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Original Research

Doula support in office hysteroscopy: results from a pilot study

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Background: This pilot study aimed to evaluate the feasibility of doula support in office hysteroscopy and the potential effectiveness of doula support during office hysteroscopy to reduce anxiety and pain. *Methods*: Twenty-eight women, median age 43.5 (range 21–73), with indications for office hysteroscopy received doula support (intervention) or routine care (control group) during the procedure. Feasibility was measured in terms of successful office hysteroscopies, duration, and adverse events. Outcome measures were Spielberg State-Trait Anxiety Inventory-S (STAI-S), and the Numeric Rate Scale (NRS) for pain intensity. *Results*: The results showed similar success rates, duration, and adverse events between the groups, with no differences in reported pain intensity. Both groups had high, comparable levels of anxiety before the procedure (Doula group mean STAI-S score = 45.4, control group = 45.8). After the procedure, the doula group showed slightly increased anxiety while the control group showed slightly decreased anxiety. There was a significant difference between groups favoring the control group when comparing STAI-S mean score post-procedure (48.6 in the Doula group versus 44.1 in the control group $p = 0.033$). However, when analyzing the mean change across groups ($p = 0.205$) that difference was not significant. *Discussion*: To conclude, this pilot study suggests that Doula support may be feasible but not superior to routine care support in office hysteroscopy. High anxiety levels may be more relevant than pain during the procedure. Further investigation of the state and trait anxiety in office hysteroscopy populations in different health care contexts is recommended.

Keywords

Anxiety; Doula support; Human support; Office hysteroscopy; Pilot study

1. Introduction

Office hysteroscopy is a widely used approach in gynecology [1], however, effective pain management during the procedure is insufficient in about a third of patients [1], with pre-procedural anxiety being significantly higher than in those attending the gynecologist's office for other reasons [2]. Suggested non-pharmacological interventions to alleviate pain and anxiety are the variation of intrauterine pressure, transcutaneous electric nerve stimulation (TENS) [3, 4] and listening to music [5] but the evidence is inconclusive [6]. Indeed, there is a lack of randomized studies exploring additional human support during office hysteroscopy.

The concept of a doula has expanded to encompass a person dedicated to providing physical, emotional, informational, and advocacy support to women during the pre-, peri-, and postnatal periods [7]. Doulas specialize in non-medical skills but do not perform clinical tasks or give medical advice. Recently, doula support has been evaluated in gynecological procedures, such as surgical management of miscarriages and abortion, demonstrating high patient satisfaction but no significant effects on anxiety and pain [8–10]. Hence, it was hypothesized that the presence of a doula supporting the patient during office hysteroscopy would be beneficial. This pilot study aimed to evaluate (a) the feasibility of doula support in office hysteroscopy and (b) the potential effectiveness of doula support during office hysteroscopy to reduce state anxiety and pain.

2. Methods

2.1 Study design and setting

This study was designed as a two-armed prospective pilot study, with an intervention and a control group and was conducted to inform the future design of a prospective, randomized controlled trial [11]. The study was conducted in a gynecological clinic in a community hospital located in southwest Sweden. Patients are referred to the hospital from primary care clinics, maternal health clinics or other hospitals in the region, and may also request care from the clinic by self-referral, which is then evaluated and responded to by the gynecological team.

The study was registered in the Research Database Registry in Västra Götalandsregionen (Sweden) with number: 254161 on 10 November 2018.

2.2 Participants

Patients who attended the clinic between October 2018 to April 2020 were eligible for participation in the study if they were at least 18 years old and had one of the following indications of office hysteroscopy: abnormal pre- or postmenopausal uterine bleeding; endometrial thickening or polyps; submucosal and some intramural fibroids; intrauterine adhesions; uterine malformations; retained intrauterine contraceptives or removal of foreign bodies. The patients also needed to understand written Swedish to apprehend the study information and consent form and respond to the self-rated questionnaires. Exclusion criteria were viable intrauterine pregnancy, active pelvic infection (including genital herpes infection) or known cervical or uterine cancer, and poor ability to understand Swedish.

