Mobile Self-Operated Home Ultrasound System for Remote Fetal Assessment During Pregnancy

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Abstract

Background: *Mobile medical devices for self-patient use are a rapidly evolving section of telehealth. We examined the INSTINCT® ultrasound system, a portable, self-operated ultrasound device attached to a commercial smartphone for remote fetal assessment. We aimed to evaluate whether it is feasible to use remote fetal assessment during pregnancy.*

Materials and Methods: *This is an observational noninterventional trial. We included women with a singleton fetus at 14+0 to 39+6 gestational weeks. Each participant received the device for a self-use period of 7–14 days and was instructed to perform one to three scans a day. Participants completed a self-assessment questionnaire to evaluate safety and usability (i.e., user experience and satisfaction). Each scan was evaluated for fetal heart activity, amniotic fluid volume, fetal tone, fetal body, and breathing movements.*

Results: *One hundred women, completing 1,360 self scans, used the device for 8.1±1.5 days, performing an average of 13.6±6.2 scans each. There were no device-related serious adverse events. Success in detection was 95.3% for fetal heart activity, 88.3% for body movements, 69.4% for tone, 92.2% for normal amniotic fluid volume, and 23.8% for breathing movements. Interobserver agreement was 94.4% for fetal heart rate activity, 85.9% for body movements, 69.5% for fetal tone, 86.9% for amniotic fluid volume, and 94.0% for breathing movements. Self-assessed user experience was rated at 4.4/5, whereas device satisfaction was rated at 3.9/5.*

Conclusion: *The INSTINCT ultrasound system is a feasible solution for remote sonographic fetal assessment. Further studies are needed to assess its role and impact in telehealth antenatal care and fetal surveillance.*

Keywords: *ultrasound, telemedicine, fetal monitoring, mobile, home, self-operated*

Introduction

Mobile medical devices for self-patient use are rapidly evolving as an important component in telehealth.[1] Such devices allow users to independently conduct simple and straightforward diagnostic and treatment procedures in the confines of one's home, while sharing it with health care professionals for clinical consultation, follow-up, and documentation. Using these devices offers advantages in patient care and involvement, with possible benefits for clinical outcomes and cost-effectiveness.[2] Amid the COVID-19 challenges, alternative designs for prenatal care are needed with mobilization of telemedicine to allow for virtual visits as opposed to only in-person consultations.[3]

The benefits of mobile medical devices are becoming more apparent in multiple fields of medicine, including both obstetrics and maternal–fetal medicine.[4,5] Many existing devices, both with and without telemedicine capabilities, are considered part of standard-of-care procedures, and some are practically house-hold appliances. Mobile medical devices include sphygmomanometers for blood pressure measurement,[6–9] glucometers and sensors for self-glucose blood monitoring,[9,10] and devices for fetal heart rate monitoring and contraction recording.[11,12] Although not all devices have proven medical benefits, some have been shown to be clinically useful and financially cost-effective with the potential to enhance patient compliance, improve time management for both patients and health care providers, and relieve patient anxiety and stress.[13]

Recently, PulseNmore Ltd., an Israeli start-up company, has developed INSTINCT®: a mobile self-operated ultrasound transducer controlled through a smartphone. The INSTINCT ultrasound system provides patients with the ability to record

and transmit images and videos of the fetus for remote telemedicine consultation. This study aimed to examine the feasibility of self-use of the INSTINCT ultrasound device by pregnant women while assessing its performance and usability (i.e., user experience and satisfaction). We hypothesized that the device would be easy to use, and provide adequate imaging allowing for appropriate visualization and postscan interpretation by a remote health care professional. Therefore, our hypothesis suggested that the device would be suitable for remote fetal assessment.

Materials and Methods

We conducted an observational noninterventional clinical trial at the maternal–fetal medicine unit in the Rabin Medical Center in Petah-Tikva, Israel. The trial was registered on the Ministry of Health MyTrial website (MOH_2019-04-22_007094).

STUDY POPULATION

Participants were recruited from three settings: women who were discharged after hospitalization in the maternal–fetal medicine ward, women presenting for antenatal care in the maternal–fetal medicine outpatient clinics, and gravidas responding to an advertisement distributed among hospital personnel and to the public through social media networks.

