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Effects of psychosocial support during labour and childbirth on breastfeeding, medical interventions, and mothers' wellbeing in a Mexican public hospital: a randomised clinical trial

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Object To evaluate the effects of psychosocial support during labour, delivery and the immediate postpartum period provided by a female companion (doula).

Design The effects of the intervention were assessed by means of a randomised clinical trial. Social support by a doula was provided to women in the intervention group, while women in the control arm received routine care.

Setting A large social security hospital in Mexico City.

Participants Seven hundred and twenty-four women with a single fetus, no previous vaginal delivery, < 6 cm of cervical dilatation, and no indications for an elective caesarean section were randomly assigned to be accompanied by a doula, or to receive routine care.

Outcome measures Breastfeeding practices, duration of labour, medical interventions, mother's emotional conditions, and newborn's health.

Methods Blinded interviewers obtained data from the clinical records, during encounters with women in the immediate postpartum period, and at their homes 40 days after birth. Relative risks and confidence intervals were estimated for all relevant outcomes.

Results The frequency of exclusive breastfeeding one month after birth was significantly higher in the intervention group (RR 1·64; I–C: 1·01–2·64), as were the behaviours that promote breastfeeding. However, the programme did not achieve a significant effect on full breastfeeding. More women in the intervention group perceived a high degree of control over the delivery experience, and the duration of labour was shorter than in the control group (4·56 hours *vs* 5·58 hours; RR 1·07 CI (95%) = –1·52 to –0·51). There were no effects either on medical interventions, mothers' anxiety, self-esteem, perception of pain and satisfaction, or in newborns' conditions.

Conclusions Psychosocial support by doulas had a positive effect on breastfeeding and duration of labour. It had a more limited impact on medical interventions, perhaps because of the strict routine in hospital procedures, the cultural background of the women, the short duration of the intervention, and the profile of the doulas. It is important to include psychosocial support as a component of breastfeeding promotion strategies.

INTRODUCTION

In Mexico intense and rapid urbanisation, where more than 60% of women now live in cities, has facilitated the substitution of models of traditional care provided to women during pregnancy, childbirth and the postpartum period with those provided by public and private obstetric services of large urban centres. Currently, 85·4% of births take place in hospitals (98% in the Mexico City metropolitan area), and only 3·3% at the house of a traditional midwife, and 10% at the pregnant woman's home[1]. Health professionals are often unaware of the important role played by companions during childbirth, such as women who are family or community members, and traditional birth attendants. In general, care is pro-

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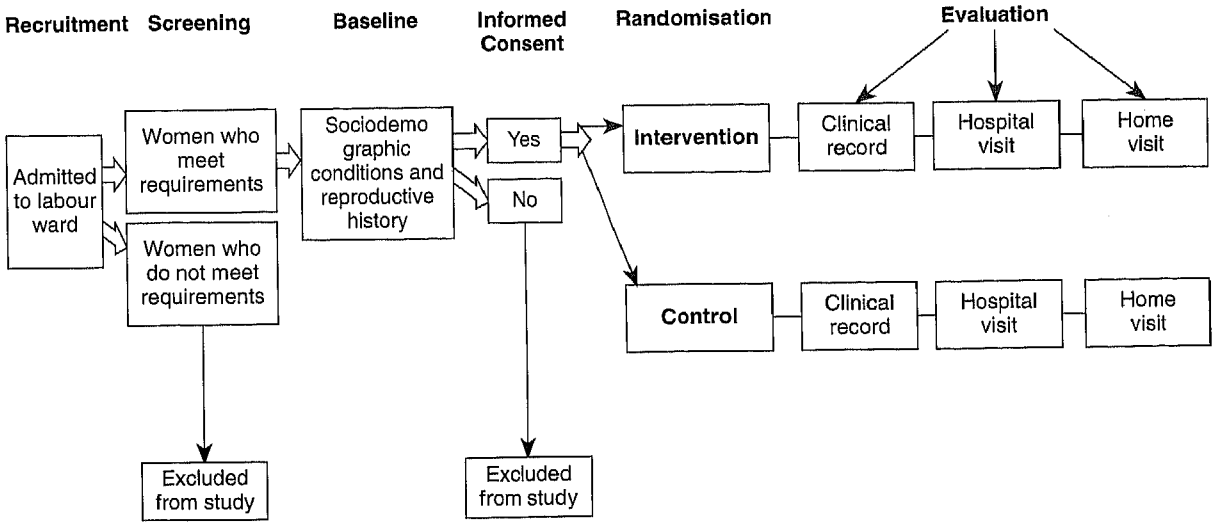