Eligible patients were informed, verbally, and in print, about the study by their treating gynecologist, before their office hysteroscopy appointment. Each patient was given time to ask questions and consider the invitation to take part at the following visit. Participants who accepted the invitation to participate signed a consent form and were randomized to one of two groups, the doula intervention or routine care.

2.3 Consent and randomisation

Participants who accepted the invitation to participate signed a consent form and were allocated to either the doula intervention or routine care. A simple randomization technique, based on week numbers (even/odd) of enrolment, was used to assign the patients to either of the two groups (Doula/control). Although simple randomization increases the risk of imbalanced groups (both numbers and covariates) [12], it was chosen for pragmatic reasons related to resources and the clinical setting. The randomization and assignment was conducted by a medical secretary who was not involved in the study. To minimize bias based on patient expectations, allocation was not revealed to the patients (before the office hysteroscopy). They were informed about the scheduled time and place and received general information about the gynaecological procedure.

2.4 Office hysteroscopy procedure

The office hysteroscopy procedure and materials used during the procedure were identical in both groups, with the same experienced gynecologist treating all patients. The office hysteroscopy was conducted outside of the operating theater setting in an appropriately sized, equipped, and staffed treatment room with adjoining, private changing facilities and toilets. The standard appointment timeframe was 45 min. In the line with local clinical practice guidelines for office hysteroscopy the women were instructed to take standard doses of NSAIDs (400 mg Ibuprofen) around 1 hour before their scheduled appointment to reducing pain during and after the procedure.

Miniature hysteroscopies (CAMPO TROPHYSCOPE® with Sheath with gliding mechanism for a primary approach to uterine cavity only with 2.9 mm outer diameter and a working channel allows the use of semirigid 5 Fr. operating instruments and bipolar electrodes) were used. All patients received local anesthesia with a paracervical block of 6 mL of mepivacaine 10 mg/mL in the cervix.

In line with routine office hysteroscopy, the choice of distension was normal saline [13] and the pressure of the distension medium was 70 mmHg. With the patient in a dorsal lithotomy position, a vaginoscopy was performed, which is the standard technique. The hysteroscopy was connected to a camera and a monitor. Depending on the findings, the following procedures were performed as required: biopsies, polypectomies, or myomectomies with the same hysteroscope. In case of failed hysteroscopy or other medical reason, for example findings that required surgery, patients were referred to operative hysteroscopy under general anesthesia at the same hospital.

2.5 Doula intervention group

A doula accompanied the participants throughout the procedure, starting from the moment the patient registered at the front desk of the hospital and ending when they left the clinic. In line with documented elements of doula support in the childbirth context [14], the doula in the present study aimed to provide: (a) attention to physical comfort; (b) emotional support (praise, reassurance, encouragement, and continuous presence); (c) information sharing (nonmedical advice, explanation of policies and procedures, anticipatory guidance) and (d) advocacy (facilitation of communication between the woman and hospital staff to assist in making informed decisions). The doula was qualified, had 12 years of experience as a doula, and was employed as an assistant nurse at the clinic. To avoid spill-over effects, she was not attending to patients in the control group.

2.6 Routine care control group

The control group received routine care, which meant that the patients, after registration, were seated in the gynecology clinic waiting room. They received basic support from an assistant nurse during the office hysteroscopy and were provided a comfortable and safe environment with acoustic, thermal, and visual comfort.

Sample size: A total of 28 women were included, 12 in the Doula intervention group and 16 in the routine care group.

The sample size was planned in line with the rule of thumb for pilot studies [15], suggesting 12 subjects in each group. The justification of this rule of thumb was based on a rationale about feasibility, and precision about mean and variance. Descriptive statistics were used to describe the clinical and background variables. For the continuous variables pain (NRS) and anxiety (STAI-S), differences between groups were analyzed using analysis of variance ANOVAs (continuous variables) and Fisher's exact test (categorized data).