We included all consenting women who were carrying a singleton fetus at 14 + 0 to 39 + 6 gestational weeks. Women with multiple gestation, a nonviable fetus at recruitment, and those with a known major fetal anatomical malformation or genetic syndrome were excluded from the study.

INSTINCT ULTRASOUND SYSTEM

The device evaluated was the INSTINCT ultrasound device (PulseNmore, Omer, Israel) (*Fig. 1*). Portable wireless ultrasound transducer, physically attached—through a type-c USB connection—to a smartphone. The smartphone then allows the user to operate the device by providing a power source (5 V, 1 A), screen viewing, and access to the control software (Pulse-n-More application). The device produces B and M mode, black and white ultrasound images and allows the user to scan, acquire, and display real-time ultrasound images with optional transmission of recorded videos.

The device comprises the following components: cordless handheld cradle that houses the transducer. The transducer probe consists of 64 piezo electric elements (central frequency of 3.5 and 2–5 MHz bandwidth). It provides 230 mm maximal depth and 60 mm focal depth (which can be set manually at 20–128 mm). The acoustic lens at the top of the transducer is coated with biocompatible silicone rubber. Thermal and mechanical indices, validated by a certified laboratory, were <1.

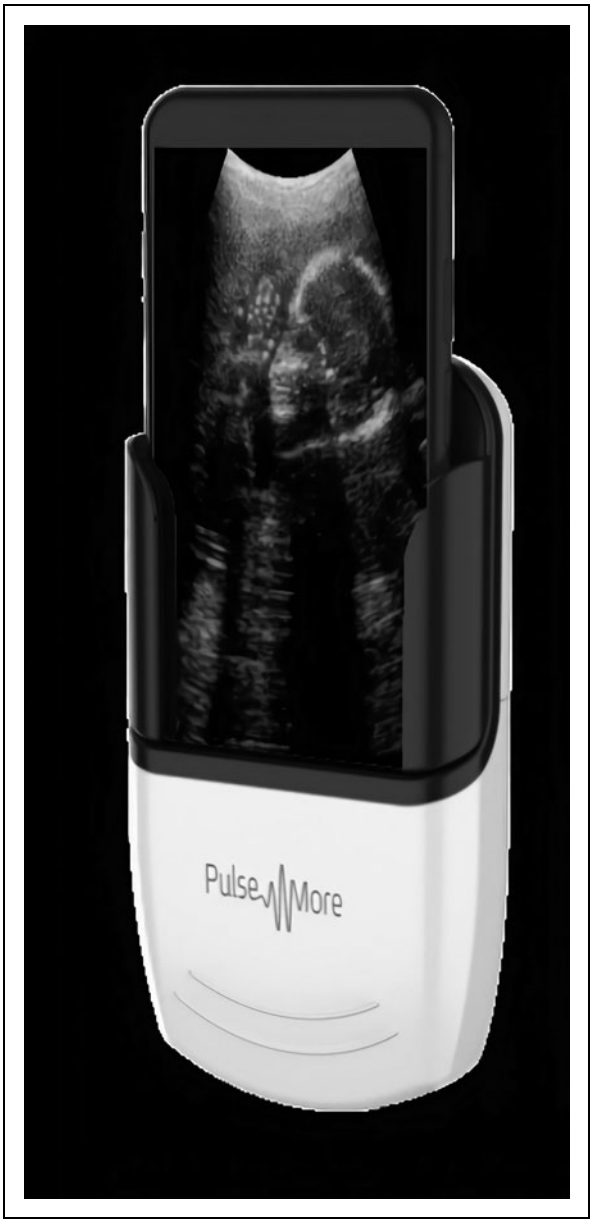

Fig. 1. INSTINCT® ultrasound system. Image of the INSTINCT transducer attached to a smartphone.

The following features can be controlled by a password-protected menu in the device's application software: gain (%), power (dB), depth (mm), dynamic range (dB), frequency (MHz), focus (mm), focus number (*n*), frame averaging, image enhancement, and speckle reduction.

