 and 33 weeks. At this stage of pregnancy, the isolating effects of the vernix caseosa are highest, causing difficulties in capturing fHR (41). Another reason for low data quality could be electrical interference since the measurements are done in a hospital, where many electronic devices are present. A neutral environment and a wider spacing of the electrodes in order to cover a bigger area may lead to higher data quality (i.e. accuracy and reliability) of fHR detection.

A tendency towards a decrease in median accuracy of fHR detection is observed in group 2 when comparing sensor position 2 to sensor position 1 (P=0.053). This indicates that replacing the Bloomlife sensor above the fetus' back is not effective for reaching higher accuracy of fHR detection, on the contrary it causes a deterioration. This finding undermines our hypothesis, which is a higher data quality for sensor position 2. At this position, the Bloomlife sensor is replaced to the fetus' back and since fHR is best detected at the fetus' back, it is expected that higher data quality will be achieved at sensor position 2. However, these results should be interpreted with caution. A decrease in accuracy of fHR detection in sensor position 2 may be due solely to the high number of measurements performed in anterior positioned placentas. In sensor position 1, an anterior placenta will undoubtedly cause difficulties in detecting fHR. By replacing the sensor above the fetus' back, we will either avoid the placenta or we just do not. In this case, we probably did not circumvent the placenta since there is a tendency towards a median decrease in the accuracy of fHR detection in sensor position 2 compared to sensor position 1.

4.1.3 Effect of BMI and GA on accuracy and reliability of fetal heart rate detection

A statistically significant correlation was found in group 2 between accuracy of fHR detection of sensor position 2 and GA (P=0.046, R= -0.374), and between reliability of sensor position 2 and GA (P=0.042, R= -0.380). A possible explanation for significant correlations in sensor position 2, but not in sensor position 1, is the low number of measurements, namely 11, performed at sensor

position 2 in women with a GA between 28 and 33 weeks compared to 18 measurements at sensor position 1. These findings are in accordance with the study results from Huhn et al, where it was reported that the success rate (SR) statistically significantly varies among GA. Women with a GA between 20 and 28 weeks had the highest values for SR, followed by women with a GA between 32 and 40 weeks and lastly the group with a GA between 28 and 32 weeks. These findings are due to the vernix caseosa, whose isolating effects are most pronounced between 28 and 33 weeks of gestation (41). In group 2, the data quality (i.e. accuracy and reliability of fHR detection) of both sensor positions are not correlated to BMI. Huhn et al assessed the signal quality in terms of SR of beat-to-beat fHR detection of the Monica AN24^{TM} (Monica Healthcare Ltd., Nottingham, UK). The SR of fHR detection was evaluated regarding maternal and fetal factors, GA, BMI and fetal position. They observed that both BMI and fetal presentation were not related to SR (41).

On the contrary, in group 1, for both sensor positions, there are no statistically significant correlations between GA and accuracy or reliability, or between BMI and accuracy or reliability of fHR detection. A reasoned explanation for the observed differences between group 1 and 2 is that the women in group 2 are trained, meaning that they are already familiar with the study set-up and therefore they are lying down on the hospital bed quieter, which subsequently leads to better data capturing and thus reliable results for data analysis.

4.1.4 Effect of placental and fetal position on accuracy and reliability of fetal heart rate detection

In group 2, a tendency is observed towards significant differences in the median accuracy and reliability of fHR detection of sensor position 2 between different placental positions (P=0.068 and P=0.058) respectively. There are no statistically significant differences in the median accuracy and reliability of fHR detection of sensor position 1 between different placental positions. Evidence can be searched in the number of measurements performed in anteriorly located placentas in sensor position 1 and sensor position 2, 54.5% and 61.5% respectively. As reported earlier, there is a chance of evading the anterior placenta in sensor position 2, possibly leading to more pronounced changes in data quality and subsequently differences are easier to report. Furthermore, there is a statistically significant increase in the median accuracy of fHR detection in sensor position 1 compared to sensor position 2 when the placenta is located anteriorly (P=0.049). When we try to detect fHR in sensor position 1 (i.e. below the belly button) in a woman with an anterior placenta, we will undoubtedly face the placenta. In sensor position 2, we replace the sensor's patch, so we either avoid the placenta or we just do not, leading to higher or lower data quality of fHR detection respectively. This logically does not apply to women where the placenta is positioned posteriorly since fHR detection is not hindered in position 1, nor in position 2.