Data for the STAI-S did not violate assumptions of normality according to the Shapiro Wilk's test. The dichotomized pain variable (NRS) was analyzed using the chi-square test. A p-value of ≤ 0.05 was set as the limit for statis-

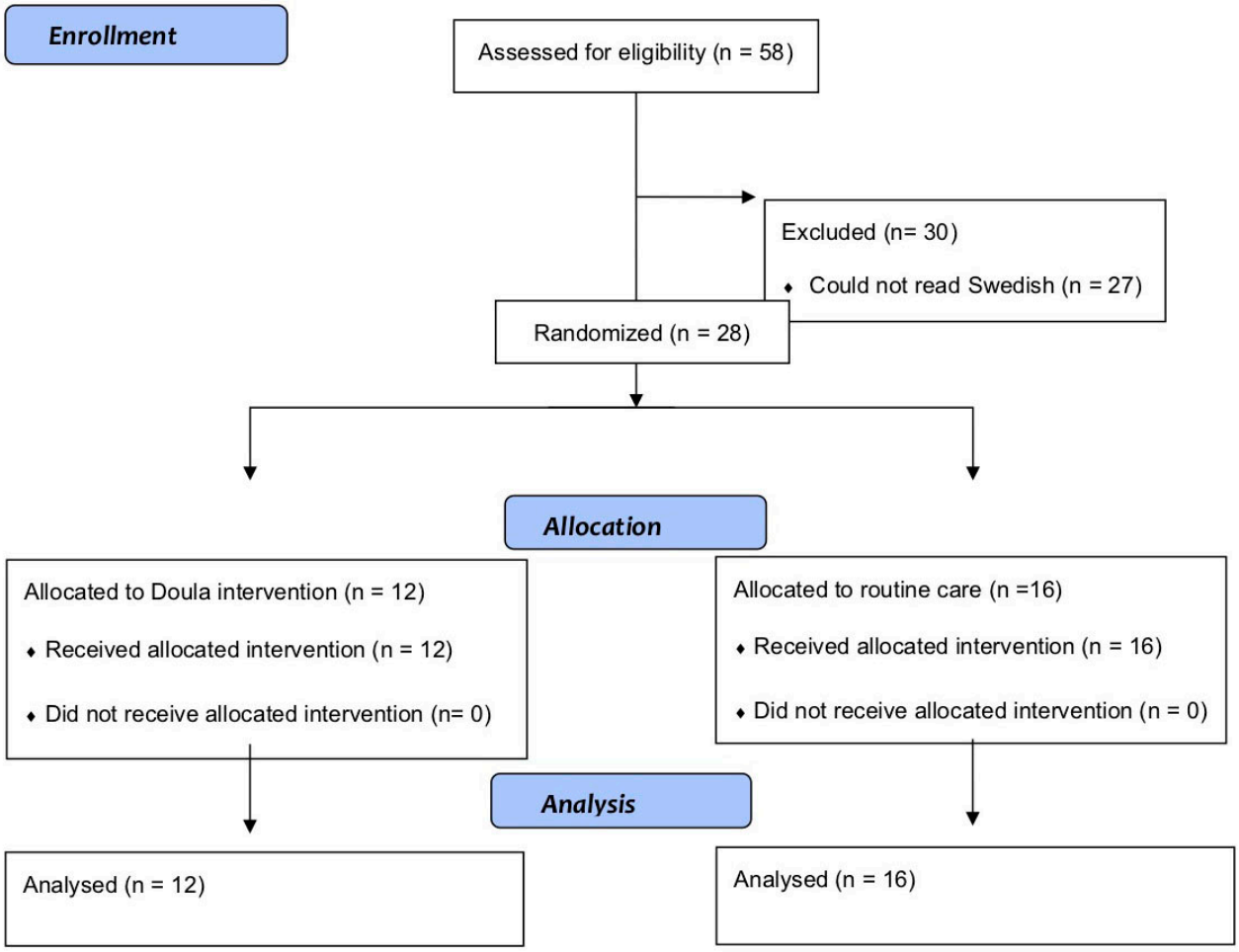

Fig. 1. Study flowchart showing enrolment of participants in the study.

tical significance in all tests. IBM SPSS Statistics version 25.0 (IBM Corp, Armonk, NY, USA) was used for all statistical analyses.

