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Randomized Controlled Trial of Interventions Used by Midwives to Treat Fear of Childbirth

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The protocol of this trial was approved by the ethics and research committee of Dr. Negrín University Hospital of Gran Canaria with CEIm code 2021-169-1 on April 4, 2021. Two amendments submitted later, on June 26, 2021, and July 30, 2021, also obtained a favorable opinion. At the same time, approval was obtained from those responsible for the center where the recruitment and intervention took place.

Clinical Trial Registration: ClinicalTrials.gov, NCT05000203, https://www.clinicaltrials.gov/search?term=NCT05000203

The authors have no conflicts of interest to report.

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Abstract

***Background*:** Fear of childbirth affects women worldwide and can have adverse consequences. Midwives have implemented a number of interventions, autonomously or as part of a professional team. However, midwives have been unable to identify the most appropriate intervention for ensuring the reduction or alleviation of this fear to provide the best perinatal outcomes.

***Objective*:** This study aimed to evaluate the effectiveness of a prenatal educational intervention followed by specific support during childbirth, designed and delivered exclusively by midwives for women with a high fear of childbirth.

***Method*:** This randomized controlled trial was performed with two arms in two phases: an online prenatal education phase followed by a support phase during childbirth. Participating women with a high fear of childbirth, which was determined using the Wijma Delivery Expectancy Questionnaire–A–Spanish version, were assigned to the experimental group or the usual care control group at a 1:1 ratio.

***Results*:** Women showed a reduction in fear of childbirth in both phases of the study. According to the intention to treat analysis, a significant mean difference was observed in the prenatal stage in favor of the intervention group, as well as a nonsignificant difference in favor of this same group after delivery.

***Discussion*:** The effectiveness of continuous specific prenatal education with preferential support during childbirth by midwives was indicated by improvements in the level of fear of childbirth.

Keywords: childbirth, counseling, fear, midwifery, prenatal education

Randomized Controlled Trial of Interventions Used by Midwives to Treat Fear of Childbirth

In recent years, public awareness of maternal mental health has considerably increased, which has led to a growing interest in the study of fear of childbirth (FOC), and investigations have attempted to elucidate the most appropriate interventions for its prevention and treatment (Dai et al., 2020). Regarding FOC, there is no single definition (Martin et al., 2021; O'Connell, Richens et al., 2018; Souto et al., 2023) in part due to heterogeneity in the methods used to study the phenomenon and also because sometimes researchers include differently related, but not always comparable, concepts such as fear, anxiety, preoccupation, and tokophobia (Souto et al., 2023). Fear—a value-laden term—is interpreted in a psychobiological dimension and perceived as predominantly negative. Although in certain cases, fear can be considered a normal emotion in pregnancy (O'Connell, Khashan et al., 2021), FOC is a nonoptimal individual condition related to the circumstances of a woman's life, evidenced by the inability to create positive meaning from childbirth and the ability to give birth, which can lead to negative or favorable effects, depending on whether the coping strategies have been part of a fearful woman's pregnancy (Souto et al., 2023). Although many variables and circumstances influence its etiology, to a large extent, FOC arises from a lack of information and self-confidence in a person's abilities, as well as from the stories told or the experiences lived by women themselves and the limited perceived social support (Dencker et al., 2019).

FOC can negatively influence pregnancy, childbirth, or post-childbirth and consequently cause pertinent mental problems, including anxiety, depression, or post-traumatic stress disorder

(Dencker et al., 2019; Hildingsson & Rubertsson, 2022). Cesarean section has been considered a method of childbirth to reduce FOC (Jenabi et al., 2020; Wigert et al., 2020), as has increased use of epidural analgesia (Smorti et al., 2020), which may indirectly exert its influence by inhibiting the onset and progression of childbirth (Klabbers et al., 2016) negatively affect the bond between a mother and her baby (Vismara et al., 2021).

Women who experience high FOC need special care and support from specially qualified health professionals who can intervene to prevent or reduce FOC-associated adverse events. Midwives are considered the most appropriate professionals to accomplish this (O'Connell et al., 2020; do Souto et al., 2022) as they can offer continuous, compassionate, and respectful care to women (Larsson et al., 2020; O'Connell et al., 2020) and focus on mothers' innate ability to give birth (Wigert et al., 2020). Furthermore, midwives can empower expectant mothers to take an active role in childbirth, allowing them to better manage their fear (O'Connell et al., 2020). Women want a positive childbirth experience in a safe environment with continuity of care and support from competent professionals who enhance their sense of personal empowerment and control through shared decision-making, even when medical intervention is necessary (O'Connell et al., 2020).

Evidence about FOC interventions is inconclusive (O'Connell, Khashan et al., 2021; Webb et al., 2021). Although some interventions can reduce FOC compared with treatments involving usual care, the reduction achieved may not be clinically significant (O'Connell, Khashan et al., 2021).

Educational programs and continuous prenatal and childbirth counseling administered by midwives are among the most notable interventions (Bakhteh et al., 2024; Swift et al., 2021). Midwives may perform these interventions autonomously or as part of a multidisciplinary team. Although the effectiveness of prenatal education in reducing FOC has been explored in the past (do Souto et al., 2022), the current research aims to evaluate the reduction of FOC in pregnant women in general. Further, most trials for FOC have been focused on a specific period of time, generally the prenatal period (Fenwick et al., 2015; Firouzan et al., 2020; Haapio et al., 2017; Kaya & Guler, 2022; Toohill et al., 2014). Therefore, research on the progression of FOC in pregnant women and the effectiveness of FOC interventions over time is lacking.

The main hypothesis of the study was that a specific prenatal education intervention aimed at reducing FOC added to another intervention that implements usual care by expanded midwives during childbirth would significantly reduce fear levels in women with high FOC to a greater extent than usual care. The main objective of this study was to evaluate the effectiveness of an intervention of prenatal education designed exclusively for women with high FOC followed by specific support provided by a midwife during childbirth, spanning the prenatal to postnatal periods. A second hypothesis was that the intervention would improve women's childbirth experiences and obstetric-neonatal outcomes. Thus, a secondary objective was to compare the effectiveness of specific support for FOC and usual care regarding maternal satisfaction with childbirth and improved obstetric–neonatal outcomes.

Methods

Design

A two-arm, randomized controlled trial was performed in two phases: prenatal and during childbirth. The study design was prepared according to the recommendations of the Consolidated Standards of Reporting Trials and registered in the ClinicalTrial.gov database (Registration No.: NCT05000203).

The ethics and research committee of the Dr. Negrín University Hospital of Gran Canaria approved the study. All participating women received written information about the study's aim and the nature of their participation.