In group 1 and 2, both sensor positions showed no statistically significant differences in the median accuracy and reliability of fHR detection between head and breech fetal presentation. Huhn et al observed that fetal presentation was not related to SR (41). A possible explanation is that the fetus almost continuously changes his position inside the uterus, making it difficult to detect fHR (42). In both groups, there are no statistically significant differences in the median accuracy and reliability of fHR detection between sensor position 1 and sensor position 2 when the fetus is in breech, possibly

due to the low number of measurements performed whereby the fetus is in breech. In order to have statistically significant results, more inclusions with a fetus in a breech presentation should be done.

In group 2, however, there is a statistically significant increase in the median accuracy and reliability of fHR detection in sensor position 1 compared to sensor position 2 when the fetus is headed downwards (P=0.016 and P=0.030) respectively. This contraindicates our hypothesis, which is a higher data quality for sensor position 2. However, it should be noticed that a central sensor position (i.e. regular sensor position) probably detects fHR better in a fetus who is in a head fetal presentation.

4.1.5 Study limitations

This study was conducted in one hospital and therefore monocentric. The total duration of the study was 40 minutes and thus only represents a snapshot of fHR detection. Some study participants may be allergic to the patch where the Bloomlife sensor is attached to, although this is rare. It can appear that data capturing was not successful, in such a case the data cannot be included for further analysis. However, the participation is not useless, since this can be a sign that data capturing can still be improved. In group 2, not all women participated equally in the study. Moreover, their GA at inclusion is also different, so does the GA at the repeated measurements.

4.2 Pregnancy apps

The use of mHealth apps is becoming more and more important among pregnant women to gain pregnancy-related knowledge. Our data revealed that every woman, except one, is looking for pregnancy-related information and that they are most interested in information concerning the development of their baby. These findings are in accordance with a study conducted by Lagan et al, wherein 97% of pregnant mothers with internet access are looking for pregnancy-related information for a variety of reasons (43).

The main reason for downloading a particular app is because they provide information, tips and advice about pregnancy on a daily/weekly basis via push messages. In this way, pregnant women do not need to look for relevant information themselves. 91.5% of the study subjects indicate that their gynecologist is the most important person to gain information from because information offered by professionals is highly valued when they have a specific health-related concern. Other ways for information procurement are websites/internet forums (87.2%) and apps (78.7%) which corresponds to the results from another study where 87% and 60% of the women used web sources and mobile pregnancy apps respectively (44).

Surprisingly, only 52.1% of the surveyed women used social media to gain information about their pregnancy. A possible explanation may be the high level of education in our study group which renders them more reserved among the use of online communities as a source of information. This also explains the relatively low percentage of women (40.0%) who find it important to communicate with other (pregnant) women via a regular chat or forum.

Moreover, women do care about the information that is provided by apps as indicated by the high percentage (70.1%) of women who find it important that apps ensure evidence-based information. By providing patient centered medical guidelines, uncertainty among pregnant women can be prevented and, in this way, women receive the reliable information they are looking for (44).

4.2.1 Study limitations

Women who participated in this study must fill in the questionnaire anonymously. This could lead to false interpretation of some questions and thus incorrect answers. However, the chance of interpreting the results falsely is low since this questionnaire is compiled in collaboration with experts. Another drawback is that the questionnaire was not validated. The educational level was high in our study population, potentially resulting in higher mHealth usage. Research among women with a lower educational level should be conducted to identify their specific needs.

Conclusions

Placing the Bloomlife sensor above the fetus' back does not provide higher accuracy, nor reliability of fHR detection. The low percentage (<50.0%) of accuracy and reliability of fHR detection indicates that there is still room for improvement. Therefore, a wider spacing of the electrodes in order to cover a bigger area should be explored. Next, we observed that BMI, placental and fetal position do not have a statistically significant effect on accuracy and reliability of fHR detection. However, a statistically significant correlation between GA and data quality (i.e. accuracy and reliability of fHR detection) was found, meaning that GA does play an important role in the detection of fHR.

The BEATLE study will continue with phase three and four. The performance of the algorithms and sensor in real-life conditions will be evaluated in phase three. Subsequently, in phase four, a new generation of the Bloomlife sensor will be tested, which is characterized by upgraded hardware whereof we hope will produce improved data quality.