2.7 Outcomes

Background data were collected by the gynecologist or a research assistant at the start of the appointment, including age, body mass index, the number of vaginal deliveries, educational achievement level, and history of endometrial surgery (curettage and/or hysteroscopy), diabetes, age, previous curettage, dyspareunia, severe dysmenorrhea, and previous hysteroscopy experience. Cervical stenosis was classified based on localization: stenosis of external cervical ostium (ECO; type I); stenosis of the distal third of cervical channel and the internal cervical ostium (ICO; type II); stenosis of the ICO (type III), and combined stenosis of ECO and ICO (type IV) [16]. Outcome data were collected at the start of the office hysteroscopy, and separate phases during the procedure.

2.8 Feasibility

Feasibility was evaluated by three outcomes:

(1) Number of successful (access to and visualization of the entire uterine cavity was possible during the same procedure), partially successful (access to uterine cavity possible, but the entire uterine cavity could not be examined) or failed (access to uterine cavity was not possible) hysteroscopies.

(2) Duration of the procedure.

(3) Complications (bleedings, false tracks, uterine perforation or cervical tears, or reactions to mepivacain (numbness and tingling of the lips or tongue, nervousness, dizziness, blurred vision, tremors, drowsiness, convulsions, sweating, unconsciousness or respiratory arrest)).

2.9 Anxiety

The Spielberg State-Trait Anxiety Inventory (STAI) was used to measure the patients' state of anxiety before and after the examination [2, 17, 18]. The STAI is a widely used measure of anxiety, validated among perinatal women, where it has shown acceptable sensitivity, specificity, and predictive values to identify cases of anxiety [19]. The assessment consists of two subscales, the STAI-S which measures the individual's anxiety in the present situation and the STAI-T which measures anxiety as a general trait in the individual. Each subscale has 20 items with each item rated using a 4-point Likert scale and a score >40 as the suggested cutoff for

clinically significant anxiety symptoms [20]. For this study, to minimize the time and number of questions asked to the participants, only the STAI-S was used to measure the situational anxiety pre- and post-procedure.

2.10 Pain

The Numeric Rating Scale (NRS), an instrument for self-reported pain intensity, was used during the procedure. The subject reports a number between 0 and 10, where 10 stands for worst possible pain, 0 indicates no pain. The NRS is similar to the commonly used Visual Analog Scale (VAS) but is less influenced by non-pain intensity factors [21]. Pain intensity was assessed via NRS 0–10 at four points in time during the procedure:

1. Introduction of hysteroscopy into the vagina.
2. Progression through the cervical canal up to the internal uterine orifice.
3. Inspection of the uterine cavity.
4. Performing the endometrial biopsy/polypectomy etc. if required.

Previous well-defined limits for unacceptable pain were used [22]. Pain was considered unacceptable if severe pain was reported during the procedure (NRS $\geq$7). In these cases, the office hysteroscopy was discontinued. The pain variable was also dichotomized, defined as $>$4 = moderate-to-severe pain [23].

3. Results

Twenty-eight women participated in the study with a median age of 43.5 (range 21–73) years. The main reason for the exclusion of potential participants was that they could not understand written Swedish, which was needed for the study information sheet and consent, and the STAI-S measurement. The flow diagram of participants through the study is shown in Fig. 1.

A total of 25 fertile women were included, 1 nullipara, 10 multiparas in the doula group, and 6 nullipara and 8 multiparas in the control group. Also, 3 postmenopausal women were included, 1 in the doula group and 2 in the control group. There were no significant differences between the two groups regarding baseline characteristics (Table 1) and indications for office hysteroscopy (Table 2).

Polyps were identified in 4 cases (33%) in the doula group and 6 (40%) in the control group, there was 1 (8.3%) case of myoma and 2 (16.7%) cases of uterine malformation in the doula group. Also, 3 (25%) cases in the doula group and 5 (33.3%) in the control group had retained Intrauterine Contraceptive Devices (IUCD) and there were 2 (16.7%) normal hysteroscopies in the doula group and 4 (26.7%) in the control group.