Fig. 1. Patient flowchart.

vided exclusively by the doctor and nurse, both of whom are well aware that events during labour and childbirth, affecting the mother or her infant, could require specialised technological attention. Such interventions, however necessary, may produce a negative effect on the labouring woman's emotional state and make one of her most important life experiences a painful and traumatic process. A mother or her infant recovering after a difficult birth may take longer to bond and there is considerably less chance of the mother being able to breastfeed the baby successfully.

The main hypothesis of this project was that psychosocial support during labour, childbirth and the immediate postpartum period provided by a 'doula'* would increase breastfeeding by ameliorating the mother's emotional status, shortening the time of labour, and decreasing medical interventions. The hypothesis was based on previous research on the issue. Studies in Guatemala, the United States and South Africa on the participation of doulas have shown positive effects[3–6], in terms of reduction of the use of anaesthesia and analgesics during labour, caesarean sections and forceps, and the length of labour. Similarly, the studies demonstrated that companion support during labour speeded up the mother's recovery, helped mother–child bonding, and reduced anxiety and depression in the first six weeks postpartum[7]. In the most recent study it was found that psychosocial support during labour had a positive effect on the start and continuation of breastfeeding[8].

METHODS

The study was conducted in a large public hospital of the Mexican Institute of Social Security where approximately 400 births a month take place. This hospital has a traditional nursery and a small rooming-in service where some breastfeeding promotion is given.

Candidates for the study were women with a single fetus, no previous vaginal delivery, who arrived at the labour and delivery unit with < 6 cm of cervical dilatation, without evidence of any severe obstetric disease or indications for an elective caesarean section. After screening and baseline questionnaires were completed and informed consent was obtained, women were distributed according to a computer-generated random number list (Fig. 1). The treatment sequence was kept at a central level; the opaque envelopes with the assignment were locked in a cabinet to which only a social worker exclusively in charge of randomisation and the principal investigator had access. An envelope with a paper inside showing to which group each woman was assigned was opened by the social worker immediately after recruitment, from Monday through Friday, between 8 a.m. and 3 p.m. in the labour and delivery unit. The social worker was, without exception, present and in charge of both endeavours. A doula was called upon for women in the intervention group; women in the control group received routine care. To avoid contamination between treatment groups, separate labour rooms, screens between the beds, or beds at opposite ends of the same room were used.

* 'Doula' is a Greek word referring to an experienced woman who helps other women. The word has now come to mean a woman experienced in childbirth who provides continuous physical, emotional and informational support to the mother before, during and just after childbirth[2].

Women in the intervention group were introduced to a doula who accompanied her with no interruption throughout labour, childbirth and the immediate postpartum period. The programme design, based on previous descriptions[3–6,8,9] and the personal advice of Dr M. Klaus, consisted of five components:

1. *Emotional support* The doula gave the woman continuous support during labour and delivery by talking to her using encouraging and calming words. Furthermore, the doula acknowledged the effort being made by the mother and answered her questions while maintaining constant visual contact.
2. *Information* The doula kept the woman informed about how her labour was progressing and, in words that were clear and easy to understand, about all the medical procedures.
3. *Physical support* The doula encouraged the woman to adopt more comfortable positions. In addition, she told her how to relax (including visualisation techniques) and to breathe. The doula gave the woman massages and held her hand when appropriate.
4. *Communication* The doula kept up a conversation so that the woman would not feel alone.
5. *Immediate contact between mother and child* The doula encouraged a woman to hold her baby immediately after birth and promoted early breastfeeding, provided that the condition of the mother and the newborn permitted it.