Social media and mHealth apps are more and more used in pregnancy care. In the EVA study, we found that women are looking for scientifically validated information. In the future, evidence-based medical apps should be integrated into daily prenatal health care, encouraging patient engagement. Health care providers should guide pregnant women through certain apps to prevent the extraction of incorrect information, which leads to more awareness of certain risks.

Our future perspective is to allow women to detect both uterine contractions, fHR and fetal movements remotely and non-invasively with the Bloomlife sensor. The EVA study subjects are willing to use such a device. 52.6% and 50.0% of them reports that they would use an app to monitor the fHR and fetal movements and uterine contractions respectively even when they are not having an increased risk of complications.

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Appendix

Table 3. Correlation between gestational age or body mass index and accuracy and reliability of fetal heart rate detection of sensor position 1 for study group 1.

Variable	Accuracy	Reliability
GA	P=0.465, R=-0.147	P=0.585, R=-0.110
BMI	P=0.347, R=-0.188	P=0.254, R=-0.227

A P-value <0.05 was considered a statistically significant correlation. R: correlation coefficient. *BMI* body mass index; *GA* gestational age.

Table 4. Correlation between gestational age or body mass index and accuracy and reliability of fetal heart rate detection of sensor position 2 for study group 1.

Variable	Accuracy	Reliability
GA	P=0.511, R=0.171	P=0.413, R=0.213
BMI	P=0.275, R=-0.281	P=0.491, R=-0.179

A P-value <0.05 was considered a statistically significant difference. R: correlation coefficient. *BMI* body mass index; *GA* gestational age.

Table 5. Comparison of accuracy and reliability of fetal heart rate detection between sensor position 1 and 2 among three different placental positions (i.e. posterior, anterior and fundal) for study group 1.

Variable	Accuracy	Reliability
Placenta position		
Posterior	P=0.715	P=0.500
Anterior	P=0.683	P=0.799
Fundal	P=0.317	P=0.317

A P-value <0.05 was considered a statistically significant difference.

Table 6. Comparison of accuracy and reliability of fetal heart rate detection between sensor position 1 and 2 among two different fetal positions (i.e. head and breech) for study group 1.

Variable	Accuracy	Reliability
Fetal position		
Head	P=0.345	P=0.683
Breech	P=1.000	P=0.109

A P-value <0.05 was considered a statistically significant difference.

Table 7. Correlation between gestational age or body mass index and accuracy and reliability of fetal heart rate detection of sensor position 1 for study group 2.

Variable	Accuracy	Reliability
GA	P=0.333, R=0.144	P=0.414, R=0.122
BMI	P=0.603, R=-0.078	P=0.392, R=-0.128

A P-value <0.05 was considered a statistically significant difference. R: correlation coefficient. *BMI* Body mass index; *GA* Gestational age.

Table 8. Correlation between body mass index and accuracy and reliability of fetal heart rate detection of sensor position 2 for study group 2.

Variable	Accuracy	Reliability
BMI	P=0.876, R=-0.030	P=0.851, R=-0.036

A P-value <0.05 was considered a statistically significant difference. R: correlation coefficient. *BMI* body mass index.

Table 9. The reliability of fetal heart rate detection between sensor position 1 and 2 among three different placental positions (i.e. posterior, anterior and lateral) for study group 2.

Variable	Reliability
Placenta position	
Posterior	P=0.463
Anterior	P=0.083
Lateral	P=0.109

A P-value <0.05 was considered a statistically significant difference.

✓ *Questionnaire*

A Dutch version of the EVA questionnaire is presented on the following pages.

INSTRUCTIES BIJ HET INVULLEN VAN DE VRAGENLIJST

Zwangeren en kersverse ouders hebben tegenwoordig toegang tot een brede waaier aan digitale informatie over gezondheid en welzijn tijdens de zwangerschap en kraamperiode. Mobiele technologie via apps op de smartphone is naast internet een toenemende en invloedrijke bron van informatie. Onderzoek toonde aan dat de meerderheid van de zwangere vrouwen gemiddeld drie apps downloadt tijdens de zwangerschap. Zorgverleners zijn echter bezorgd om de kwaliteit van de informatie die wordt aangeboden in de mobiele apps. Daarom willen we met deze bevraging het multimedia- en app gebruik nagaan van zwangere vrouwen.

Alle Vlaamse zwangeren of recent bevallen moeders, die voldoende Nederlands begrijpen en ≥ 18 jaar zijn worden vriendelijk uitgenodigd om deel te nemen aan de studie. Het betreft een eenmalige, enquête en het invullen van de vragenlijst neemt ongeveer 15 minuten in beslag.