Participants

Participating women were selected from the Maternal and Child Hospital of Gran Canaria prenatal diagnosis unit; a third-level referral hospital for childbirth care in the province of Las Palmas (Canary Islands, Spain). At this hospital, 3,173 vaginal births and 348 cesarean sections were conducted in 2022 and the birthing unit comprised 10 childbirth rooms for noninterventional or high-level intervention care. Further, a team of 10 midwives works during each shift, organized according to the "one-to-one" model in childbirth care.

Convenience sampling was used in the prenatal diagnosis unit among women who underwent the protocolized obstetric morphological ultrasound between weeks 20 and 24 of pregnancy. Potential participants were included in the recruitment process if they met the following criteria: >18 years, gestational age of 20–24 weeks, and normal morphological

ultrasound. The exclusion criteria were inability to complete the online questionnaire and/or presence of a language barrier.

The inclusion criterion for women to participate in the trial included the presence of high FOC at the time of recruitment, which was determined with the score obtained through the Wijma Delivery Expectancy Questionnaire–A–Spanish version (WDEQ–A–Sp; Ortega-Cejas et al., 2021). Taking the variability in cut-off points for the different levels of FOC in the studies reviewed into consideration (Richens et al., 2018) and the fact that no study had used the Spanish version of this tool to date, we decided to define the cut-off points based on a pilot sample with the first 100 women who completed the WDEQ–A–Sp questionnaire. We grouped them into three subgroups according to their scores: high FOC (scores in the fourth quartile; ≥ 77 points), moderate FOC (scores in the second and third quartile; 76–41 points), and low FOC (scores in the first quartile; ≤ 42 points).

Intervention

Midwives are the health care professionals who monitor and supervise pregnancy, childbirth, and the postpartum period, i.e., the setting in which this study was performed. The usual prenatal care consisted of successive and individual consultations with a midwife in primary health care centers; this is combined with face-to-face group education on more general aspects. Further, care includes follow-up medical care according to established protocol visits but does not include routine screening for detecting and managing FOC. Women who come to the maternity unit at the Maternal and Child Hospital of Gran Canaria predominantly receive care from midwives together with the medical team throughout the process, depending on

circumstances and various individual factors. Regardless of their assigned group, all women who participated in this trial received usual care from the medical and midwifery teams.

Specific Prenatal Intervention

Women in the intervention group received online group antenatal education sessions via videoconferencing specifically designed to address FOC and oriented on the theory of self-care deficit. Self-care agency, a multidimensional concept in Orem's self-care deficit nursing theory, includes motivation, decision-making, energy, and knowledge necessary to perform self-care actions; basic conditioning factors affect individuals' development and exercise of self-care agency (Hart & Foster, 1998). Videoconferencing education enabled health care professionals and participating women to interact via mobile and/or computer devices. The professional responsible for conducting the sessions was the lead researcher: a midwife trained to deliver and implement health education programs according to the specific needs of women with FOC.

Five sessions were conducted in groups of seven to 10 women, organized according to a predetermined schedule (see Supplementary Digital Content [http://links.lww.com/NRES/A522], Table 1). The sessions started after approximately 30 weeks of gestational age, at a rate of one session per week, without interfering with usual prenatal care. The specific sessions were organized as follows:

1. First session, called *Becoming Conscious*, was centered on understanding fear as a basic emotion shared by everyone. The women were able to recognize their own fears and the associated factors.
2. The second session, *Plannin'*, was designed to create a childbirth plan as an instrument

for communicating with professionals. This session focused on answering the women's questions related to the hospital's operation and the birthing unit staff's vision regarding management of factors that usually lead to greater uncertainty and fear in women.

3. Third session, *Childbirth*, the women were introduced to the most physiological view of childbirth, explaining the influence of emotions and hormones in its onset and development, with special emphasis on the woman's innate ability to cope.
4. Fourth session, *Accompaniment*, aimed to explain the midwife's skills and availability as the reference professional trained to accompany a woman during childbirth. Furthermore, the importance and functions of the trusted person chosen by a woman to accompany her during the perinatal process were discussed.
5. Fifth session, *Different Childbirth*, focused on the process of birthing prodromes, on the procedures that are individually performed within the birthing unit—according to each woman's personal factors, as well as the meaning and management of pain.

Each session was divided into four parts, with a total mean duration of 90 min:

1. Contact was established to promote group reflection, and facilitation questions associated with each session's main topic were posed.
2. The most relevant aspects were discussed, according to the reported experiences of women with FOC in previous births (O'Connell et al., 2020).
3. Videos featuring the midwives who were going to collaborate in the birth phase of the trial were viewed. The purpose of the videos was to offer a virtual tour of the environment where the childbirth would take place, apart from introducing the midwives who would be involved in the mother's care, who then explained the procedures and pain management options available.

4. Several brief therapy tasks were proposed based on the ideas proposed by Beyebach and Vega (2016). Per session, performing 1–3 was recommended; this was done to allow patients to express and become aware of FOC and acquire distraction strategies to cope with the pain of childbirth. The women performed this part independently and voluntarily at home, without monitoring by the principal investigator. At the end of each session, time was allocated for discussion and questions.

The women were in constant contact with the principal investigator via instant messaging, which they used to get answers to their questions between sessions. Failure to attend any of the scheduled sessions resulted in withdrawal from the study. Women in the intervention group were encouraged to attend usual follow-up appointments with their midwives and obstetricians and take advantage of group antenatal classes usually offered at their primary care center.

Specific Intervention During Childbirth

The women in the intervention group who had completed the prenatal phase were included during the birth phase, where the specific approach was implemented when they attended the delivery unit of the Maternal and Child Hospital of Gran Canaria for their childbirth. In this phase, through continuity in care and the promotion of the exercise of self-care agency, a group of midwives who were experts and motivated to support pregnant women with FOC was organized. Their attitudes and experiences in supporting women with FOC were assessed using a questionnaire designed based on previous studies (de Vries et al., 2020). Three midwives were selected for each of the five working groups in an attempt to ensure that these midwives would accompany the women in the childbirth room.

The intervention was initiated when a woman in the experimental group was identified on admission. From that moment, the midwife from the expert group acted as the reference and responsible midwife for the pregnant woman and offered her support together with the rest of the maternity unit staff. The midwife also informed the rest of the team that the pregnant woman experienced high FOC. The support provided by the midwife was recorded on an online form after the support.

Outcome Measures

The primary outcome variables considered were the intra- and inter-group changes in FOC. FOC was measured before and after the prenatal phase and after childbirth to achieve this. The tool used for the prenatal measurement of FOC was WDEQ–A–Sp—an instrument comprising 31 items with response options based on a Likert scale, where 0 and 5 indicated "extremely" and "not at all." The total score ranged from 0 to 155 (higher scores corresponded to greater fear). An overall Cronbach's alpha coefficient of 0.91 and an omega coefficient of 0.93 were reported for this instrument. After childbirth, the FOC was evaluated using the Wijma Delivery Experience Questionnaire–B–Spanish version (WDEQ–B–Sp; Roldán-Merino et al., 2021) composed—in this case—of 33 items whose total score ranged between 0 and 165 points. Similar to the prenatal version, it had a high internal consistency, with a Cronbach's alpha and an omega coefficient for the entire questionnaire of 0.93.