3.1 Feasibility outcomes

In two cases (n = 2), one in the doula group and one in the control group, office hysteroscopy was classified as non-successful. In the doula group, one office hysteroscopy could not be performed due to pain at the entrance to the cervix, so a blind endometrial biopsy was performed. In the other case, the polyp recession could be started but had to be stopped due to pain and bleeding. The first case was scheduled for a hysteroscopy under general anesthesia, whereas in the second case, a second office hysteroscopy was performed, and the polyp was completely resected.

In the doula group, three hysteroscopies were classified as partially successful. In these cases, biopsies were performed, and the base of the polyp was sectioned, even though the polyp could not be fully removed. After three months, ultrasound controls were normal and did not require further interventions.

There were no significant differences between the groups regarding cervical stenosis. Cervical stenos type II was found in one woman from each group, and one cervical stenosis type III was found in the control group.

The mean duration of the procedure was 18.6 minutes (range 4–40) in the doula group and 18.9 minutes (range 8–40) in the control group (Table 2), with no significant difference between groups. There were no procedure-related complications (bleedings, false tracks, uterine perforation or cervical tears) in any of the groups, and no participant in any of the two groups reported side-effects of mepivacain.

Table 1. Baseline and clinical characteristics of participants.

	Doula group	Control group	Total	*p*-value[1]
	n = 12	n = 16	n = 28	
Age, mean	47.5 $\pm$ 13.6	40.3 $\pm$ 12.1		0.32
Parity, mean	1.6 $\pm$ 1.3	1.18 $\pm$ 1.1		0.29
Suspected of polyp	7 (46.7%)	8 (53.3%)	15 (100%)	
Abnormal uterine bleeding	1 (100%)	0	1 (100%)	
Remove of IUCD	2 (20%)	8 (80%)	10 (100%)	

[1] Values are from comparisons between groups, analyzed with ANOVA (continuous variables). IUCD, Intrauterine Contraceptive Devices.

3.2 Effectiveness

There were no differences in pain assessments between the groups, see Table 2. For the anxiety outcome STAI-S, both groups had high, comparable levels of state anxiety before the procedure. After the procedure, the doula group showed slightly increased state anxiety, while the control group showed slightly decreased anxiety. There was a significant difference between groups favoring the control group when comparing STAI-S mean score post-procedure, but not when analyzing mean change across groups (Table 2 and Fig. 1). There were no significant differences in post-procedural anxiety and age, duration of the procedure, the reason for office hysteroscopy, or parity.

3.3 Post hoc power analysis

The present pilot study showed a mean pain score of VAS 35 mm during office hysteroscopy, with a mean standard deviation of 18 mm for the whole sample. In line with a previous RCT [24], ewe considered a 10 mm difference in mean pain between the two groups to be clinically relevant. Based on these figures, we conducted a post hoc power analysis

Table 2. Principal outcome measures showing group comparisons.

	Doula group	Control group	*p*-value[1]
Successful office hysteroscopy	11 (92%)	15 (94%)	0.84
Partially successful office hysteroscopy	3 (8%)	0	0.256
Mean duration of procedure, minutes	18.5 (SD 13.7)	18.8 (SD 11.8)	0.38
VAS vaginoscopy, mean	0	0.2 (SD 0.6)	0.21
VAS cervix, mean	0.42 (SD 0.7)	1.3 (SD 1.6)	0.091
VAS uterine cavity, mean	1.7 (SD 1.7)	1.5 (SD 1.9)	0.85
VAS treatment, mean	3.2 (SD 1.4)	3.7 (SD 2.6)	0.671
Dichotomized pain VAS >4, cervix, n	0/12 (0%)	1/16 (6%)	0.57
Dichotomized pain VAS >4, uterine cavity, n	1/11 (9%)	2/12 (17%)	0.67
Dichotomized pain VAS >4, treatment, n	1/5 (20%)	5/12 (42%)	0.56
STAI-S pre-procedure, mean score	45.41 (SD 10.22)	45.81 (SD 6.2)	0.90
STAI-S post-procedure, mean score	48.58 (SD 4.9)	44.1 (SD 5.4)	0.033
Mean change pre to post-procedure STAI-S, mean score	3.3 (SD 11.6)	−1.5 (SD 5.1)	0.205