Gelieve steeds één antwoord aan te duiden. Indien meerdere antwoorden mogelijk zijn, wordt dit aangegeven bij de vraagstelling. Teneinde een objectieve weergave te bekomen willen we u vragen zo eerlijk mogelijk te antwoorden. Uw persoonlijke mening en ervaring is van groot belang. Er bestaan geen 'goede' of 'foute' antwoorden. Gelieve de vragenlijst zo volledig mogelijk in te vullen. Dit laat ons toe om een goed beeld te krijgen in het gebruik van multimedia en apps door zwangeren en recent bevallen vrouwen. Gelieve de vragenlijst slechts éénmalig in te vullen.

Uw deelname is vrijwillig. De enquête is strikt vertrouwelijk en de gegevens zullen anoniem worden verwerkt. U hoeft nergens een naam op te geven.

Gelieve hier uw toestemming te geven voor deelname aan de studie door het vakje aan te vinken:
□ Ik verklaar hierbij akkoord te zijn om deel te nemen aan de studie.

We danken u van harte voor uw medewerking!

Algemene gegevens

Datum van invullen vragenlijst:
□□(dag) □□ (maand) 20 □□ (jaar)

Wat is uw geboortejaar?
□□□□ (jaar)

Bent u op dit moment zwanger?

□ Nee, wat is uw meest recente bevallingsdatum? □□(dag) □□ (maand) 20 □□ (jaar)
□ Ja, wat is uw verwachte bevallingsdatum? □□(dag) □□ (maand) 20 □□ (jaar)

Wat is uw wettelijke burgerlijke status?

□ gehuwd
□ wettelijk samenwonend met partner
□ ongehuwd
□ weduwe
□ gescheiden
□ alleenstaand
□ andere, specifieer: _____

Wat is de hoogste opleiding die u voltooid hebt? (een opleiding afgerond met een diploma of getuigschrift)

□ lager onderwijs
□ secundair of middelbaar onderwijs
□ hoger onderwijs (niet-universitair)
□ universitair onderwijs

Wat is uw huidig hoofdberoep? (indien niet in zwangerschaps/bevallingsverlof). *Meerdere antwoorden zijn mogelijk.*

□ zelfstandige of vrij beroep
□ bediende/ambtenaar
□ arbeidster
□ huisvrouw
□ werkzoekend
□ invalide
□ student
□ ander, specifieer: _____

Aantal zwangerschappen: _____

Aantal bevallingen: _____

Gebruik technologie

1. Beschikt u over een computer of laptop?
   □ Ja
   □ Neen
2. Beschikt u over een email-adres?
   □ Ja
   □ Neen
3. Beschikt u over internettoegang?
   □ Ja
   □ Neen
4. Beschikt u over Smartphone/iPhone?
   □ Ja
   □ Neen
5. Beschikt u over Tablet PC/iPAD/iPOD?
   □ Ja
   □ Neen

6. In welke mate maakt u gebruik van volgende apparaten/technologieën?

	Elke dag	Meerdere keren per week	Meerdere keren per maand	Eén keer per maand	Minder dan één keer per maand	Nooit
Computer/laptop						
GSM						
Smartphone/iPhone						
Tablet PC/iPAD/iPOD						
Andere, specifieer:						

Onderstaande vragen 7-9 enkel te beantwoorden, indien men over een smartphone of tablet beschikt

7. Wat is het merk en model van uw Smartphone?
   _____

8. Van welke toepassing van uw smartphone of iPhone maakt u gebruik? *Meerdere antwoorden zijn mogelijk.*

   □ bellen
   □ SMS
   □ apps
   □ internet
   □ camera (foto/video)
   □ GPS
   □ andere toepassingen, specifieer: _____

9. Wat is het merk en model van uw TabletPC/iPAD/iPOD?
   _____

Informatiebronnen

10. Van welke onderstaande informatiebronnen maakt(e) u gebruik bij het zoeken naar bijkomende toelichting over de zwangerschap? *Meerdere antwoorden zijn mogelijk*.