Maternal satisfaction was measured as a secondary outcome variable using the Childbirth Experience Questionnaire Spanish version (CEQ–E; Soriano-Vidal et al., 2016). This instrument consisted of 22 items organized in four dimensions (personal capacity, professional support,

perceived security, and participation), which were scored on a 4-point Likert scale, with higher scores identifying the most satisfied women. The instrument provides a global score or a score by dimensions. The internal consistency measured by Cronbach's alpha was 0.88 for the global score (Soriano-Vidal et al., 2016). Other secondary outcome variables that were taken into consideration included the type of beginning (spontaneous and induced) and completion of childbirth (eutocic/dystocic and vaginal/cesarean section), the use of oxytocin to provoke contractions during childbirth (yes/no), the use of epidural analgesia during childbirth (yes/no) and the total duration of childbirth from the time the woman entered the childbirth room (measured in hours).

Sample Size

The required sample size was estimated for the main outcome variable, with the measurement of FOC in the same sample at two different times. A standardized mean difference of −0.46 was obtained in favor of maternal education/psychoeducation based on the result reported by Hosseini et al. (2018) regarding the effectiveness of the intervention group in reducing FOC compared with the control group. Applying the simplified formula (García-García et al., 2013) for calculating a sample size that compared two means—accepting a bilateral error of 5% and a power of 80%—we obtained n = 16 / (difference of means) 2 =16 / 0.2116 = 76 participants. Assuming a loss of 20% participants and using the pertinent formula—n (number of participants without losses) × (1/1 − R) = 76 × (1/1 − 0.20) = 95 participants for each group—a total number of participating women was estimated at 190, considering the two-arm design.

Randomization

A simple random assignment was performed to one of the two arms (Group A–Experimental Group and Group B–Control Group) with a 1:1 allocation ratio using a random number table generated with the website "RANDOM.ORG-Integer Generator." Reading the table from left to right, a number was assigned to each woman in order of inclusion in the trial, at least until the sample size was completed in both groups. Women who randomly received an even number were included in the intervention group, and women who received an odd number were included in the control group.

Women were informed regarding their allocation to the pertinent groups. Owing to the nature of the study, blinding the women participating in the prenatal phase was not possible. During childbirth, the caregivers were blinded to the control group of women, and the results were analyzed in a blinded manner by an external statistician who was unaware of the group allocation.

Data Collection

Data from women participants were obtained as follows:

- *Baseline measurement*: Performed between 20 and 24 weeks of gestational age, and baseline FOC was evaluated using the WDEQ–A–Sp questionnaire score, in addition to collecting baseline sociodemographic and obstetric variables.
- *Post-intervention prenatal measure*: FOC was reevaluated using the WDEQ–A–Sp questionnaire score after completing five online education sessions in the prenatal phase of the intervention group and approximately 36 weeks of gestational age in the control

group.

- *Post-intervention post-natal measure*: Final measurement was performed in the first 10 days after childbirth, evaluating the FOC experience through the WDEQ–B–Sp questionnaire score and maternal satisfaction with childbirth through the CEQ–E questionnaire score.

Data related to obstetric outcomes of childbirth were collected from the electronic medical records of participating women.

Analysis

Analysis of the results was performed using the following two strategies:

- An intention-to-treat analysis was performed to approximate the reality of daily clinical practice, where all women participating in the experimental group (Group A) who completed the trial were included, regardless of whether they received the specific intervention during childbirth or not, and the women participating in the control group (Group B).
- A per-protocol analysis was performed, and the following three groups were formed: women participating in the experimental group who received prenatal intervention and intervention during childbirth (Group A), women participating in the control group (Group B), and women participating in the experimental group who received prenatal intervention but not intervention during childbirth (Group C).

The Jamovi® statistical program (Version 2.3.21.0; https://www.jamovi.org/) was used for data analysis. Statistical significance was indicated by $p < .05$. Categorical variables were

described using frequency and percentage distributions, and inter-group comparisons were performed via Pearson's chi-square test.

The quantitative variables were described via means and standard deviations, and the inter-group comparisons of mean values were performed using the student's t-test, with a 95% confidence interval.

The intention-to-treat and per-protocol analyses of the primary outcome measure were obtained through repeated measures analysis of variance (ANOVA) after normalizing the scores of both versions of the WDEQ–Sp questionnaire from 0 to 100 points; a post hoc contrast (Tukey's test) was performed to verify the groups that showed the differences.

The secondary outcome measures was analyzed using the Mann–Whitney U test in case of intention-to-treat analysis and using one-way ANOVA in case of per-protocol analysis. Contingency tables were created for the qualitative variables, and the Pearson chi-square test was applied. Homogeneity of variances was tested using the Levene test, and the homogeneity of the sample distribution was tested using the Shapiro–Wilk test.

Ethics Statement

The protocol of this trial was approved by the ethics and research committee of Dr. Negrín University Hospital of Gran Canaria (code: 2021–169–1) and revised with two amendments. At the same time, approval was obtained from those responsible for the center where the recruitment and intervention took place. The research team's main interest was to

respond to the proposed objectives: protecting the safety and privacy of the participating women minimizing possible risks. An information document explaining the study's objectives was given to the participants, and written informed consent was obtained from all.

Results

Between August 2021 and June 2022, 214 women were included in the trial. The final sample comprised 24 more women than initially calculated. These women participants were randomized into the experimental (n = 117) and control (n = 97) groups. Figure 1 shows the study flowchart for recruitment, exclusion, randomized included, randomized, lost to follow-up and their causes, and total sample analyzed at each stage. Follow-up was completed in December 2022.

At baseline, participants were 21.3 weeks gestation at the start of the intervention and 36.1 weeks of gestation by the post-intervention prenatal measurement; the post-intervention postnatal measurement occurred on average in the first 5 days after birth. The baseline characteristics of each group are shown in Table 1.

Results Regarding FOC

Descriptive data on the FOC measure were obtained using the WDEQ–A–Sp and WDEQ–B–Sp questionnaires before and after standardization of scores for each of the analyses (see SDC Tables 2 and 3). Post hoc comparisons of the intention-to-treat and per-protocol analyses are shown in Table 2. These comparisons reflect the results of intra-individual and inter-group mean differences in both study phases. The results of both analyses are presented graphically in Figure 2.