The experiment continued in the period immediately after birth when the doula visited the mother in the inpatient ward. During that encounter, the doula told her about the benefits of breastfeeding, and the problems she might encounter, as well as how to solve them to facilitate successful breastfeeding. The visit lasted between 45 minutes and one hour. The intervention followed a standardised protocol, which was used as the basis for the training course to the doulas who participated in the study. The standardised intervention was slightly modified after a short pilot study. Once established, the protocol did not suffer major deviations.

We considered that women selected to work as doulas if the intervention proved to be effective, could be adopted as part of the institution's staff. It was decided, therefore, to train and hire retired nurses (ie, women who were still young but old enough to allow the soon-to-be mothers to identify with them as with their own mothers). Though no longer working, they were still energetic and wanted to continue being active. Furthermore, although it was not thought to be indispensable, most of them had children of their own which enabled them to better understand the childbirth experience. Out of 22 candidates who were trained, the best 10 were invited to participate in the trial.

RESULTS

The main outcomes of the trial were exclusive and full breastfeeding at one month postpartum. Full breastfeeding was defined as the use of breast milk as the sole source of milk regardless of supplementation with other fluids such as water and herbal teas[10]. Exclusive breast-feeding was used to describe infants who were fed breast-milk as the only source of milk and did not receive herbal teas and/or water[11].

We recorded changes in duration of labour, medical interventions (ie, epidural anaesthesia, use of forceps and caesarean section); women's emotional state (ie, perceived control over labour, anxiety, perception of pain, satisfaction and self-esteem); fetal and neonatal conditions (ie, Apgar scores and meconium staining); and knowledge about behaviours that promoted successful breastfeeding. The evaluation was made by two blinded social workers that reviewed the women's clinical records and visited them in the immediate postpartum period and at their homes at one month after birth. Obviously, neither the women nor the doulas could be blinded, as is usually the case with behavioural or psychosocial interventions. We also implemented a qualitative component to assess women and providers' perception about routine delivery care and the experimental[12].

The sample size was calculated on an expected increase of at least 10% in the prevalence of infants fully breastfed one month after birth (from 45% to 55%). With an a of 0·05 (for a one-tailed test), a power of 80% and a 20% attrition rate, it was calculated that 370 women were needed in each group, (for a total number of 740). The baseline prevalence of fully breastfed newborns was taken from a previous study done at the Mexican Institute of Social Security and reassessed during the early stages of the trial. Although all interventions have the potential of producing negative effects, we decided to use a one-sided test, based on the fact that no negative effects of psychosocial support during labour have ever been documented[13].

Information was gathered in pre-coded questionnaires. The project's field supervisor revised each data collection form. Computer programs were used to enter, verify and validate the information. A random selection of 10% of each of the questionnaires was subjected to a double entry, verification and validation process on two consecutive occasions. Eight summary variables were constructed from different questions included in the data collection forms:

1. *Socio-economic level* This variable is an index which measures differences within groups with a similar status using six socioeconomic variables[14].
2. *Breastfeeding pattern* This variable was constructed with information provided by various questions about newborns' feeding during the first month of life including type (s) of milk given, introduction of liquids such as teas and water, and the time when weaning took place.
3. *Anxiety* Spielberger's State-Trait Anxiety Inventory[15], translated into Spanish, was used. It has been validated for pregnant women in Latin America[16] and used in previous randomised trials of social support during pregnancy[17].
4. *Perceived control during childbirth* A 'control' inventory[18] validated for the Mexican population by the National Institute of Public Health in Mexico was used.
5. *Pain* Measured by using a visual analogue pain rating scale based on a validated instrument[19,20].
6. *Duration of labour* Measured based on the information included in the clinical records (the time when labour started and the time of delivery).
7. *Satisfaction* Measured by asking a direct question included in the postpartum questionnaire.
8. *Maternal self-esteem* Measured by using the Coppersmith's inventory that has been translated into Spanish and validated by Lara-Cantú *et al*[21].

Table 1. Characteristics at recruitment. Values are given either as mean or *n/n* (%). PROM = premature rupture of the membranes.

