The effect of home ultrasound on maternal anxiety in patients with previous recurrent pregnancy loss: A randomized control trial

Liat Mor, MD; Eran Weiner, MD; Or Marom, MD; Daniel Tairy, MD; Moran Nardi-Arad, MD; Giulia Barda, MD; Liliya Tamayev, MD; Michal Levy, MD

BACKGROUND: Patients with previous recurrent pregnancy loss are subject to increased maternal anxiety and reduced antenatal attachment during the subsequent pregnancy. Maternal anxiety is associated with worse pregnancy and neonatal outcomes. Home ultrasound is a feasible tool with the potential to alleviate maternal anxiety by ensuring fetal well-being.

OBJECTIVE: This study aimed to investigate the impact of complementing standard prenatal care with twice-weekly telemedicine visits incorporating home ultrasound on maternal anxiety and antenatal attachment in individuals with a history of recurrent pregnancy loss.

STUDY DESIGN: In this randomized controlled trial, patients with a history of 2 or more prior abortions were randomized early in their subsequent pregnancy in a 1:1 ratio into either the control group, which received standard high-risk prenatal care, or the study group, which received additional twice-weekly home-ultrasound sessions. The home-ultrasound scans assessed fetal pulse, movements, and amniotic fluid volume, aiming to provide maternal reassurance. Patients performed the scans themselves using the Pulsenmore device, with real-time guidance from a physician. Maternal anxiety was assessed using the validated State-Trait Anxiety Inventory Scale (STAI-S) and the Revised Prenatal Distress Questionnaire (NuPDQ), while maternal attachment was measured with the validated Maternal Antenatal Attachment Scale (MAAS-2) at 3 time points during pregnancy. The primary outcome was the STAI-S score at the final prenatal visit. A sample size of 50 patients was calculated to detect a 20% difference in the primary outcome.

RESULTS: Of the 57 patients recruited, 50 completed the follow-up, 25 in each group. There were no significant differences in demographics between the groups. The primary outcome (STAI score at the last visit) was significantly lower in the device group compared to the control group (P=.037). In addition, the study group exhibited a greater reduction in STAI scores between the first and last visits (P=.045), and a significantly higher MAAS score at the end of the follow-up period (P=.046).

CONCLUSION: Integrating routine home-ultrasound telemedicine visits into prenatal care can significantly reduce maternal anxiety during pregnancy and contribute to greater maternal attachment in individuals with a history of recurrent pregnancy loss. These results emphasize the potential benefits of home ultrasound as a tool to alleviate anxiety, provide a sense of control, and foster a deeper maternal connection among pregnant individuals who have experienced previous pregnancy loss.

Key words: antenatal attachment, home-ultrasound, maternal anxiety, recurrent pregnancy loss, telemedicine

Introduction

Spontaneous pregnancy loss is a relatively common phenomenon, with 10% to 15% of clinically recognized pregnancies ending in miscarriage.[1] Recurrent pregnancy loss (RPL) is a disorder defined by 2 or more failed pregnancies.[2] According to various studies, pregnancy loss has been described as a traumatic event for couples, even if the loss occurs at a very early stage of pregnancy.[3-5] Few controlled trials dealt with the effects of miscarriages on the psychological status of pregnant individuals during a subsequent pregnancy.[4,6,7] These studies establish proof of considerably increased pregnancy-specific anxiety in pregnant patients with a history of spontaneous abortion compared to those with intact pregnancies. Bergner et al. demonstrated that patients after early miscarriages are deeply affected by pregnancy-specific anxiety during their subsequent pregnancy, mainly before the critical time point during which the previous miscarriage took place.[4]

Mobile and remote ultrasound devices have become increasingly available in recent years. Combining telemedicine systems into routine antenatal care has various hypothetical benefits, including reduced economic burden and increased system efficiency. Importantly, it may be more convenient for patients.[8-10]

In an effort to confirm fetal wellbeing and subsequentially reduce maternal anxiety, we aimed to examine the efficacy of incorporating "at-home ultrasound" alongside routine prenatal care in a subset of patients with a history of RPL. The primary objective was to assess whether this supplementary approach could effectively mitigate maternal anxiety during pregnancy for individuals who have experienced RPL, thus offering them increased reassurance and emotional comfort.