Results Regarding Maternal Satisfaction

Descriptive data were obtained for the intention-to-treat and per-protocol analyses to measure maternal satisfaction using the CEQ–E questionnaire (see SDC Tables 4 and 5). In the intention-to-treat analysis, a significant mean difference of 4 points were obtained in favor of the experimental group (p = .044) for the total questionnaire score. In terms of dimension, the safety dimension demonstrated a significant difference of 0.33 points (p = .009). Differences were obtained in favor of the experimental group in the capacity, professional and participation dimensions with 0.13 (p = .090), 0.053 (p = .204), and 0.13 (p = .090), respectively. The results of the per-protocol analysis on this outcome measure between the three groups are shown in Table 3.

Obstetric Results

Obstetric outcomes were described (see SDC Tables 6 and 7) and were analyzed using intention-to-treat and per-protocol analysis.

The analysis between study groups for the start of childbirth shows that there was a significant association between the group to which the women belonged and the type of start of childbirth. The results of the χ^2 test were 6.56 (OR = 0.38; 95 % CI 0.18, 0.80, p =.010) and 11.1 (p = .004) in the intention-to-treat and per-protocol analysis, respectively.

Regarding the type of childbirth completion, the per-protocol analysis revealed a significant association between the group to which the women belonged and the type of childbirth completion; the result of the χ^2 analysis was 17.2 (p = .028) in the per-protocol

analysis. However, this association could not be affirmed in the intention-to-treat analysis. with a χ^2 result of 3.97 (p = .411).

A significant correlation was observed between group membership and use of epidural analgesia when comparing both groups in terms of epidural analgesia use. In the intention-to-treat analysis result $\chi 2$ of 6.63 (OR = 3.50; 95 % CI 1.30, 9.42, p = .010) and the analysis per-protocol of 14.8 (p < .001). Regarding the use of oxytocin during childbirth, a χ^2 of 11.0 (p = .004) was obtained in the per-protocol analysis; however, in the intention-to-treat analysis obtained χ^2 of 2.33 (OR = 1.78; 95 % CI 0.84, 3.73, p = .127).

Finally, regarding duration of childbirth, the difference in means was −3.09 hr in favor of Group A (p <.001) for the intention-to-treat analysis. Mean differences were identified between Groups A and B of −2.55 hr (p = .039) in the per-protocol analysis, 5.24 hr (p = .025) between Groups A and C, and 7.79 hr (p < .001) between Groups B and C.

Discussion

This trial evaluated the effect of a specific intervention to reduce FOC during pregnancy through online group education sessions and ongoing support and care during childbirth. The results support the main hypothesis, indicating that prenatal online group education carried out by midwives is effective in reducing FOC in pregnant women with a high level of fear. However, the secondary hypothesis cannot be accepted; the intervention during childbirth consisting of continuous support by a midwife was not more effective in improving women's childbirth experience or obstetric and neonatal outcomes than usual care. To the best of our knowledge, this

is the first midwife-led trial to reduce FOC using a comprehensive intervention—both prenatally and during childbirth—and monitoring the change in FOC at three different points in time. Further, it is also the first clinical trial to evaluate an intervention to reduce FOC in Spanish-speaking women, as this topic has been scarcely studied in Spain (Dai et al., 2020).

Interventions for FOC demonstrate high variability in terms of not the strategies used to reduce FOC, as well as the professionals responsible for performing these interventions (do Souto et al., 2022; O'Connell, Khashan et al., 2021; Webb et al., 2021). Therefore, comparisons between studies must be interpreted with caution owing to the presence of notable differences in the characteristics of the samples, health systems, and reported professional practices. Thus, although there are numerous studies of interventions to address FOC, we focus this discussion on the results of those that assess the work of midwives (Henriksen et al., 2020; Larsson et al., 2016) who have worked in the field of FOC for years through different types of counseling, promoting normal childbirth, strengthening women's confidence in themselves and their ability to give birth, and providing skills to help women make informed decisions in terms of their pregnancies and childbirth.

Most trials for FOC that included prenatal education interventions like ours have demonstrated effectiveness. However, not all results were significant. Intranatal interventions have been studied less and have shown contradictory results regarding their effectiveness in reducing FOC. Regarding the combination of both interventions in the same study, we have not found trials comparable to ours.

The studies that have reported favorable results change in FOC scores and are comparable to our methods generally combine mixed educational/psycho–educational and continuity of care approaches. Do Souto et al. (2022), in a recent scoping review on interventions performed by midwives to reduce FOC, indicated that midwives played facilitating roles in implementing various strategies, with counseling and psycho–education being the most common interventions in which they were involved. In general, studies report that these interventions enable women to identify and express their fears, thereby increasing their ability to cope with the childbirth process (do Souto et al., 2022).

However, Webb et al. (2021) reported that interventions with an educational component were not the most effective, especially when elective cesarean section rates were used to indicate effectiveness. This trial does not allow us to answer this question since its design did not allow us to identify women who opted for an elective cesarean section due to high FOC. This can be considered a limitation of this study; however, it must be taken into account that in the environment in which it was carried out—the Spanish public health system—women do not generally have the option to have an elective cesarean section; if they want this option, they have to seek private health care.

Among the trials that used midwifery-led educational/psycho–educational techniques and whose results showed a significant intra- or inter-group reduction in FOC scores, those based on the educational program “Birth Emotions and Looking to Improve Expectant Intervention stand out Fear (BELIEF)” was strongest (Fenwick et al., 2015; Firouzan et al., 2020; Toohill et al., 2014). In this program, in contrast to our online group sessions, midwives listen and respond to

women's feelings about childbirth, provide information about the pros and cons of vaginal and cesarean births, and teach women strategies for coping with the elements of childbirth that they identify as distressing, including contact with the midwife. The possibility of contacting a midwife at any time, as was also offered in the prenatal phase, may have been a key factor in the effectiveness of the intervention provided, as many of women participants made use of this service and resolved their concerns between the sessions and in the days leading up to the birth.

The solution-focused therapy offered by Kaya and Guler (2022) with individual videoconferencing sessions on coping with fears of childbirth in women with severe FOC appears to support the usefulness of combining educational and psychological techniques. In the present study, an attempt was made to implement this aspect by means of facilitation questions to make them aware of their emotions and the short therapy tasks. Indeed, Swift et al. (2021) supported the effectiveness of combining individual and group face-to-face education with improved antenatal care, which was similar to the care provided in our setting.

Considering the results obtained in the different interventions for women with high FOC, a combination of usual face-to-face individual and group care—complemented with specific online educational reinforcement taught by the same midwife—appeared to ensure a desirable reduction in FOC in this group of women. Similar techniques have effectively alleviated fears of childbirth, including providing information brochures or visiting the birth unit, which gives a greater sense of security among women (Haapio et al., 2017). In our case, although the visit was "virtual," we believe it had a very similar effect to an in-person visit.