STUDY CONDUCT

Each participant received the device for a self-use period of 7–14 days, along with a Galaxy S8 Samsung smartphone with an already installed application by PulseNmore used to

operate it. The phone had no SIM card and was locked in airplane mode to ensure participant privacy, in accordance with IRB requirements. Participants were also given an electrical charger for the smartphone and designated ultrasound gel tubes.

Each participant received personal face-to-face instructions on how to use the device and its associated mobile application. Furthermore, the first ultrasound scan was preformed immediately after recruitment, guided by an experienced ultrasound technician who adjusted the device settings as needed for the participant. These settings remained constant during the study period for each participant. This initial scan was considered part of participant's training and was not included in the data analysis and assessment.

Participants were instructed to perform up to three scans per day, with a minimum of at least one daily. The maximum number of scans was limited within the device's application to a maximum of three in a single 24-h period with at least 30 min required between each scan, to avoid excessive use of the device.

Every scan was segmented into six separate recordings, each lasting 15–45 s, totaling 3 min per scan. Before each segment, an animated video demonstrated how to complete the scan, specifically indicating how to move the device across the maternal abdomen (Supplementary Video S1). These videos were used to ensure full uterine and fetal visualization regardless of gestational age and were based on a standardized previously published six-step approach.[14]

The scans were stored on the internal memory of the smart phone, and were downloaded upon completion of the study period, when each participant returned her device after use. According to IRB constraints, the scans were not interpreted until after delivery, to avoid any bias on routine standard of care during pregnancy follow-up.

DATA COLLECTION, ANALYSIS, AND DEFINITIONS

Demographic, medical, and obstetrical data were obtained for each participant. Furthermore, perinatal outcomes—including gestational age at delivery, birthweight, and gender—were collected. Preterm birth was defined as birth before 37 + 0 gestational weeks, whereas small for gestational age was defined as birthweight below the 10th percentile, determined according to a nationally accepted nomogram.[15]

After the trial period, upon returning the device, each participant completed a self-assessment questionnaire to evaluate adverse events during the trial period. Furthermore, each participant was given a series of questions, scored on a scale of 1 to 5, designed to evaluate their user interface experience and overall satisfaction (*Fig. 2*). After delivery, maternal and perinatal outcomes were collected as well as any adverse events that had occurred during the remainder of the pregnancy.

Each scan was independently assessed by two professionals, either an obstetrician–gynecologist or an experienced ultrasound technician. Scans were evaluated for the following biophysical parameters, scored as either seen or not seen: fetal heart activity, subjective assessment of normal amniotic fluid volume, fetal tone, fetal body movements, and fetal breathing movements (for those at or beyond 27 + 0 gestational weeks). We also defined a composite sonographic parameter of fetal viability if at least one of the following was observed: heart activity, tone, body, or breathing movements.

OUTCOME MEASURES

The primary outcome measure was defined as safety (i.e., the occurrence of any serious adverse event [SAE], maternal or fetal, during the trial period that was related to device use). The definition of success was set, *a priori*, as the absence of device-related SAEs. SAE was defined as any adverse event resulting in one or more of the following: death, a life-threatening event, hospitalization and disability (for maternal SAE) or malformations, distress, or death (for fetal SAE). All other adverse pregnancy outcomes, occurring postrecruitment—either obstetric, maternal, or perinatal—were recorded and categorized as either serious or nonserious events.

Secondary outcomes included performance, namely, the extent to which the postscan evaluation successfully identified each of the sonographic parameters. Success was defined *a priori* as the ability of the ultrasound scan to be positively interpreted, operationalized as the ability to demonstrate at least 70% of defined sonographic features. We also analyzed the degree of overall interobserver agreement between each two professionals interpreting the same scan. Finally, a secondary outcome was also defined for usability, according to a positive user experience and satisfaction, if the postscan assessment questions scored an overall average of at least 3.5 points on a scale of 1 to 5.

STATISTICAL ANALYSIS

Data were analyzed using the SAS® software (Version 9.3; SAS Institute, Cary, NC). Categorical variables, sample size, and absolute and relative frequencies were provided with upper and lower limits of 95% confidence intervals (CIs). Continuous variables, sample size, arithmetic mean, standard deviation (SD), median, and range were provided.