[1] Values are from performed ANOVAs (continuous variables) and Fisher's exact test (categorized data). NRS, Numeric Rating Scale; STAI-S, Spielberg's State Anxiety Inventory-Situation subscale.

which showed that, to detect a minimal 10 mm difference between the groups, with 80% power on the 0.05 significance level, 51 patients would be required in each group. Assuming 20% dropout [24], we suggest that a future full scale RCT based on this pilot would need 61 patients in each group, resulting in a total required sample of 122 patients.

4. Discussion

This pilot study evaluated the feasibility and potential effectiveness of doula support in office hysteroscopy, suggesting that feasibility was acceptable (success rates, complications, duration of procedure) but the results indicate poor effectiveness of the doula support regarding pain and anxiety. Unexpectedly, all participants presented high levels of state anxiety both before and after the procedure but relatively low pain ratings.

There were two cases, one in the doula group and one in the control group, where the office hysteroscopy was unsuccessful. However, the percentage of successful office hysteroscopies was above 90% in both groups, which is comparable with data from previous studies [15, 25].

Moreover, there were no complications or patient-reported side-effects. The mean duration of the office hysteroscopy was similar in the two groups, around 18 minutes. The recommendation is that office hysteroscopy should not exceed 30 minutes [13].

Both the intervention and control groups showed low and comparable pain ratings overall during the office hysteroscopy, suggesting that the setting and design may have been beneficial to minimize pain perception. State anxiety pre to post-procedure increased slightly in the doula group and decreased very little in the control group (Table 2). This might reflect high levels of anxiety in the study population [26, 27], which we did not measure in our attempt to minimize the questionnaires. High pre- and post-procedural anxiety highlight a vulnerability in the population that is relevant to address. For future investigations of human support in office hysteroscopy, we suggest that trait anxiety should be added as a variable. Qualitative studies might also reveal important aspects.

We did not systematically evaluate patient satisfaction, which is a limitation of this study. However, reports from staff and patient's spontaneous comments after the procedure indicated that some aspects of doula support are positive. The gynecologist and other staff members expressed appreciation for the doula's presence in examination rooms and that doulas created a more patient-centered clinical experience. In agreement with our experiences, a study [9] described that a gynecologist and staff reported that doulas allowed them greater freedom to focus on technical aspects of the procedure without sacrificing patient comfort.

Another study evaluating doula support in surgical management of miscarriage showed that 72% of the study participants reported that it was important to have someone with them during the procedure, but the support person did not have to be a doula [28]. According with these results, the lack of a doula effect in our study could be due to high-quality routine care, including adequate psychosocial support from the normal gynecological team. Also, the small sample used in this pilot warrants caution to any interpretation of effects. An adequately powered RCT based on the pilot data is suggested for future research.

Two potential intervention biases were observed. Undeliberate, the assistant nurses took a more active role with the patients, similar to the doula practice, and their attitudes toward the patient changed. While this observation is bias to the randomized study design, it is our impression that the change of attitude among the staff may be positive in terms of improving patient care. The increased focus on support to facilitate communication and patient engagement is in line with the principles of patient-centered care [29].

There is also a risk of bias with the STAI-S measurement due to the recent COVID-19 pandemic. During March and April 2020, patients reported that they were more nervous

and anxious about coming to the hospital. They also reported difficulties in differentiating between their anxiety related to the procedure, and to their overall distress related to COVID-19, similar to that reported in other studies [30, 31].

5. Conclusions

To conclude, this study explored doula support within the gynecological health care team, suggesting that while there was no indication of the effectiveness of doulas on pain or anxiety during office hysteroscopy, pre- and post-procedural anxiety among the patients may be higher than previously believed. Moreover, high anxiety levels may be more of an issue than the pain during the procedure, therefore, it is recommended that the anxiety state and trait in different hysteroscopy populations and health care contexts are further investigated.