The results obtained in the intrapartum phase demonstrated that the women in the control group—who maintained a higher level of fear in the prenatal phase—managed to reduce their fear after childbirth to a level similar to that of the women in the intervention group. We interpreted this to mean that the support provided by the midwives during childbirth was effective in reducing FOC in both groups. Notably, the intervention group achieved a lower level after childbirth; however, this difference was not significant. This highlighted the importance of the support provided by the midwives in the labor ward, who have a common practice of addressing women's fears and anxieties—even if those with high FOC have not previously been identified.

The results of the different studies that have evaluated the effect on the FOC of the continuity of care administered by midwives in pregnancy and childbirth care are contradictory. Furthermore, the studies that have attempted to explore this topic experience certain methodological weaknesses. Although Hildingsson et al. (2018) reported favorable results using the modified caseload midwifery care model, no differences were noted in the multicenter study performed by Kjærgaard et al. (2008). The latter study compared the FOC of Swedish women, where prenatal and maternity care was provided by different midwives, with that of Danish women, where all care during pregnancy and birth is provided by the same midwife. Similar levels of FOC were reported in both groups of women, both at the end of pregnancy and on arrival at the maternity unit and knowing which midwife would be caring for their birth did not seem to make a difference. However, in our trial, women knew the collaborating midwives through reproduced recordings and were mostly cared for by them. More robust studies are needed to assess whether the fact that a woman with high FOC knows the midwife who will

attend her birth is a critical factor in achieving a significant reduction in her fears.

Psycho–education implemented by midwives—along with other usual care practices—has shown that, in addition to being effective in reducing FOC, they can help achieve more positive childbirth experiences (do Souto et al., 2022). Indeed, FOC is a construct closely related to satisfaction with childbirth (Rúger-Navarrete et al., 2023); notably, few intervention studies on FOC have evaluated this outcome variable. Although the data obtained in this study seem to support this fact—with higher satisfaction scores in the four dimensions of the CEQ–E in the experimental group—the results were not significant. Considering this outcome measure, within the studies reviewed, we only found that Fenwick et al. (2015) explored satisfaction regarding the mode of birth, finding no statistically significant differences. For their part, Swift et al. (2021) observed significant inter-group differences, although they only evaluated satisfaction with prenatal care. The convenience of including in future intervention studies on FOC the measurement of women's satisfaction as a variable to measure the effectiveness of the interventions.

In Spain, this problem has remained unseen despite the increase in significance and relevance of FOC in many countries in recent years (Dai et al., 2020). The need to identify women with high FOC in Spain has been partially solved with the recent validation of two instruments: the WDEQ–Sp (Ortega-Cejas et al., 2021; Roldán-Merino et al., 2021) and the FOC Questionnaire (CFQ–e; González-de la Torre et al., 2022). The choice of the WDEQ–Sp as the FOC assessment tool in this study was influenced by the fact that it is currently considered the gold standard in FOC measurement instruments (Richens et al., 2018). Although both

instruments have good psychometric properties, both have the limitation that cut-off points have not yet been proposed regarding which score should be considered a high FOC for Spanish women (González-de la Torre et al., 2022; Ortega-Cejas et al., 2021; Roldán-Merino et al., 2021). More recently, the Birth Anticipation Scale has been validated in Spain (Rúger-Navarrete et al., 2023), which also measures FOC, although information on its psychometric properties is scarcer.

Finally, while costs are likely to be low, future studies are needed to assess the cost-effectiveness of the interventions evaluated in the study. This information would support the implementation in terms of setting up a midwife-led program for the diagnosis, monitoring, and counseling of women with high FOC, including ongoing training of these professionals in the most effective interventions to address FOC. Similar programs already exist in some countries, such as Sweden (Larsson et al., 2016), where women with high FOC are referred for individual counseling by a multidisciplinary team in which the midwife plays a key role.

Limitations

Among the limitations of our study, we highlighted that although all women participating were recruited in the public health system, a percentage of women had received combined medical care (public and private) and decided at the end of pregnancy to give birth in a private facility. This led to some withdrawals from the study in the intrapartum phase. Another limitation in the intrapartum phase is that, for organizational reasons, some women were able to get help from midwives other than those involved in the study. There was also the limitation of blinding the women participants, which was not possible due to the design of the study—similar

to other studies (Firouzan et al., 2020; Haapio et al., 2017; Kaya & Guler, 2022; Swift et al., 2021; Toohill et al., 2014). Finally, it must be considered that although the number of participants in the first phase met the required sample size, the number of participants who completed the second phase does not meet this premise.

Conclusion

Evidence of the effectiveness of the specific antenatal education intervention midwives deliver in reducing the level of FOC is established. This intervention, through continued support during childbirth, appeared to improve women's experiences of childbirth and obstetric outcomes with higher rates of spontaneous onset and completion of epidurals and less use of epidural analgesia compared with women receiving usual care; however, the results are not statistically significant. The conclusions support the usefulness of implementing early detection and educational intervention programs in women with a high FOC during pregnancy, aimed at reducing the fears associated with the physiological process of childbirth.

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Figure Legends

Figure 1. Flowchart that describes the recruitment process and the phases of intervention

Figure 2. Graphic description of intra-individual group and between-group fear of childbirth measurements for ITT and PP analysis.