Sensitivity analysis was computed using a 2 × 2 table for the rate of detectability for professional interpreters for each sonographic feature. Overall, interobserver agreement was

Open Questions:
1. Overall, how many times did you use the device while in your possession?
2. On average, how many times a day did you use the device while in your possession?
3. Did you use the device by yourself or with someone else (and with whom)?
4. Did you experience any malfunction, i.e. wanting to but unable to operate the device (Estimate how many times)?
5. Please write any other comments for user experience and suggestions for improvement
User Experience Questions: Please indicate your answer to each of the following questions, in a scale of 1-thru-5 (1-Poor, 2-Low, 3-Medium, 4-Good, 5-Excellent)
1. How easy was it to use the device?
2. How easy was it to use the application?
3. How easy was it to perform the scan?
4. The easy was it to hold the device?
5. How convenient was it to watch the screen?
6. How well did you identify fetal heartbeat?
7. How well did you identify fetal movements?
8. How easy was it to attach the device to the phone?
9. How easy was it to detach the device from the phone?
User Satisfaction Questions: Please indicate your level of agreement to each of the following statements, in a scale of 1-thru-5 (1-Disagree, 2-Mild, 3-Medium, 4-High, 5-Totally agree)
1. If possible, I would use the device for more time than allocated
2. If possible, I would perform more scans than allocated
3. I enjoyed using the device
4. The device contributed to my sense of security during its use
5. The device contributed to my sense of relaxation during its use
6. The device contributed to my sense of connection with the fetus
7. I would recommend a friend to use the device
8. I would continue to use the device during this pregnancy, regardless of the study
9. I would consider to purchase the device in this or next pregnancy, regardless of the study

Fig. 2. Self-assessment questionnaires. Self-assessment questionnaires to evaluate adverse events, user interface, and overall satisfaction. The questionnaire included a series of open and closed questions and statements.

calculated for analyzing the agreement between the professionals interpreting the scans, obstetricians or ultrasound technicians, by the following formula: overall agreement = number of cases with agreement/number of cases × 100.

ETHICS DECLARATION

The study was approved by the local institutional review board at the Rabin Medical Center (No. 0004-19) and the National Ethical Committee of the Israeli Ministry of Health (No. 2019-10098). All participants provided written informed consent before study participation. Scans were done blinded and the results were not made available to health care providers, thereby having no impact on clinical–obstetrical care.

Results

We enrolled 101 women between July and December 2019. Of the recruited women, only one was excluded as her fetal scan at recruitment revealed a major fetal anomaly, compatible with the exclusion criteria. Therefore, data for 100 women, who completed 1,360 self-scans in total, were available for analysis.

Baseline demographics as well as medical and obstetrical characteristics of the study participants are outlined in *Table 1*. The mean (SD) number of days the device was used by each participant was 8.1 (1.5) days (range 4–14 days) with each performing an average (SD) of 13.6 (6.2) scans (range 2–32), or 1.7 (0.7) scans per day (range 0.3–3). An example of an individual participant scan output is featured in Supplementary Video S2. This was a 34-year-old woman recruited at 19 + 0 gestational weeks.

Table 1. Maternal Baseline Characteristics of Study Participants, *N* = 100

Maternal age, years	32.9 ± 4.4	32.0 (21.0–43.0)
Education level, years	16.0 ± 2.6	16.0 (11.0–26.0)
High school diploma	22 (22%)	
College/university degree	78 (78%)	
Employment status		
Homemaker	7 (7%)	
Health care-related occupation	34 (34%)	
Other occupation	59 (59%)	
Prepregnancy weight, kg	62.4 ± 12.6	59.5 (41.0–100.0)
Height, m	1.6.0 ± 0.1	1.6 (1.5–1.8)
BMI, kg/m^2	23.6 ± 4.6	22.4 (17.2–37.6)
Obesity (≥30 kg/m^2)	10 (10%)	
Pre-existing chronic disease	33 (33%)	
Hypothyroidism	10 (10%)	
Type 1 or type 2 diabetes mellitus	5 (5%)	
Asthma	4 (4%)	
Endometriosis	2 (2%)	
Psoriasis	2 (2%)	
Factor 5 Leiden, heterozygote	2 (2%)	
Familial Mediterranean fever	2 (2%)	
Chronic hypertension	1 (1%)	
Crohn's disease	1 (1%)	
Other conditions[a]	16 (16%)	
Prior abdominal surgery[b]	6 (6%)	
Gravidity	2.5 ± 1.4	2.0 (1.0–7.0)
Parity	1.1 ± 1.1	1.0 (0–5.0)
Nulliparity	41 (41%)	
Multiparity (≥4)	3 (3%)	