Materials and methods

Study population

The study population comprises pregnant patients recruited between 12 to 16 weeks of gestation. Eligible patients include patients with a history of recurrent (2 or more) pregnancy losses in the first trimester. This study is a registered randomized controlled prospective trial listed on ClinicalTrials.gov, approval number NCT05656846 issued on 15/07/2022, and was authorized by the

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AJOG MFM at a Glance

Why was this study conducted?

Patients with previous recurrent pregnancy loss are subject to increased maternal anxiety and reduced antenatal attachment during the subsequent pregnancy. Maternal anxiety is associated with worse pregnancy and neonatal outcomes. Home ultrasound is a feasible tool with the potential to alleviate maternal anxiety by ensuring fetal well-being.

Key findings?

Home ultrasound is associated with reduced maternal anxiety and increased antenatal attachment compared to routine high-risk care.

What does this add to what is known?

Health care providers should consider integrating home ultrasound into routine high-risk follow-ups for patients with recurrent pregnancy loss due to its anxiety-relieving potential.

institutional ethics committee approval number WOMC-22-0130 (granted on 07/09/2022).

In this randomized controlled trial, eligible patients were recruited during routine visits to the maternal-fetal outpatient clinic. They received a detailed explanation of the study's protocol, objectives, and methodology, including the distinction between the 2 study groups. Willing participants provided informed consent. Each patient was randomly assigned to 1 of the 2 study groups at the initial visit: the home-ultrasound group and the control group using a web-based system based on a permuted block algorithm.

Routine high-risk care for patients with a history of RPL consists of an appointment once every 3 weeks during the first and early second trimesters which includes an appointment with an antenatal nurse, an ultrasound by a technician, and a fetal-maternal specialist visit. Notably, during these weeks, all pregnant patients are referred to routine antenatal tests performed at the community health centers-including nuchal translucency and 2 anatomical scans; therefore, the medical attention is vaster than those scheduled at our clinics. Patients in the home-ultrasound group received routine high-risk prenatal care with additional twice-weekly telemedicine appointments with an obstetrician-gynecologist. Each telemedicine session was approximately 5 minutes long. During the sessions, each patient was questioned about fetal movements, vaginal discharge, and general feeling, and an ultrasound scan assessing for a fetal heartbeat, amniotic fluid volume, fetal tone, and fetal movements was performed with live guidance and instructions from the physician. Any abnormal findings observed during these assessments were thoroughly documented for further evaluation and monitoring. Notably, the patients in this study group could not access the ultrasound mode of the device without medical real-time guidance and assessment. This limitation was chosen to avoid misuse and potential effects on the measured anxiety rates.

Following randomization, all participants completed 3 validated questionnaires:

The first questionnaire is the State-Trait Anxiety Inventory (STAI),[11] which assesses acute anxiety. It comprises 20 statements reflecting different rates of anxiety. Patients rate each statement on a scale- 1 indicating strong disagreement and 4 indicating strong agreement. The total score is calculated by summing all ratings, with positive statements reversely summed. Higher scores indicate greater anxiety.

The second questionnaire, the Maternal Antenatal Attachment Scale (MAAS),[12] assesses maternal attachment to the fetus during pregnancy with higher scores related to increased maternal attachment.

The third questionnaire is the Revised Prenatal Distress Questionnaire,[13] which evaluates the overall pregnancy experience with higher scores indicating worse pregnancy-associated distress.

All 3 questionnaires used in this study were chosen after consulting a clinical psychiatrist with expertise in women's health and were meticulously examined to meet our needs.

All patients completed the same questionnaires again at 2 additional time points: halfway through participation (around 19 weeks) and at the end of the study follow-up (around 24 weeks). During this visit, patients returned the home ultrasound device to a team member.

Device instructions

After completing the questionnaires, patients were provided with instructions on operating the INSTINCT home ultrasound device (Pulsenmore®), including frequency and means of communication with the study team. Patients received a written manual for device operation and signed a contract to return the device at the study's conclusion.