    □ ik heb geen informatie opgezocht (ga naar vraag 12)
    □ boeken
    □ media (tijdschriften, kranten, radio, televisie, enz.)
    □ websites/internetfora
    □ sociale media (o.a. facebook)
    □ apps
    □ partner
    □ (schoon)moeder
    □ zus(sen)
    □ vriendin(nen)
    □ andere familieleden of kennissen
    □ andere zwangere vrouwen
    □ gynaecoloog
    □ huisarts
    □ vroedvrouw
    □ Kind en Gezin
    □ infosessies voor toekomstige ouders
    □ andere, welke?:_____

11. Naar welke specifieke informatie over de zwangerschap bent u op zoek gegaan? *Meerdere antwoorden zijn mogelijk.*
    □ Algemene gezondheid
    □ Ontwikkeling van de baby
    □ Gezondheid tijdens de zwangerschap (o.a. levensstijl, voeding, enz.)
    □ Medische opvolging van de zwangerschap
    □ Ongemakken/klachten tijdens de zwangerschap
    □ Arbeid en bevalling
    □ Kraamperiode
    □ Borstvoeding
    □ Flesvoeding
    □ Seksualiteit

- □ Emoties, beleving, gemoedstoestand
- □ Administratieve en praktische zaken (o.a. hospitalisatieverzekering, kindergeld, kraamgeld, terugbetaling mutualiteit, ouderschapsverlof, moederschapsrust, vaderschapsverlof, enz.)
- □ Andere, specifieer: _____Heeft u apps gedownload/gebruikt tijdens uw zwangerschap?

Gebruik van zwangerschapsapps

12. Heeft u apps gedownload/gebruikt tijdens uw zwangerschap?

    □ Ja
    □ Neen (ga naar vraag 15)

13. Geef hier weer welke zwangerschapsapp(s) u heeft gedownload/gebruikt?

    _____
    _____
    _____

14. Kies minstens één tot maximaal drie apps die u hebt gedownload/gebruikt om te beoordelen.

    BEOORDELING APP 1

    Naam van de app: _____

    In welke store heeft u de app gedownload?

    □ Apple store
    □ Google Play store
    □ Andere, specifieer: _____

    Welke versie van de app heeft u gedownload?
    Dit kan u vinden in de aanvullende informatie van de app in de store (vb. versie 2.3)
    _____

    Hoe heeft u deze app leren kennen? *Meerdere antwoorden zijn mogelijk*

    □ via een zoektocht in de app store
    □ via media (tijdschriften, kranten, radio, televisie, enz.)
    □ via websites/internetfora
    □ via sociale media (o.a. facebook)
    □ via reclameadvertenties op diverse media
    □ via partner
    □ via (schoon)moeder
    □ via zus(sen)
    □ via vriendin(nen)
    □ via andere familieleden of kennissen
    □ via andere zwangere vrouwen
    □ via gynaecoloog
    □ via huisarts
    □ via vroedvrouw
    □ via Kind en Gezin
    □ andere, welke?:_____

    Heeft u voor deze app betaald?
    □ Ja, welk bedrag heeft u betaald? _____ euro
    □ Neen

    Om welke reden of vanuit welke nood/behoefte heeft u deze app gedownload? *Meerdere antwoorden zijn mogelijk*

    □ omdat informatie, tips, adviezen over de zwangerschap dagelijks/wekelijks wordt gegeven (via push berichten)
    □ omdat praktische en administratieve informatie wordt gegeven (o.a. hospitalisatieverzekering, kindergeld, kraamgeld, terugbetaling mutualiteit, ouderschapsverlof, moederschapsrust, vaderschapsverlof, enz.)
    □ omdat ik een persoonlijk dagboek kan bijhouden
    □ omdat ik een kalender kan bijhouden om de groei en ontwikkeling van de baby/zwangerschap te volgen
    □ omdat ik zelf foto's/filmpjes kan opladen

- □ omdat ik bepaalde functies van de app kan delen via sociale media (o.a. Facebook)
- □ omdat handige checklists worden voorzien (o.a. babyuitzet, babynamen, enz.)
- □ omdat een agenda is opgenomen waarin ik mijn afspraken kan noteren
- □ omdat een grafiek/statistiek kan bijgehouden worden (o.a. gewicht)
- □ omdat een calculator/meters zijn opgenomen (o.a. weeëntimer, zwangerschapsmeter, enz.)
- □ omdat contact met andere zwangeren kan worden gelegd (o.a. via chat of een forum)

Waarom hebt u specifiek voor deze app gekozen? *Meerdere antwoorden zijn mogelijk*

- □ omdat de app afkomstig is van een betrouwbare organisatie/instantie/instelling
- □ omdat de app goed beoordeeld werd door andere gebruikers
- □ omdat de app reeds veelvuldig werd gedownload
- □ omdat de app werd aanbevolen door andere zwangeren of recent bevallen moeders
- □ omdat de app werd aanbevolen door een zorgverlener (vroedvrouw, huisarts, gynaecoloog, enz.)
- □ andere, namelijk _____

Hoe frequent heeft u deze app geraadpleegd?