Data presented as mean ± SD and median (range) for continuous variables and as *n* (%) for categorical variables.

[a]Single occurrence of other chronic medical conditions (attention deficit disorder, hearing loss, IgA nephropathy, pseudotumor cerebri, renal insufficiency, fatty liver, gastrointestinal dysmotility, chronic pancreatitis, Chiari malformation, chronic neutropenia, astrocytoma, anorexia nervosa, bipolar disorder, and cerebral arteriovenous malformation).

[b]Prior abdominal surgery included myomectomy, oophorectomy, cholecystectomy, and bariatric surgery.

BMI, body mass index; SD, standard deviation.

SAFETY OUTCOMES

Only a single event, considered to be a non-SAE, was categorized as device related (*Table 2*). This event was a heating sensation caused directly by the device that was felt briefly by the participant. Upon investigation, it was found to be a malfunctioning device that was continuing to transmit power to the transducer even when inactive. The device was repaired and the problem did not recur thereafter. Otherwise, a total of 30 of the participants experienced adverse events after their inclusion in the study. Specifically, two pregnancy-related maternal complications and two fetal complications categorized as SAEs were reported; these events, however, were unrelated to device use. The first SAE was maternal influenza with respiratory distress requiring intensive care. The second SAE was intrapartum placental abruption causing nonreassuring fetal heart rate that required urgent cesarean delivery. In addition, two cases of shoulder dystocia occurred, both categorized as neonatal SAE. The remainder were non-SAEs, including maternal and neonatal expected pregnancy-related and postpartum complications: hypertensive disorders ($n = 6$), gestational diabetes ($n = 2$), gestational thrombocytopenia ($n = 1$), premature contractions with arrested preterm labor ($n = 2$), fetal tachycardia ($n = 1$), intrapartum fever ($n = 3$), preterm birth ($n = 10$), postpartum hemorrhage with ($n = 2$) or without ($n = 2$) birth canal trauma, and adherent placenta ($n = 1$).

PERFORMANCE OUTCOMES

Detection rate was 95.3% for fetal heart activity, 88.3% for body movements, 69.4% for tone, 23.8% for breathing movements, 92.2% for normal amniotic fluid volume, and 98.9% for fetal viability (*Table 3*). Interobserver agreement was 94.4% for fetal heart rate activity, 85.9% for body movements, 69.5% for fetal tone, 94.0% for breathing movements, 86.9% for amniotic fluid volume, and 97.6% for fetal viability (*Table 3*).

In a subanalysis, stratified according to two possible confounders, we analyzed the success in detection by body mass index (BMI) and gestational age categories. Our results

Table 2. Obstetrical, Maternal and Fetal, Outcomes of Study Participants, *N* = 100

Spontaneous	85 (85%)	
Controlled ovarian hyperstimulation	6 (6%)	
Assisted reproduction techniques	9 (9%)	
Pregnancy complications, prerecruitment	18 (18%)	
History indicated cervical cerclage	1 (%)	
First trimester bleeding	4 (4%)	
Single umbilical artery	1 (1%)	
Gestational diabetes mellitus	9 (9%)	
Arrested preterm labor	2 (2%)	
Third trimester bleeding	1 (%)	
Device-related adverse events		
Serious	0	
Nonserious	1 (1%)	
Pregnancy complications, postrecruitment		
Serious	4 (4%)	
Nonserious	25 (25%)	
Mode of delivery		
Spontaneous vaginal delivery	66 (66%)	
Assisted vaginal delivery	7 (7%)	
Cesarean delivery	27 (27%)	
5-Minute Apgar score ≤7	1 (1%)	
GA at enrollment, weeks	23.6 ± 6.0	22.0 (14.0–37.0)
Neonatal gender, female	54 (54%)	
GA at birth, weeks	38.8 ± 1.5	39.0 (34.0–41.4)
Neonatal birthweight, g	3204 ± 443.6	3185 (2143–4210)
Neonatal birthweight, percentile	55.4 ± 26.7	56 (8–97)