Characteristics	Intervention	Control
Age	22·5	22·5
Completed high school	276/361 (76·5)	279/363 (76·6)
Living with a stable partner	319/361 (88·4)	320/363 (88·2)
Smoked during pregnancy	20/361 (5·5)	25/363 (6·9)
Primiparae	336/361 (93·1)	329/363 (90·6)
Gestation (weeks)	39·1	39·2
Prenatal care	357/361 (98·9)	360/363 (99·2)
No. prenatal visits	7·4	7·2
Planned pregnancy	286/361 (79·2)	289/363 (79·6)
Cervical dilatation < 4 cm	70/357 (19·6)	70/357 (19·6)
PROM	286/361 (18·2)	78/359 (21·7)

Table 2. Reasons for loss of subjects at the home interview, one month postpartum. Values given as *n* (%).

Reasons	Intervention	Control
Wrong address or change of home	15 (75)	21 (58·3)
Woman never found at home	2 (10)	2 (5·6)
Woman refused to continue participating	0·0	9 (25)
Unfavourable perinatal outcome*	2 (10)	2 (5·6)
Other reasons	1 (5)	2 (5·6)
TOTAL	20 (100)	36 (100)

*Stillbirths or perinatal deaths.

Statistical analysis

All analyses were conducted on an intention-to-treat basis. Once the above-mentioned indices were compiled, contingency tables were prepared and association measures (χ^2 test) were obtained among the variables of interest. In the case of continuous, normally distributed variables, the means of both groups were compared by using Student's *t* test. For those variables with a nonnormal distribution, nonparametric tests were used such as the median comparison test of Wilcoxon and of Kruskal-Wallis. To assess differences between intervention and control groups, relative risks with 95% confidence intervals were calculated. Prognostic variables considered were mother's age, centimetres of cervical dilation at recruitment, and premature rupture of membranes. However, since there were no differences between women in the intervention and control groups in any of these variables (Table 1), there was no need for adjustment in the impact assessment.

Follow up

Women who met the inclusion criteria (728 of 3081 interviewed) were asked to give their informed consent to take part in the study. Only four women refused. The 724 remaining women were asked to fill in a brief baseline questionnaire, which inquired about sociodemographic characteristics, the use of reproductive health services, habits during pregnancy, health background, and expectations about breastfeeding and emotional condition. Afterwards, women were randomised: 361 were assigned to the intervention group, and 363 to the control group.

No woman was lost to follow up in the hospital. Twenty women in the intervention group and 36 among the controls were lost at the time of the home interview, one month after delivery. The most common reasons for the losses are included in Table 2. There were no important differences in characteristics between the two groups found (Table 1). Comparison of the baseline data shows that randomisation produced two homogeneous groups.

Effect of the intervention

Table 3 provides details about feeding patterns of the newborn infants. The frequency of exclusive breastfeeding one month after birth was significantly higher in the intervention group (12% *vs* 7%; RR

Table 3. Effects of the intervention on feeding patterns of the newborn at one month postpartum. Values are given as *n/n* (%).

Effects	Intervention	Control	RR	95% CI
Exclusive breastfeeding*	41/334 (12·3)	24/320 (7·5)	1·64	1·01–2·64
Full breastfeeding**	125/334 (37·4)	116/321 (36·3)	1·00	·82–1·22
Breastfeeding plus formula	141/334 (42·2)	131/321 (40·9)	1·03	·86–1·24
Feeding on demand	242/316 (76·6)	229/289 (79·2)	·97	(·89–1·05)
Behaviours that promote breastfeeding				
Calm environment during breastfeeding sessions	187/309 (60·5)	74/299 (24·7)	2·45	1·97–3·04
Care of the nipples	71/334 (21·3)	30/318 (9·4)	2·25	1·51–3·36
Reasons for not breastfeeding†				
Lack of milk	6/34 (17·6)	16/36 (44·4)	·40	·18–·90
Medical problems of mother	15/34 (44·1)	8/36 (22·2)	1·99	·97–4·07
Hospitalisation of mother	5/34 (14·7)	1/36 (2·8)	5·29	·65–43·03
Complementing with formula on doctor's advice	17/122 (13·9)	34/140 (24·3)	·57	·34–·97

*Ref. 11.
**Ref. 10.
†Only for women who stopped breastfeeding.

1·64, CI (95%) = 1·01–2·64). Overall, the proportion of exclusive breastfeeding was low: most of the mothers who breastfed also offered their newborns teas, juices and/or water. Full breastfeeding was the prevalent feeding pattern in 37% and 36% in the intervention and control groups, respectively. Breastfeeding plus formula was even more common. Feeding on demand was prevalent in both groups, without any difference between them.