Data collection

The data collection process encompassed several key elements, including demographic characteristics such as age, pregnancy history, delivery history, obstetrical and medical history, and medication usage. Moreover, the outcomes of the completed questionnaires were meticulously documented for further analysis and evaluation.

Primary outcome

The primary outcome was the STAI score at the third time point- end of follow-up, coinciding with the initiation of fetal movements.

Secondary outcomes

The secondary outcomes included were the change (delta) in The State-Trait Anxiety Inventory (STAI) score between recruitment and end of participation around 22 to 24 weeks of gestation as well as the results of the MAAS

and the Revised Prenatal Distress questionnaires.

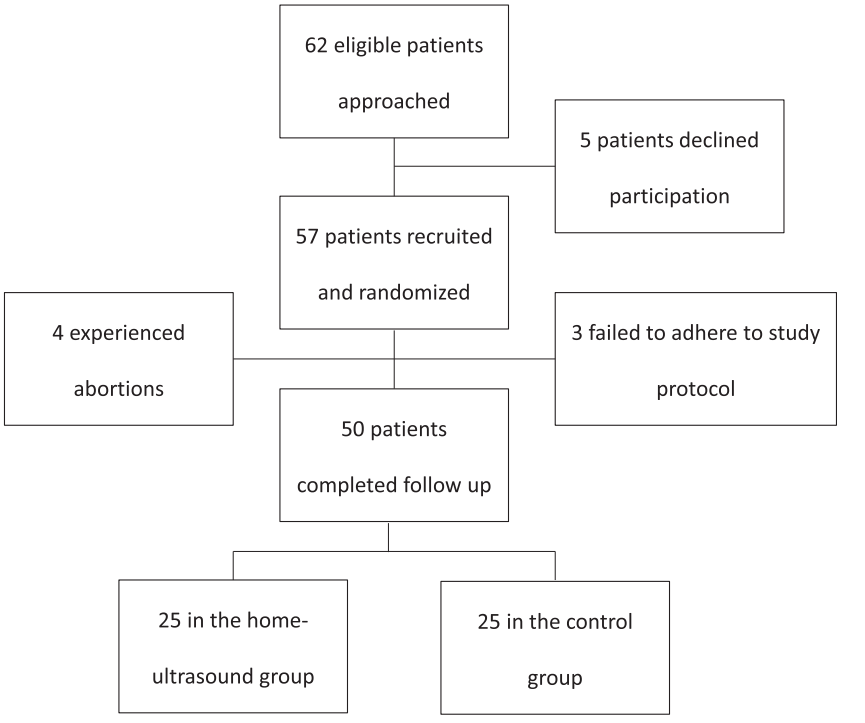
Sample size calculation

To calculate the sample size, we assumed that the STAI score for a patient with recurrent pregnancy losses in the second trimester was 40 units with a standard deviation of 5 units based on prior research.[4] To detect a decrease of 8 units in the STAI score with 80% power and a significance level of 0.05, 50 individuals (25 per group) needed to be recruited. We assumed a 15% loss to follow-up and, therefore, aimed to recruit an overall number of 57 patients.

Statistical analysis

Data were analyzed with SPSS, version 28 (IBM Corp. Released 2021. IBM SPSS Statistics for Windows, Version 28.0. Armonk, NY: IBM Corp). Mean± standard deviation or median (range) of all continuous variables was calculated and compared using the Student's t-test or the nonparametric Mann-Whitney test as appropriate. Categorical variables were calculated as rate (percentage) and compared with Chi-square or Fisher's exact test as appropriate. All tests were 2-tailed, and the threshold for statistical significance was defined as *P*-value <.05.

FIGURE 1
Flow chart describing the study population



Mor. The effect of home ultrasound on maternal anxiety in patients with previous recurrent pregnancy loss: A randomized control trial. Am J Obstet Gynecol MFM 2024.