Figure 1

Flowchart that describes the recruitment process and the phases of intervention

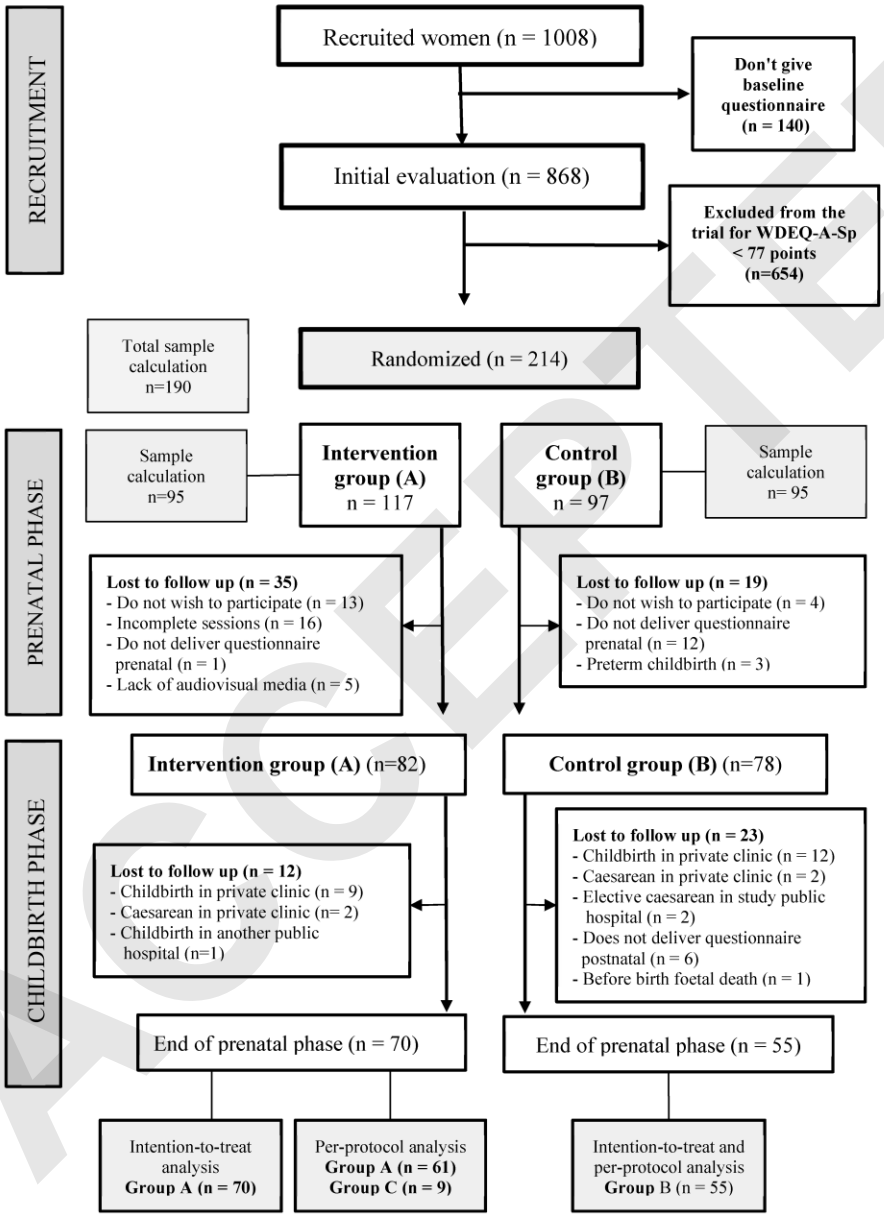
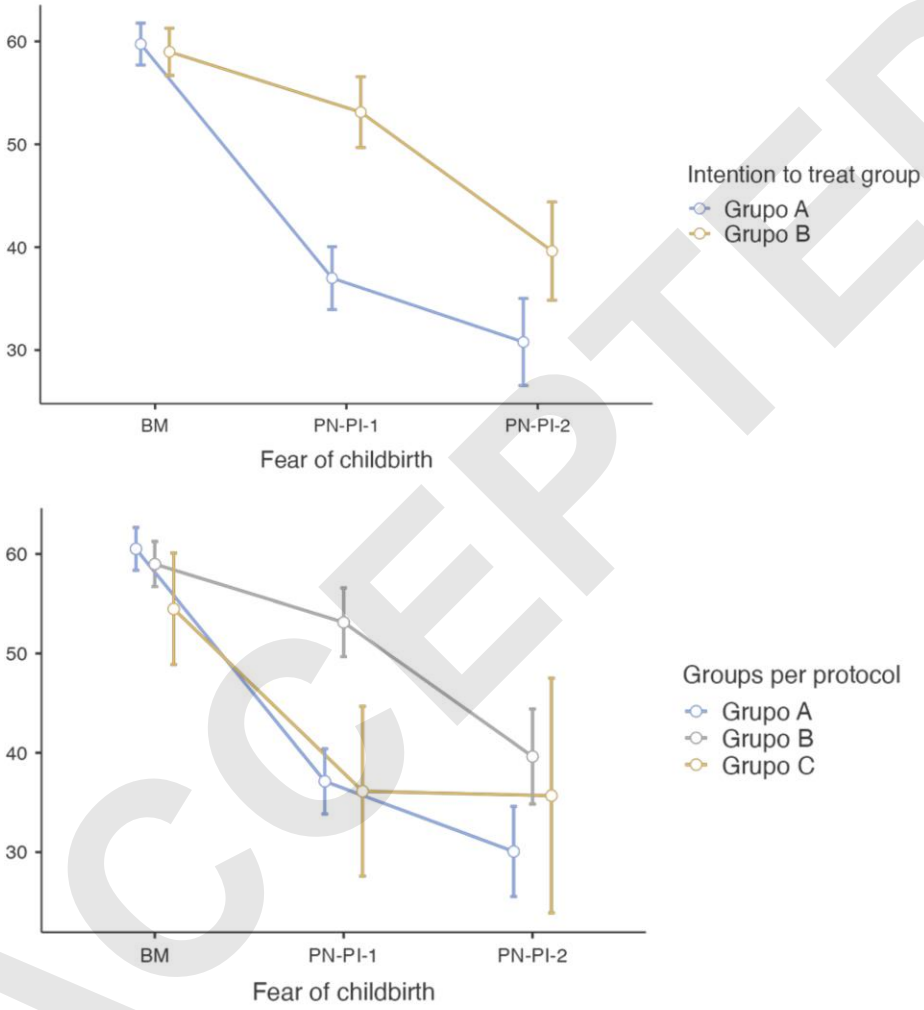


Figure 2

Graphic description of intra-individual group and between-group fear of childbirth[a] measurements for ITT and PP analysis.



Note.ITT = intention-to-treat; PP = per-protocol; BM = baseline measure; PN-PI-1 = post-intervention prenatal measure; PN-PI-2 = post-intervention post-natal measure.

[a] Fear of childbirth measured with Wijma Delivery Expectancy Questionnaire-A-Spanish version.

Table 1

Baseline variables of the study groups

Categorical baseline variables	**Experimental group**	**Control group**	**Pearson χ^2**
	***n* (%)**	***n* (%)**	
Couple			*p*= .851
With couple	107 (91.5)	88 (90.7)	
Single	10 (8.5)	9 (9.3)	
Level Studies			*p* = .401
Primary studies	19 (16.2)	20 (20.6)	
Secondary studies	48 (41.0)	44 (45.4)	
University studies	50 (42.7)	33 (34.0)	
Parity			*p* = .236
Primipara	73 (62.4)	68 (70.1)	
Multiparous	44 (37.6)	29 (29.9)	
Completion of last childbirth[a]			*p* = .728
Vaginal birth	32 (72.7)	20 (69.0)	
Caesarean section	12 (27.3)	9 (31.0)	

Quantitative baseline variables	**Experimental group**		**Control group**		**Student' t-test**
	M	***SD***	***M***	***SD***	
Fear of Childbirth[b]	91.68	13.02	92.88	14.91	*p* = .530
Maternal age	32.33	4.70	31.99	5.71	*p* = .629
Gestational age	21.32	0.65	21.29	0.76	*p* = .784
Gestations	1.98	1.31	1.86	1.07	*p* = .444

Note. Experimental group = 117; Control group =97; *M* = mean; *SD* = Standard deviation.
[a] Multiparous women (N = 44 in experimental group and N= 29 in control group).
[b] Fear of childbirth measured with Wijma Delivery Expectancy Questionnaire-A-Spanish version.