Author contributions

RM, LD and JH designed the trial. RM ran the trial and recruited patients. RM, LD and JH analysed the data. RM, LD and JH and LSW interpreted the data and wrote the paper.

Ethics approval and consent to participate

To minimize the risk of harm to the participants, we used previously defined limits for unacceptable pain during the office hysteroscopy, which was discontinued if pain increased above this limit. Both groups received support, but while the experimental group was supported throughout the visit by a qualified doula, the control condition received basic support from an assistant nurse. All participants were informed that participation in the study was voluntary and declining to or withdrawing from the study would not affect their treatment at the clinic. All individual data was anonymized and coded before analyses. The study was approved by the Regional Ethics Review Board in Gothenburg, registration number 840-18.

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Conflict of interest

The authors declare no conflict of interest.

References

[1] Siristatidis C, Chrelias C. Feasibility of office hysteroscopy through the "see and treat technique" in private practice: a prospective observational study. Archives of Gynecology and Obstetrics. 2011; 283: 819–823.

[2] Gupta JK, Clark TJ, More S, Pattison H. Patient anxiety and experiences associated with an outpatient "one-stop" "see and treat" hysteroscopy clinic. Surgical Endoscopy. 2004; 18: 1099–1104.

[3] Lisón JF, Amer-Cuenca JJ, Piquer-Martí S, Benavent-Caballer V, Biviá-Roig G, Marín-Buck A. Transcutaneous Nerve Stimulation for Pain Relief during Office Hysteroscopy. Obstetrics & Gynecology. 2017; 129: 363–370.

[4] Amer-Cuenca JJ, Marín-Buck A, Vitale SG, La Rosa VL, Caruso S, Cianci A, *et al.* Non-pharmacological pain control in outpatient hysteroscopies. Minimally Invasive Therapy & Allied Technologies. 2019; 29: 10–19.

[5] Angioli R, De Cicco Nardone C, Plotti F, Cafà EV, Dugo N, Damiani P, *et al.* Use of Music to Reduce Anxiety during Office Hysteroscopy: Prospective Randomized Trial. Journal of Minimally Invasive Gynecology. 2014; 21: 454–459.

[6] Mak N, Reinders IMA, Slockers SA, Westen EHMN, Maas JWM, Bongers MY. The effect of music in gynaecological office procedures on pain, anxiety and satisfaction: a randomized controlled trial. Gynecological Surgery. 2017; 14: 14.

[7] Kayne MA, Greulich MB, Albers LL. Doulas: an Alternative yet Complementary Addition to Care during Childbirth. Clinical Obstetrics and Gynecology. 2001; 44: 692–703.

[8] Chor J, Hill B, Martins S, Mistretta S, Patel A, Gilliam M. Doula support during first-trimester surgical abortion: a randomized controlled trial. American Journal of Obstetrics and Gynecology. 2015; 212: 45.e1–45.e6.

[9] Chor J, Lyman P, Ruth J, Patel A, Gilliam M. Integrating Doulas into first-Trimester Abortion Care: Physician, Clinic Staff, and Doula Experiences. Journal of Midwifery & Women'S Health. 2018; 63: 53–57.

[10] Chor J, Lyman P, Tusken M, Patel A, Gilliam M. Women's experiences with doula support during first-trimester surgical abortion: a qualitative study. Contraception. 2016; 93: 244–248.

[11] Leon AC, Davis LL, Kraemer HC. The role and interpretation of pilot studies in clinical research. Journal of Psychiatric Research. 2011; 45: 626–629.

[12] Suresh K. An overview of randomization techniques: an unbiased assessment of outcome in clinical research. Journal of Human Reproductive Sciences. 2011; 4: 8–11.

[13] Campo RF, Santangelo S, Gordts C, Di Cesare H, Van Kerrebroeck MC, De Angelis A, *et al.* Outpatient hysteroscopy. Facts, Views and Vision in Obstetrics and Gynaecology. 2018; 10: 115–122.