Results

Based on our power calculation, 62 eligible patients were invited to participate in the study. Five patients declined, while 57 provided their consent and were subsequently recruited and randomized. Among these, 29 were assigned to the device group and 28 to the control group. In both groups, 2 patients per group experienced abortions adjacent to recruitment before completing questionnaires. Furthermore, 2 patients from the control group and one from the device group failed to adhere to the study protocol and were therefore not included in the analysis. Ultimately, 50 patients successfully completed the entire study protocol- 25 in each group (Figure 1).

Maternal demographic characteristics are summarized in Table 1. No statistically significant differences were observed in terms of maternal age, gravidity, parity, number of previous abortions, gestational age at recruitment, use of assisted reproductive technology, or maternal utilization of antidepressant therapy. Moreover, the number of prenatal clinic visits during the study period did not differ.

The questionnaire results are presented in Table 2. At both recruitment and mid-follow-up, there were no significant differences in anxiety levels between the patients receiving additional home ultrasound and the control group, as evidenced by the STAI-S1 and STAI-S2 scores (50 [30-73] vs 48 [20-72], *P*.406 and 34 [22-57] vs 37 [20-72], *P*=.412, respectively). The primary outcome (STAI-S3) was significantly lower in the device group compared to the control group (30 [20-61] vs 40 [22-78], *P*=.037). Furthermore, a significant reduction in anxiety levels from recruitment to the end of follow-up was observed in the home-ultrasound group compared to the control group (−14 [−44−(13)] vs −2 [−32−(26)], *P*=.045). Additionally, the number of patients that experienced decreased anxiety as perceived by this measure was insignificantly greater in the device group compared to the control (88% vs 76%, *P*=.269).

The Revised Prenatal Distress Questionnaire scores did not exhibit significant differences between the 2 groups at all 3 time-points, nor did the change in distress levels between study initiation and conclusion.

While the results of the MAAS questionnaire at the recruitment and mid-follow-up did not show statistically significant differences between the groups, there MAAS-3 score at end of follow-up was significantly higher in the study group compared to the control group (78.5 [46-90] vs 75 [46-87], *P*=.046).

TABLE 1
Maternal demographics and pregnancy characteristics of the study groups

	Home ultrasound (n=25)	Control (n=25)	*P*-value
Maternal age (years)	33.7±8.5	34.2±9.7	.771
Gravidity	5 [2-14]	5 [2-14]	.555
Parity	1 [0-6]	1 [0-4]	.897
Previous abortions	3 [2-11]	2 [2-11]	.071
Gestational age at recruitment	15.13±1.3	15.3±0.9	.872
Assisted reproductive technology	3 (12)	3 (12)	1
Maternal use of antidepressant therapy	4 (16)	5 (20)	1
Number of high-risk clinic appointments during the study period	4.3±1.5	4.1±1.7	.441

Continuous variables are presented as mean±SD or median [range] as required and categorical variables as n (%). *P*-values in bold are statistically significant.

Mor. The effect of home ultrasound on maternal anxiety in patients with previous recurrent pregnancy loss: A randomized control trial. Am J Obstet Gynecol MFM 2024.

Additionally, an insignificant trend in in maternal attachment from the beginning to the end of the follow-up period was evident (Δ MAAS 3-1, *P*=.126). Moreover, more patients from the device group exhibited increased antenatal attachment, yet this trend was also insignificant (80% vs 60%, *P*=.122).

Discussion

Principal findings

In this randomized control trial, we investigated the anxiety-relieving effects of supplementary home ultrasound sessions alongside routine follow-up for patients with recurrent pregnancy loss. This proof-of-concept approach leverages the potential of home ultrasound as an innovative tool to mitigate anxiety in pregnant individuals with a history of recurrent pregnancy loss, offering a novel avenue for improving their overall well-being during this critical phase.