Table 2

Comparisons 'post-hoc' fear of childbirth measures in ITT and PP analysis

Comparison of fear of childbirth with WDEQ-A-Sp (Group)		ITT Analysis		PP Analysis	
		MD	*p* Tukey	*MD*	*p* Tukey
BM (A)	PN-PI-1 (A)	22.74	< .001	23.39	< .001
BM (A)	PN-PI-2 (A)	28.95	<.001	30.45	< .001
PN-PI-1 (A)	PN-PI-2 (A)	6.20	.054	7.05	.068
BM (B)	PN-PI-1 (B)	5.86	.012		-
BM (B)	PN-PI-2 (B)	19.36	<.001		-
PN-PI-1 (B)	PN-PI-2 (B)	13.50	<.001		-
BM (C)	PN-PI-1 (C)		-	18.35	< .001
BM (C)	PN-PI-2 (C)		-	18.79	.084
PN-PI-1 (C)	PN-PI-2 (C)		-	0.43	1.000
BM (A)	BM (B)	0.75	.997	1.52	.988
BM (A)	BM (C)		-	6.03	.553
BM (B)	BM (C)		-	4.51	.864
PN-PI-1 (A)	PN-PI-1 (B)	−16.13	<.001	−16.00	< .001
PN-PI-1 (A)	PN-PI-1 (C)		-	0.99	1.000
PN-PI-1 (B)	PN-PI-1 (C)		-	16.99	.011
PN-PI-2 (A)	PN-PI-2 (B)	−8.83	.074	−9.56	.106
PN-PI-2 (A)	PN-PI-2 (C)		-	−5.62	.994
PN-PI-2 (B)	PN-PI-2 (C)		-	3.93	1.000

Note. WDEQ-A-Sp = Wijma Delivery Expectancy Questionnaire-A-Spanish version; ITT = intention-to-treat; PP = per-protocol; MD = difference mean; BM = baseline measure; PN-PI-1 = post-intervention pre-natal measure; PN-PI-2 = post-intervention post-natal measure.

Table 3

Comparisons 'post-hoc' maternal satisfaction measures in PP analysis

Comparison of satisfaction with CEQ-E (Group)		PP Analysis	*p* value
		MD	
Global Score (A)	Global Score (B)	4.86	.072
Global Score (A)	Global Score (C)	5.93	.345
Global Score (B)	Global Score (C)	1.07	.964
Personal capacity Score (A)	Personal capacity Score (B)	0.21	.196
Personal capacity Score (A)	Personal capacity Score (C)	0.35	.403
Personal capacity Score (B)	Personal capacity Score (C)	0.14	.847
Professional support Score (A)	Professional support Score (B)	0.08	.654
Professional support Score (A)	Professional support Score (C)	0.12	.731
Professional support Score (B)	Professional support Score (C)	0.04	.963
Perceived security Score (A)	Perceived security Score (B)	0.33	.050
Perceived security Score (A)	Perceived security Score (C)	0.10	.895
Perceived security Score (B)	Perceived security Score (C)	−0.23	.593
Participation Score (A)	Participation Score (B)	0.21	.196
Participation Score (A)	Participation Score (C)	0.35	.403
Participation Score (B)	Participation Score (C)	0.148	.847

Note. CEQ-E = Childbirth Experience Questionnaire Spanish version; PP = per-protocol; MD = mean difference.

Suplementary material

Supplementary material table 1

Distribution and theme of prenatal education sessions

Session		Question and Topic	Video	Brief Therapy
1	"Becoming aware"	Fears towards childbirth? _____ The emotion of fear The fear of childbirth	Reception area at MCHGC	Resource box _____ Rarewell letter _____ The amulet
2	"Planning"	How do you wish childbirth? _____ Birth plan	Triage area of the MCHGC	Anthropologist task _____ Task of 1,2,3,4..
3	"Childbirth"	Personal abilities to his coping? _____ Physiologic process of childbirth	MCHGC monitoring/ observation area	The mantra
4	"Accompaniment"	What to expect from the chosen person? Midwife role? _____ Family and midwife support	MCHGC unit birth	Detect and implement strengths
5	"Different childbirth"	Resources to cope with pain? _____ Options and situations around childbirth	MCHGC puerperium and neonatology area	Expert Tips

Note. MCHGC = Maternal and Children's Hospital of Gran Canaria.

Supplementary material table 2

Descriptive fear of childbirth measures for intention-to-treat analysis

Measures FOC (ITT analysis)	Group[a]	M	SD	95% CI		MD
				Inf	Sup	
Baseline WDEQ-A-Sp (measure raw)	Group A	92.5	13.00	89.6	95.3	-0.74
	Group B	93.2	15.28	89.7	96.6	
Baseline WDEQ-A-Sp (0-100 scale)	Group A	59.6	8.39	57.8	61.5	-0.47
	Group B	60.1	9.86	57.9	62.3	
Prenatal post-intervention WDEQ-A-Sp (measure raw)	Group A	57.4	21.41	52.7	62.1	-26.56
	Group B	84.0	21.49	79.2	88.8	
Prenatal post-intervention WDEQ-A-Sp (0-100 scale)	Group A	37.1	13.82	34.0	40.1	-17.13
	Group B	54.2	13.86	51.1	57.3	
Post-natal WDEQ-B-Sp (measure raw)	Group A	50.8	29.54	43.0	57.8	-14.58
	Group B	65.4	29.47	57.4	73.3	
Post-natal WDEQ-B-Sp (0-100 scale)	Group A	30.8	17.90	26.5	35.1	-8.83
	Group B	39.6	17.86	34.8	44.5	

Note. FOC = fear of childbirth; WDEQ-A-Sp = Wijma Delivery Expectancy Questionnaire-A-Spanish version; ITT = intention-to-treat; WDEQ-B-Sp = Wijma Delivery Experience Questionnaire-B-Spanish version; M = mean; SD = Standard deviation; CI = confidence interval; MD = difference mean.