Data presented as mean ± SD and median (range) for continuous variables and as *n* (%) for categorical variables.

[a]Single occurrence of other chronic medical conditions (attention deficit disorder, hearing loss, IgA nephropathy, pseudotumor cerebri, renal insufficiency, fatty liver, gastrointestinal dysmotility, chronic pancreatitis, Chiari malformation, chronic neutropenia, astrocytoma, anorexia nervosa, bipolar disorder, and cerebral arteriovenous malformation).

[b]Prior abdominal surgery included myomectomy, oophorectomy, cholecystectomy, and bariatric surgery.

GA, gestational age.

Table 3. Detectability and Interobserver Agreement

SONOGRAPHIC PARAMETER	DETECTABILITY	INTEROBSERVER AGREEMENT
Fetal heart activity	95.3 (94.5–96.1)	94.4 (93.0–95.6)
Fetal body movement	88.3 (87.1–89.5)	85.9 (84.0–87.7)
Fetal tone	69.4 (67.7–71.2)	69.5 (67.0–71.9)
Amniotic fluid volume	92.2 (91.1–93.1)	86.9 (85.0–88.6)
Fetal breathing movements[a]	23.8 (20.8–27.1)	94.0 (92.6–95.2)
Fetus viability[b]	98.9 (98.4–99.2)	97.6 (96.6–98.3)

Data presented as percentages (95% CI).

[a]For women/fetuses at or beyond 27 + 0 gestational weeks.

[b]Fetus viability was defined as a composite outcome including any one of the following: fetal heart activity, tone, body, or breathing movements.

CI, confidence interval.

demonstrate similar detection across BMI categories for all sonographic features. However, a significant better detection for all sonographic features was achieved for scans conducted prior, compared with those after 24 gestational weeks (*Table 4*).

USER-EXPERIENCE SATISFACTION

The overall response for the device user interface evaluation was 4.4 ± 0.6 (range 1–5), and average result of the user satisfaction was 3.9 ± 1.2 (range 1–5) (*Table 5*). Both were analyzed for the mean responses recorded by the participants on a scale of 1 to 5, in a set of questions, as detailed in *Figure 2*.

Successful detection by participants, who were specifically asked to evaluate their independent ability to see fetal heartbeat and movements on the postscan questionnaires, was 80.8% (95% CI 71.7–88.0) and 82.8 (95% CI 73.9–89.7), respectively.

Discussion

We conducted an observational study to evaluate the INSTINCT ultrasound system. The device proved to be effective through providing a detection rate of 70–95% for all but a single sonographic parameter. Fetal breathing movement was poorly detected, only 23% of the scans, while detection peaked at 98% for a composite parameter of fetal viability. Usability goals were also met with participant responses crossing the predetermined cutoff of 3.5, averaging 4.4 out of 5 and 3.9 out of 5 for user for user experience and satisfaction, respectively.

The INSTINCT device can provide significant advantages for patients and medical professionals. Fetal surveillance for complicated pregnancies requires frequent ambulatory visits

Table 4. Detectability Stratified According to Body Mass Index and Gestational Age Categories