Our main findings were: (1) Patients receiving additional home ultrasound

TABLE 2
Questionnaire results of the study groups

	Home ultrasound (n=25)	Control (n=25)	*P*-value
STAI-1 score	50 [30-73]	48 [20-72]	.406
STAI-2 score	34 [22-57]	37 [20-72]	.412
STAI-3 score	30 [20-61]	40 [22-78]	.037
ΔSTAI 3-1	−14 [−44−(13)]	−2 [−32−(26)]	.045
Number of patients with reduced STAI scores	22 (88)	19 (76)	.269
Revised Prenatal Distress Questionnaire-1 score	19 [7-27]	18 [5-30]	.466
Revised Prenatal Distress Questionnaire-2 score	13.5 [5-26]	16 [6-25]	.561
Revised Prenatal Distress Questionnaire-3 score	11 [5-23]	12.5 [5-25]	.828
Δ Revised Prenatal Distress Questionnaire 3-1	5 [−2−(10)]	5 [−7−(8)]	.718
MAAS- 1	74 [46-85]	74.5 [52-88]	.522
MAAS- 2	76 [53-86]	72.5 [56-90]	.347
MAAS- 3	78.5 [46-90]	75 [46-87]	.046
Δ MAAS 3-1	4 [−7−(15)]	2 [−15−(12)]	.126
Number of patients with increased MAAS scores	20 (80)	15 (60)	.122

Continuous variables are presented as mean±SD and categorical variables as n (%). *P*-values in bold are statistically significant. STAI- The State-Trait Anxiety Inventory questionnaire; MAAS- Maternal antenatal attachment questionnaire. All questionaries designated as questionnaire 1 (STAI/RPDQ/MAAS) were reported between weeks 12 to 16 of gestation, questionnaire 2 was filled between 18 to 20 weeks and questionnaire 3 was filled between 23 to 25 weeks.

Mor. The effect of home ultrasound on maternal anxiety in patients with previous recurrent pregnancy loss: A randomized control trial. Am J Obstet Gynecol MFM 2024.

follow-up demonstrated lower anxiety levels at the 22 to 24 weeks mark compared to patients receiving routine high-risk care. (2) Home ultrasound is associated with a noteworthy decrease in personal anxiety levels during the follow-up period, as demonstrated by the change of STAI levels from the beginning to the end of the follow-up (ΔSTAI). (3) Home ultrasound follow-up was found to be significantly linked with increased maternal attachment to the pregnancy and her fetus at the end of the follow-up period, further underscoring this intervention's emotional and psychological advantages.

Results

Anxiety is prevalent and increased among patients with a history of previous pregnancy loss.[14] Largely, anxiety tends to decrease during the course of pregnancy, with significantly reduced anxiety towards the third trimester, similar to those of individuals with no history of pregnancy loss.[7] Though excepted, the profound reduction portrayed in this study results in individuals receiving home-ultrasound follow-up exceeds the reduction in anxiety seen in patients of routine follow-up, thus emphasizing the anxiety-relieving effect this intervention adds.

Maternal anxiety is associated with worse pregnancy and neonatal outcomes.[15-17] Hence, means of anxiety relief are sought. The reassuring effect of ultrasound in early pregnancy is debated. While few studies established that ultrasound has an anxiety-relieving effect among pregnant individuals,[18-20] a Cochrane review from 2015 concluded that there is insufficient data to prove so.[21] However, this study's results emphasize the anxiety-reducing effect of such follow-up in this cohort of patients, with a greater and more significant decrease in anxiety in the home-ultrasound group compared to the control.

Clinical implications

The utilization of telemedicine technologies has the potential to enhance the antenatal care journey for patients and lead to cost savings in healthcare, all while maintaining positive health outcomes for both the mother and the baby.[10] Home ultrasound, a cutting-edge technology, enables remote ultrasound examinations, including self-operated ultrasound performed by pregnant individuals at home and data transmission to healthcare teams. Hadar et al. conducted an observational study using the same *INSTINCT* ultrasound device developed by Pulsenmore used in this current study and concluded that home-ultrasound was successful in the basic assessment of fetal well-being and may be a feasible and accessible tool for patients and clinicians.[22] However, it should be emphasized that due to the profound anxiety and sensitivity regarding pregnancy outcomes in patients with RPL, the home ultrasound technology should be carefully supported by a medical-team in order to avoid misuse or misinterpretation that might result in increased anxiety.