[a] Group A (N=82); Group B (N=78)

Supplementary material table 3

Descriptive fear of childbirth measures for per-protocol analysis

Measures FOC (PP analysis)	Group[a]	M	SD	95% CI		MD (Groups)
				Inf	Sup	
Baseline WDEQ-A (measure raw)	Group A	93.8	12.95	90.5	97.1	2.37 (A-B)
	Group B	91.4	13.85	87.7	95.2	6.99 (B-C)
	Group C	84.4	9.66	77.0	91.9	9.36 (A-C)
Baseline WDEQ-A (0-100 scale)	Group A	60.5	8.36	58.4	62.7	1.53 (A-B)
	Group B	59.0	8.93	56.6	61.4	4.51 (B-C)
	Group C	54.5	6.23	49.7	59.3	6.04 (A-C)
Prenatal post-intervention WDEQ-A (measure raw)	Group A	57.5	20.58	52.3	62.8	-24.8 (A-B)
	Group B	82.3	20.02	76.9	87.8	26.35 (B-C)
	Group C	56.0	16.31	43.5	68.5	1.54 (A-C)
Prenatal post-intervention WDEQ-A (0-100 scale)	Group A	37.1	13.28	33.7	40.5	-16.0 (A-B)
	Group B	53.1	12.91	49.6	56.6	16.99 (B-C)
	Group C	36.1	10.52	28.0	44.2	0.994 (A-C)
Post-natal WDEQ-B (measure raw)	Group A	49.6	29.68	42.0	57.2	-15.8 (A-B)
	Group B	65.4	29.47	57.4	73.3	6.49 (B-C)
	Group C	58.9	28.95	36.6	81.1	-9.28 (A-C)
Post-natal WDEQ-B (0-100 scale)	Group A	30.1	17.99	25.5	34.7	-9.56 (A-B)
	Group B	39.6	17.86	34.8	44.5	3.94 (B-C)
	Group C	35.7	17.54	22.2	49.2	-5.63 (A-C)

Note. FOC = fear of childbirth; WDEQ-A-Sp = Wijma Delivery Expectancy Questionnaire-A-Spanish version; PP = per-protocol; WDEQ-B-Sp = Wijma Delivery Experience Questionnaire-B-Spanish version; M = mean; SD = Standard deviation; CI = confidence interval; MD = difference mean.

[a] Group A (N=61); Group B (N=55); Group C (N=9)

Supplementary material table 4

Descriptive satisfaction measures for analysis intention-to-treat analysis

Measures satisfaction (ITT analysis)	**Group**[a]	**M**	**SD**
CEQ-E Global Score	Group A	69.39	11.02
	Group B	65.29	12.52
CEQ-E Personal capacity Score	Group A	2.70	0.65
	Group B	2.54	0.66
CEQ-E Professional support Score	Group A	3.80	0.43
	Group B	3.73	0.55
CEQ-E Perceived security Score	Group A	3.13	0.71
	Group B	2.81	0.77
CEQ-E Participation Score	Group A	2.70	0.65
	Group B	2.54	0.08

Note. ITT = intention-to-treat; CEQ-E = Childbirth Experience Questionnaire Spanish version; M = mean; SD = Standard deviation.

[a] Group A (N=70); Group B (N=55)

Supplementary material table 5

Descriptive satisfaction measures for per-protocol analysis

Measures satisfaction (PP analysis)	**Group**[a]	**M**	**SD**
CEQ-E Global Score	Group A	70.15	10.86
	Group B	65.29	12.52
	Group C	64.22	11.37
CEQ- E Personal capacity Score	Group A	2.75	0.63
	Group B	2.54	0.66
	Group C	2.39	0.75
CEQ-E Professional support Score	Group A	3.82	0.43
	Group B	3.73	0.55
	Group C	3.69	0.47
CEQ-E Perceived security Score	Group A	3.14	0.72
	Group B	2.81	0.77
	Group C	3.04	0.62
CEQ-E Participation Score dimension	Group A	2.75	0.63
	Group B	2.54	0.66
	Group C	2.39	0.75

Note. PP = per-protocol; CEQ-E = Childbirth Experience Questionnaire Spanish version; M = mean; SD = Standard deviation.

[a] Group A (N=61); Group B (N=55); Group C (N=9)

Supplementary material table 6

Descriptive data from the analysis intention-to-treat of obstetric outcomes

Obstetric outcomes	Group A[a] **N (%)**	Group B[b] **N (%)**
Type of onset of childbirth (ITT analysis)		
Onset of induced childbirth	31 (44.3%)	37 (67.3%)
Onset of spontaneous childbirth	39 (55.7%)	18 (32.7%)
Type of completion of childbirth (ITT analysis)		
Eutocic-cephalic	55 (78.6%)	40 (72.7%)
Dystocic-Forceps	7 (10%)	9 (16.4%)
Urgent cesarean section	5 (7.1%)	6 (10.9%)
Dystocic-breech	1 (1.4%)	-
Eutocic-podalic	2 (2.9%)	-
Epidural analgesia (ITT analysis)		
No	21 (30%)	6 (10.9%)
Si	49 (70 %)	49 (89.1%)
Oxytocin (ITT analysis)		
No	31 (44.3%)	17(30.9%)
Si	39 (55.7 %)	38 (69.1%)
Childbirth duration (ITT analysis)	Group A[a] **M (SD)**	Group B[b] **M (SD)**
Hours	7.59 (5.41)	10.8 (6.00)

Note. ITT = intention-to-treat; ; M = mean; SD = Standard deviation

[a] Group A (N=70)
[b] Group B (N=55)

Supplementary material table 7

Descriptive data from the per-protocol analysis of obstetric outcomes

Obstetric outcomes	Group A[a] N (%)	Group B[b] N (%)	Group C[c] N (%)
Type of onset of childbirth (PP analysis)			
Onset of induced childbirth	30 (49.2%)	37 (67.3%)	1 (11.1%)
Onset of spontaneous childbirth	31 (50.8%)	18 (32.7%)	8 (88.9%)
Type of completion of childbirth (PP analysis)			
Eutocic-cephalic	48 (78.7%)	40 (72.7%)	7 (77.8%)
Dystocic-Forceps	6 (9.8%)	9 (16.4%)	1 (11.1%)
Urgent cesarean section	5 (8.2%)	6 (10.9%)	-
Dystocic-breech	-	-	1 (11.1%)
Eutocic-podalic	2 (3.3%)	-	-
Epidural analgesia (PP analysis)			
No	15 (24.6%)	6 (10.9%)	6 (66.7%)
Si	46 (75.4%)	49 (89.1%)	3 (33.3%)
Oxytocin (PP analysis)			
No	23 (37.7%)	17(30.9%)	8 (88.9%)
Si	38 (62.3 %)	38 (69.1%)	1 (11.1%)
Childbirth duration (PP analysis)	Group A[a] M (SD)	Group B[b] M (SD)	Group C[c] M (SD)
Hours	8.26 (5.34)	10.8 (6.00)	3.02 (3.37)

Note. PP = per-protocol; M = mean; SD = Standard deviation

[a] Group A (N=61)
[b] Group B (N=55)
[c] Group C (N=9)