- □ dagelijks
- □ wekelijks
- □ maandelijks
- □ Andere, specifieer: _____

Hoelang gebruikt u deze app? Of hoe lang hebt u deze app gebruikt?
Gelieve het aantal weken of maanden weer te geven.

_____

In welke mate zou u deze app aanbevelen aan andere zwangere vrouwen?

- □ Ik zou deze app niet aanbevelen aan zwangeren
- □ ik zou deze app maar aan weinig zwangeren aanbevelen
- □ Ik zou deze app aan verschillende zwangeren aanbevelen
- □ Ik zou deze app aan veel zwangeren aanbevelen
- □ Ik zou deze app aan iedere zwangere aanbevelen

Hoe zou u deze app in het algemeen beoordelen?

- □ ★ Een van de slechtste apps die ik ooit heb gebruikt
- □ ★★
- □ ★★★ Gemiddeld
- □ ★★★★
- □ ★★★★★ Een van de beste apps die ik ooit heb gebruikt

BEOORDELING APP 2

Naam van de app: _____

In welke store heeft u de app gedownload?

- □ Apple store
- □ Google Play store
- □ Andere, specifieer: _____

Welke versie van de app heeft u gedownload?
Dit kan u vinden in de aanvullende informatie van de app in de store (vb. versie 2.3)
_____

Hoe heeft u deze app leren kennen? *Meerdere antwoorden zijn mogelijk*

- □ via een zoektocht in de app store
- □ via media (tijdschriften, kranten, radio, televisie, enz.)
- □ via websites/internetfora
- □ via sociale media (o.a. facebook)
- □ via reclameadvertenties op diverse media
- □ via partner
- □ via (schoon)moeder

- □ via zus(sen)
- □ via vriendin(nen)
- □ via andere familieleden of kennissen
- □ via andere zwangere vrouwen
- □ via gynaecoloog
- □ via huisarts
- □ via vroedvrouw
- □ via Kind en Gezin
- □ andere, welke?:_____

Heeft u voor deze app betaald?

- □ Ja, welk bedrag heeft u betaald? _____ euro
- □ Neen

Om welke reden of vanuit welke nood/behoefte heeft u deze app gedownload? *Meerdere antwoorden zijn mogelijk*

- □ omdat informatie, tips, adviezen over de zwangerschap dagelijks/wekelijks wordt gegeven (via push berichten)
- □ omdat praktische en administratieve informatie wordt gegeven (o.a. hospitalisatieverzekering, kindergeld, kraamgeld, terugbetaling mutualiteit, ouderschapsverlof, moederschapsrust, vaderschapsverlof, enz.)
- □ omdat ik een persoonlijk dagboek kan bijhouden
- □ omdat ik een kalender kan bijhouden om de groei en ontwikkeling van de baby/zwangerschap te volgen
- □ omdat ik zelf foto's/filmpjes kan opladen
- □ omdat ik bepaalde functies van de app kan delen via sociale media (o.a. Facebook)
- □ omdat handige checklists worden voorzien (o.a. babyuitzet, babynamen, enz.)
- □ omdat een agenda is opgenomen waarin ik mijn afspraken kan noteren
- □ omdat een grafiek/statistiek kan bijgehouden worden (o.a. gewicht)
- □ omdat een calculator/meters zijn opgenomen (o.a. weeëntimer, zwangerschapsmeter, enz.)
- □ omdat contact met andere zwangeren kan worden gelegd (o.a. via chat of een forum)

Waarom hebt u specifiek voor deze app gekozen? *Meerdere antwoorden zijn mogelijk*

- □ omdat de app afkomstig is van een betrouwbare organisatie/instantie/instelling
- □ omdat de app goed beoordeeld werd door andere gebruikers
- □ omdat de app reeds veelvuldig werd gedownload
- □ omdat de app werd aanbevolen door andere zwangeren of recent bevallen moeders
- □ omdat de app werd aanbevolen door een zorgverlener (vroedvrouw, huisarts, gynaecoloog, enz.)
- □ andere, namelijk _____

Hoe frequent heeft u deze app geraadpleegd?