The use of patient-operated ultrasound devices with specialized remote assistance offers significant advantages, including optimized specialist resource utilization, potentially leading to overall cost savings in healthcare. However, there are notable disadvantages, such as increased dependence on specialist availability, potential for higher specialist workloads, and reliance on robust communication technologies. Balancing these factors through comprehensive patient training, decision support systems, and hybrid supervision models is essential to maximize benefits and minimize drawbacks.

Research implications

Further studies are needed to validate and refine the implementation of home ultrasound in clinical practice. A deeper investigation into the potential cost-effectiveness and accessibility of home ultrasound devices is also warranted to ensure that this intervention can be widely adopted and benefit a more extensive range of patients.

Strengths and limitations

This study is not without limitations. First, all participating patients desired and consented to such follow-up, while unwilling patients did not consent. Hence, this might point to a potential selection bias. Second, though the questionnaires indicate the subjective concept of anxiety and attachment, no other objective parameters were reported (eg, cortisol levels, heart rate). Additionally, labor and neonatal outcomes were not gathered, so the potential impact of the stress relief demonstrated in the device group could not be assessed. We also did not collect specific demographic data such as education level or socioeconomic status, limiting the generalizability of our findings. Lastly, since each patient was under the care of a different doctor, distinguishing the anxiety-relieving effect of the twice-weekly telemedicine meetings from the impact of the personal doctor-patient relationship formed during the study is challenging and may confound the evaluation of the ultrasound intervention itself.

The study possesses notable strengths. Firstly, it represents pioneering research, as it appears to be the inaugural investigation into the impact of at-home ultrasound follow-up on anxiety alleviation within this specific patient cohort. Secondly, the extended duration of at-home ultrasound follow-up provided an extensive window for the comprehensive evaluation of anxiety and attachment dynamics over an extended period. Thirdly, despite the randomization method not factoring in maternal demographic characteristics, it is noteworthy that the participating patients exhibited no statistically significant differences in terms of gravidity, parity, or the use of antidepressants. These variables, known to potentially influence anxiety levels throughout pregnancy, were well-balanced across the study groups, reinforcing the robustness of our findings.

Conclusions

The findings of our study suggest a promising proof of concept for the potential benefits of home ultrasound in alleviating anxiety among pregnant individuals who have experienced previous pregnancy loss. Our results suggest that providing the expectant parents with the ability to monitor their pregnancies at home fosters a deeper emotional connection with their unborn child. This innovative approach holds promise for enhancing the overall well-being of pregnant individuals, emphasizing the importance of

personalized care and support during such a critical period in their lives. Since it is a simple and feasible intervention, healthcare providers may consider integrating home ultrasound into routine high-risk follow-up for this specific subset of patients.

Condensation

Telemedicine-guided home ultrasound significantly reduces anxiety and aids in increasing maternal attachment among pregnant individuals with recurrent pregnancy loss. ■

CRediT authorship contribution statement

Liat Mor: Writing – original draft, Project administration, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Eran Weiner:** Writing – review & editing, Supervision, Resources, Project administration, Methodology, Conceptualization. **Or Marom:** Writing – review & editing, Validation, Investigation, Data curation. **Daniel Tairy:** Writing – review & editing, Validation, Project administration, Data curation. **Moran Nardi-Arad:** Writing – review & editing, Methodology, Formal analysis, Data curation. **Giulia Barda:** Writing – review & editing, Supervision, Methodology, Investigation. **Liliya Tamayev:** Writing – review & editing, Visualization, Validation, Supervision, Data curation. **Michal Levy:** Writing – review & editing, Writing – original draft, Validation, Supervision, Resources, Project administration, Methodology, Investigation, Formal analysis, Conceptualization. ■

Supplementary materials

Supplementary material associated with this article can be found in the online version at doi:10.1016/j.ajogmf.2024.101447.

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Author and article information

From the Department of Obstetrics & Gynecology, The Edith Wolfson Medical Center, Holon, Israel, affiliated with the Faculty of Medicine, Tel Aviv University, Tel Aviv, Israel.

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Corresponding author: Liat Mor, MD. liatmor1@gmail.com