SUBGROUP AND CRITERIA	FETAL PULSE	FETAL BODY MOVEMENT	FETAL TONE	FETAL BREATHING MOVEMENTS[a]	AMNIOTIC FLUID VOLUME
BMI, kg/m^2					
Underweight >18.0	96.1 (92.5–98.3)	87.9 (82.6–92.0)	70.4 (63.7–76.5)	39.5 (24.0–56.6)	90.3 (85.4–94.0)
Normal 18.0–24.9	95.9 (94.9–96.8)	88.5 (87.0–90.0)	69.9 (67.7–72.0)	24.3 (20.5–28.5)	92.4 (91.1–93.6)
Overweight 25.0–29.9	93.7 (90.8–95.9)	84.8 (80.8–88.2)	71.6 (66.8–76.0)	8.5 (3.8–16.1)	93.9 (91.1–96.1)
Obese >30	94.0 (91.0–96.3)	91.7 (88.3–94.4)	64.3 (59.0–69.3)	28.4 (20.9–36.8)	90.0 (86.4–92.9)
p-Value	0.131	0.734	0.336	0.805	0.826
GA, weeks					
≤24.0	96.2 (95.0–97.2)	91.5 (90.0–92.8)	75.6 (73.4–77.7)	NA	95.4 (94.2–96.4)
>24.0	94.7 (93.5–95.8)	84.1 (81.9–86.2)	61.2 (58.3–64.0)	23.8 (20.8–27.1)	87.8 (85.8–89.6)
p-Value	0.030	0.030	0.014	NA	0.022

Data presented as percentages (95% CI).

[a]For women/fetuses at or beyond 27 + 0 gestational weeks.

NA, not applicable.

or hospitalization and can be also recommended, at a lower frequency, for low-risk pregnancies or for semimedical indications, such as maternal anxiety. The prospect of performing these follow-ups remotely in a telemedicine setup—either by Doppler-based auscultation devices or, as presented here, by an on-screen ultrasound system—is appealing. The vision is that such systems will be able to improve maternal, fetal, and neonatal outcomes; be cost-effective while improving maternal anxiety, satisfaction, and engagement of patients; and enhance accessibility in geographically and economically underserved areas. Furthermore, this technology may provide a solution for patient follow-ups in accordance with social distancing policies that were recently imposed during the COVID-19 pandemic.

A similar approach, and one of the earliest examples of the benefits of a remote hand-held ultrasound, demonstrated that a lung ultrasound can be easily performed by an unexperienced provider and remotely interpreted by an expert sonographer.[16]

Table 5. Satisfactory and Usability Self-Assessments Among Participants

SCORE	MEAN ± SD	MEDIAN (RANGE)
User experience	4.4 ± 0.6	4.4 (1–5)
User satisfaction	3.9 ± 1.2	4.2 (1–5)

Data presented as mean ± SD.

Recognizing the technology's potential, Israel's largest health maintenance organization (HMO), Clalit Health Services, has recently launched TYTO®. This is a home-based telemedicine device that allows to perform a remote physical examination—inspection through video, auscultation through microphone, and body temperature measurements through a thermometer. All of these are transmitted to a pediatrician who can then provide consultation, diagnosis, and treatment. In a research setting, the device was compared with other standalone devices among 50 children, demonstrating it to be superior in image quality, with a higher chance of reaching a diagnosis.[17] Fetal telemonitoring poses greater challenges for research and implementation, and is mostly at pilot and exploratory phases without robust evidence to demonstrate a positive impact on pregnancy outcomes. Clinical trials for antenatal telemonitoring systems have demonstrated that fetal electrocardiography, performed at home after labor induction, successfully produced output tracing in ~90% of instances.[18] Wireless remote fetal telemonitoring was shown to increase patient adherence to antenatal care in rural areas,[19] enhance patient satisfaction,[20,21] and be cost-effective[22] DeNicola et al.[13] in a recent comprehensive literature review

identified that remote fetal monitoring with virtual consultations, mostly in settings where there are barriers to facility-based visitations or for high-risk obstetric patients, such as hypertension and diabetes, can decrease outpatient visits. Currently recruiting, the HOspital care versus TELemonitoring in high-risk pregnancy (HOTEL) trial explores whether telemonitoring can play a role in improving perinatal outcomes among high-risk gestations, while considering patient safety, satisfaction, and cost-effectiveness.[23]