[14] Amram NL, Klein MC, Mok H, Simkin P, Lindstrom K, Grant J. How Birth Doulas Help Clients Adapt to Changes in Circumstances, Clinical Care, and Client Preferences during Labor. Journal of Perinatal Education. 2014; 23: 96–103.

[15] Julious SA. Sample size of 12 per group rule of thumb for a pilot study. Pharmaceutical Statistics. 2005; 4: 287–291.

[16] Bettocchi S, Bramante S, Bifulco G, Spinelli M, Ceci O, Fascilla FD, *et al.* Challenging the cervix: strategies to overcome the anatomic impediments to hysteroscopy: analysis of 31,052 office hysteroscopies. Fertility and Sterility. 2016; 105: e16–e17.

[17] Kokanali MK, Cavkaytar S, Guzel Aİ, Topçu HO, Eroğlu E, Aksakal O, *et al.* Impact of preprocedural anxiety levels on pain perception in patients undergoing office hysteroscopy. Journal of the Chinese Medical Association. 2014; 77: 477–481.

[18] Spielberger CD, Gorsuch RL. Palo Alto, CA. Manual for the State-Trait Anxiety Inventory (Form Y). Palo Alto, CA: Consulting Psychologists Press. 1983.

[19] Meades R, Ayers S. Anxiety measures validated in perinatal populations: a systematic review. Journal of Affective Disorders. 2011; 133: 1–15.

[20] Grant K, McMahon C, Austin M. Maternal anxiety during the transition to parenthood: a prospective study. Journal of Affective Disorders. 2008; 108: 101–111.

[21] Thong ISK, Jensen MP, Miró J, Tan G. The validity of pain intensity measures: what do the NRS, VAS, VRS, and FPS-R measure? Scandinavian Journal of Pain. 2018; 18: 99–107.

[22] de Freitas Fonseca M, Sessa FV, Resende JAD, Guerra CGS, Andrade CM, Crispi CP. Identifying Predictors of Unacceptable Pain at Office Hysteroscopy. Journal of Minimally Invasive Gynecology. 2014; 21: 586–591.

[23] Gerbershagen HJ, Rothaug J, Kalkman CJ, Meissner W. Determination of moderate-to-severe postoperative pain on the numeric rating scale: a cut-off point analysis applying four different methods. British Journal of Anaesthesia. 2011; 107: 619–626.
[24] Fouda UM, Gad Allah SH, Elshaer HS. Optimal timing of misoprostol administration in nulliparous women undergoing office hysteroscopy: a randomized double-blind placebo-controlled study. Fertility and Sterility. 2016; 106: 196–201.
[25] Bradley LD, Widrich T. State-of-the-art flexible hysteroscopy for office gynecologic evaluation. Journal of the American Association of Gynecologic Laparoscopists. 1995; 2: 263–267.
[26] Cicinelli E. Hysteroscopy without Anesthesia: Review of Recent Literature. Journal of Minimally Invasive Gynecology. 2010; 17: 703–708.
[27] Cicinelli E, Rossi AC, Marinaccio M, Matteo M, Saliani N, Tinelli R. Predictive factors for pain experienced at office fluid minihysteroscopy. Journal of Minimally Invasive Gynecology. 2007; 14: 485–488.
[28] Wilson SF, Gurney EP, Sammel MD, Schreiber CA. Doulas for surgical management of miscarriage and abortion: a randomized controlled trial. American Journal of Obstetrics and Gynecology. 2017; 216: 44.e1–44.e6.
[29] Gagliardi AR, Green C, Dunn S, Grace SL, Khanlou N, Stewart DE. How do and could clinical guidelines support patient-centred care for women: Content analysis of guidelines. PLoS ONE. 2019; 14: e0224507.
[30] Rajkumar RP. COVID-19 and mental health: a review of the existing literature. Asian Journal of Psychiatry. 2020; 52: 102066.
[31] Röhr S, Müller F, Jung F, Apfelbacher C, Seidler A, Riedel-Heller SG. Psychosocial Impact of Quarantine Measures During Serious Coronavirus Outbreaks: A Rapid Review. Psychiatrische Praxis. 2020; 47: 179–189.