- □ dagelijks
- □ wekelijks
- □ maandelijks
- □ Andere, specifieer: _____

Hoelang gebruikt u deze app? Of hoe lang hebt u deze app gebruikt?
Gelieve het aantal weken of maanden weer te geven.

In welke mate zou u deze app aanbevelen aan andere zwangere vrouwen?

- □ Ik zou deze app niet aanbevelen aan zwangeren
- □ ik zou deze app maar aan weinig zwangeren aanbevelen
- □ Ik zou deze app aan verschillende zwangeren aanbevelen
- □ Ik zou deze app aan veel zwangeren aanbevelen
- □ Ik zou deze app aan iedere zwangere aanbevelen

Hoe zou u deze app in het algemeen beoordelen?

- □ ★ Een van de slechtste apps die ik ooit heb gebruikt
- □ ★★
- □ ★★★ Gemiddeld
- □ ★★★★

□ ★★★★★ Een van de beste apps die ik ooit heb gebruikt

BEOORDELING APP 3

Naam van de app: _____

In welke store heeft u de app gedownload?

□ Apple store
□ Google Play store
□ Andere, specifieer: _____

Welke versie van de app heeft u gedownload?
Dit kan u vinden in de aanvullende informatie van de app in de store (vb. versie 2.3)
_____

Hoe heeft u deze app leren kennen? *Meerdere antwoorden zijn mogelijk*

□ via een zoektocht in de app store
□ via media (tijdschriften, kranten, radio, televisie, enz.)
□ via websites/internetfora
□ via sociale media (o.a. facebook)
□ via reclameadvertenties op diverse media
□ via partner
□ via (schoon)moeder
□ via zus(sen)
□ via vriendin(nen)
□ via andere familieleden of kennissen
□ via andere zwangere vrouwen
□ via gynaecoloog
□ via huisarts
□ via vroedvrouw
□ via Kind en Gezin
□ andere, welke?:_____

Heeft u voor deze app betaald?
□ Ja, welk bedrag heeft u betaald? _____ euro
□ Neen

Om welke reden of vanuit welke nood/behoefte heeft u deze app gedownload? *Meerdere antwoorden zijn mogelijk*

□ omdat informatie, tips, adviezen over de zwangerschap dagelijks/wekelijks wordt gegeven (via push berichten)
□ omdat praktische en administratieve informatie wordt gegeven (o.a. hospitalisatieverzekering, kindergeld, kraamgeld, terugbetaling mutualiteit, ouderschapsverlof, moederschapsrust, vaderschapsverlof, enz.)
□ omdat ik een persoonlijk dagboek kan bijhouden
□ omdat ik een kalender kan bijhouden om de groei en ontwikkeling van de baby/zwangerschap te volgen
□ omdat ik zelf foto's/filmpjes kan opladen
□ omdat ik bepaalde functies van de app kan delen via sociale media (o.a. Facebook)
□ omdat handige checklists worden voorzien (o.a. babyuitzet, babynamen, enz.)
□ omdat een agenda is opgenomen waarin ik mijn afspraken kan noteren
□ omdat een grafiek/statistiek kan bijgehouden worden (o.a. gewicht)
□ omdat een calculator/meters zijn opgenomen (o.a. weeëntimer, zwangerschapsmeter, enz.)
□ omdat contact met andere zwangeren kan worden gelegd (o.a. via chat of een forum)

Waarom hebt u specifiek voor deze app gekozen? *Meerdere antwoorden zijn mogelijk*

□ omdat de app afkomstig is van een betrouwbare organisatie/instantie/instelling
□ omdat de app goed beoordeeld werd door andere gebruikers
□ omdat de app reeds veelvuldig werd gedownload
□ omdat de app werd aanbevolen door andere zwangeren of recent bevallen moeders
□ omdat de app werd aanbevolen door een zorgverlener (vroedvrouw, huisarts, gynaecoloog, enz.)
□ andere, namelijk _____

Hoe frequent heeft u deze app geraadpleegd?

- □ dagelijks
- □ wekelijks
- □ maandelijks
- □ Andere, specifieer: _____

Hoelang gebruikt u deze app? Of hoe lang hebt u deze app gebruikt?
Gelieve het aantal weken of maanden weer te geven.

_____

In welke mate zou u deze app aanbevelen aan andere zwangere vrouwen?