Several publications have addressed concerns regarding use of home-based over the counter fetal monitoring devices. Sound amplification systems or Doppler auscultation devices may render false reassurance in untrained hands as they only provide a snapshot of the fetal heartbeat.[24,25] Similar cautions have been made against ultrasound imaging for nonmedical purposes (i.e., imaging or videos taken as a memento).[26,27] Nevertheless, it is important to stress that the current INSTINCT device is not intended for nonmedical recreational self-assessments, but rather for self-use accompanied by professional, although remote, interpretation and consultation. Moreover, diagnostic ultrasounds have been extensively used for more than half a century with no evidence of harm or teratogenicity and are, therefore, considered safe for use during pregnancy.[28] The INSTINCT device features, including its thermal and mechanical indices—which are considered the most practical and understandable risk assessment surrogates—are well within the acceptable and recommended safety boundaries for prenatal diagnostic ultrasound.[29,30]

Importantly, the future setting to assess home-made ultrasound scans will be immediate and/or on-line interpretation by a health care professional, who can trigger an appropriate response, such as rescan or referral to a health care facility, in case of clinical or technical abnormal scans. Our study was not intended to prove perinatal benefits in terms of improved morbidity and mortality. Rather, this was a small-scale feasibility trial and evidence is still needed to prove its effectiveness for long-term health and financial benefits. As for other telemedicine devices, large-scale prospective randomized controlled trials are still needed before their wide-scale implementation.

Future prescan instructions can be improved and may have to be individualized according to gestational week, as the six-segment approach may perform better if tailored for the gestational age at which it is being done. Breathing movements were poorly detected due to constant movement of the transducer across the maternal abdomen, without preinstructed poses in the scan. This made it difficult for observers to see breathing movements. However, with improved tailoring of the prescan instructions, we believe this can be significantly improved.

The average result of the user experience questionnaires was 3.9 ± 1.2, which may seem low. The lowest scoring statement in this score was "I would consider to purchase the device in this or next pregnancy, regardless of the study" at 3.2, whereas the highest scoring statement was: "I would recommend a friend to use this device" at 4.2. As this was a clinical trial without an accompanying telemedicine consultation, we assume that in a real-life scenario—with an offline or online consultation providing medical–obstetrical feedback, this would increase user's experience score and willingness to pay for the device and its service.

Conclusion

The INSTINCT ultrasound system is a feasible solution—practical, safe, and effective for remote sonographic fetal assessment. It offers excellent potential for expecting mothers to perform a basic fetal sonographic assessment on their own and to have it interpreted, either online or offline, by a professional from afar. It remains to be seen whether this can enhance pregnancy outcomes, provide financial benefits for patients, and improve maternal reassurance. Possible future enhancements of the device, may provide additional features for autonomic artificial intelligence interpretations of the scans.

Acknowledgments

The authors thank the devoted team of research coordinators: Lihi Cohen-Rotman, Adva Yaacobian, Dana Wahab-Tzemach, and Michal Mor. Also, to the dedicated ultrasound technicians engaged in participant instruction and scan interpretation: Sharon Roth, Veronique Liani, and Shira Lieberman. Without their untiring assistance and commitment, this study could not have been performed. The authors thank Enago (www.enago.com) for the article review and editing support.

Authors' Contributions

All authors state that they had a significant part of the article, have taken part in writing the article, reviewing it, and revising its intellectual and technical content. All authors assume responsibility and accountability for the results. E.H. took care of conception and design, data acquisition, analysis and interpretation, drafting and revising, and final approval. L.W. was responsible for conception and design, drafting and revising, and final approval. K.T.-G., M.E., A.S., S.B.-H., R.B., E.S., O.H., S.D., N.A.B.-S., S.S., A.P., I.N., Y.W., and H.Z.-D. were involved in data acquisition, analysis and interpretation, drafting and revising, and final approval. A.W. carried out conception and design, data acquisition, analysis and interpretation, drafting and revising, and final approval.

Disclosure Statement

No competing financial interests exist.

Funding Information

No funding was received.

Supplementary Material

Supplementary Video S1
Supplementary Video S2

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Received: December 5, 2020
Revised: December 24, 2020
Accepted: December 30, 2020
Online Publication Date: March 15, 2021