- □ Ik zou deze app niet aanbevelen aan zwangeren
- □ ik zou deze app maar aan weinig zwangeren aanbevelen
- □ Ik zou deze app aan verschillende zwangeren aanbevelen
- □ Ik zou deze app aan veel zwangeren aanbevelen
- □ Ik zou deze app aan iedere zwangere aanbevelen

Hoe zou u deze app in het algemeen beoordelen?

- □ ★ Een van de slechtste apps die ik ooit heb gebruikt
- □ ★★
- □ ★★★ Gemiddeld
- □ ★★★★
- □ ★★★★★ Een van de beste apps die ik ooit heb gebruikt

15. Ik zou een app gebruiken die mij informatie geeft over de activiteit van mijn baarmoeder.

- □ Ja, zelfs wanneer ik geen verhoogd risico heb op complicaties.
- □ Ja, wanneer ik via mijn zorgverlener vernomen heb dat ik een verhoogd risico heb op complicaties.
- □ Nee, ik wil deze niet gebruiken.

16. Ik zou een app gebruiken die mij informatie geeft over de hartslag en bewegingen van mijn ongeboren kindje.

- □ Ja, ongeacht of ik complicaties heb tijdens mijn zwangerschap.
- □ Ja, maar enkel wanneer ik complicaties heb tijdens mijn zwangerschap.
- □ Nee, ik wil deze niet gebruiken.

Beveiligd platform

Op een beveiligd platform zou u op een elektronische manier kunnen communiceren met andere personen. Uw gegevens en gegevensuitwisseling zou op een beveiligde manier gebeuren en u zou zeker zijn dat de persoon waarmee u communiceert effectief die persoon is (wat bijvoorbeeld niet altijd het geval is op Facebook,…). Ook de privacy kan in een dergelijk platform gegarandeerd worden.

17. Stel dat dergelijk beveiligd platform beschikbaar zou zijn, in welke mate zou u dan interesse hebben om dergelijk platform te gebruiken? Gelieve de uitspraken te beoordelen van 1 tot 10 (1= niet geïnteresseerd, 10=zeer sterk geïnteresseerd).

Ik heb interesse om een beveiligd platform te gebruiken om:

te communiceren met andere (zwangere) vrouwen via gewone chat of forum	0	1	2	3	4	5	6	7	8	9	10
te communiceren met andere (zwangere) vrouwen via videochat	0	1	2	3	4	5	6	7	8	9	10
extra informatie te verkrijgen specifiek gericht op uw individuele situatie of probleem via video	0	1	2	3	4	5	6	7	8	9	10
extra informatie te verkrijgen specifiek gericht op uw situatie via een online folder	0	1	2	3	4	5	6	7	8	9	10

gezondheidsgegevens uit te wisselen met uw zorgverlener	0	1	2	3	4	5	6	7	8	9	10
vragen te kunnen stellen aan uw zorgverlener (te vergelijken met e-mail)	0	1	2	3	4	5	6	7	8	9	10
vragen te kunnen stellen aan uw zorgverlener via videochat	0	1	2	3	4	5	6	7	8	9	10

18. In de veronderstelling dat u een vaste arts of vroedvrouw heeft en een beveiligd forum gebruikt wordt, zou u ermee akkoord gaan dat ook andere zorgverstrekkers uw gegevens bekijken, vragen beantwoorden,…?

    □ Ja, ik ga hiermee akkoord
    □ Ja, ik ga hiermee akkoord, maar alleen als mijn vaste zorgverstrekker afwezig is (bv. omwille van verlof, ziekte,…)
    □ Neen, ik ga hiermee niet akkoord, want ik zie dit als een schending van mijn privacy
    □ Opmerkingen: _____

19. Ik vind het belangrijk dat een digitale app rondom de zwangerschap een medisch certificaat heeft (Dit is een app die enkel verkrijgbaar is op voorschrift van een arts en een CE-markering heeft, wat wil zeggen dat de app overeenstemt met de Europese regelgeving voor veiligheid, gezondheid, milieu en consumentenbescherming).

    □ Nee
    □ Ja, omdat ik dan zeker ben dat:

        □ De informatie evidence-based is (gebaseerd op medisch-wetenschappelijke literatuur)
        □ Indien relevant, opgemeten parameters (bv bloeddruk) accuraat gemeten zijn
        □ Mijn gegevens in de app of, indien relevant, die gedeeld worden met mijn zorgverleners goed beveiligd zijn