Knowledge about behaviours recommended to promote breastfeeding (eg, ensuring a calm environment during the breastfeeding sessions and an adequate care of the nipples) was significantly better in the intervention group. Also studied were the reasons why breastfeeding was interrupted or supplemented in both groups. In the intervention group the most common reasons were related to the mother's health status. On the contrary, women in the control group interrupted or complemented breastfeeding based either on popular beliefs ('the milk dried up') or on doctor's recommendation (Table 3).

Table 4 shows the effect of the programme on the length of labour and the frequency of medical interventions. There was a significant difference in the median duration of labour, with a shorter time for women who received the intervention (4·56 hours *vs* 5·58 hours; I–C = –1·02; CI (95%) = –1·52– –0·51). On the other hand, there were no statistically significant differences in the proportion of women who received an epidural anaesthesia, or in the frequency of forceps use, and caesarean section.

An Apgar score of < 7 at 1 and 5 minutes after birth was very rare in both groups, with no differences between them. Clinical records registered meconium staining in an almost identical proportion in the intervention (18%) and control groups (19%).

The effects of the intervention on the mothers' emotional state are presented in Table 5. A statistically significant larger proportion of women in the intervention group perceived a high level of control over labour than their counterparts in the comparison group (RR 1·14; CI (95%) = 1·03–1·27). There were no differences in reported anxiety, self-esteem, pain and satisfaction with the childbirth experience. It is interesting to notice that no woman in either group fell in the category of 'high self-esteem'.

DISCUSSION

Although all women in the experimental group followed the protocol very carefully, thereby avoiding important biases and contamination, we achieved only marginal positive effects on a small number of outcomes: exclusive breastfeeding, knowledge about breastfeeding-promoting behaviours, length of labour, and women's perception of control over their labour and delivery.

The effects on exclusive breastfeeding are not negligible when compared with those achieved with other breastfeeding promotion interventions[22]. Taking into account that medical procedures were not modified but women's perception of the reproductive experience improved, the effects on breastfeeding should be attributed to the latter. However, the prevalence of exclusive breastfeeding was very low in both groups. Important efforts currently under way in Mexico, such as the 'Baby Friendly Hospital' initiative promoted by UNICEF and other collaborating agencies,

Table 4. Effects of the intervention on labour and medical interventions during childbirth. Values are given either as mean or *n/n* (%). CS = caesarean section.

Effects	Intervention	Control	I–C	RR	95% CI
Duration of labour (h)	4·56	5·58	−1·02	–	−1·52–0·51
Epidural anaesthesia	295/335 (88·1)	302/346 (87·3)	–	1·01	·95–1·07
Forceps	12/356 (2·8)	12/356 (3·4)	–	·86	·38–1·96
CS	85/357 (23·8)	97/356 (27·2)	–	·87	·68–1·12

Table 5. Effects of the intervention on emotional condition in the immediate postpartum period. Values are given as mean and *n/n* (%).

Effects	Intervention	Control	I–C	RR	95% CI
Control over labour*					
Mean	79·8	77·1	2·69	–	1·03–4·34
Low (20–46)	2/357 (0·6)	4/353 (1·1)			
Medium (47–73)	96/357 (26·9)	125/353 (35·4)		1·14	1·03–1·27
High (74–100)	259/357 (72·5)	224/353 (63·5)			
Anxiety**					
Mean	49·1	49·2	−0·06		−0·76–0·64
Low (27–46)	94/358 (26·3)	102/357 (28·6)			
Medium (47–50)	134/358 (37·4)	129/357 (36·1)		1·05	·90–1·23
High (51–67)	130–358 (36·3)	126/357 (35·3)		1·05	·89–1·23
Self-Esteem†					
Mean	18·6	18·9	−0·29	–	−0·89–0·31
Low (0–16)	85/336 (25·3)	80/316 (25·3)			
Medium (17–33)	251/336 (74·7)	236/316 (74·7)		1·0	·83–1·20
Pain during labour‡					
Low	10/356 (2·8)	15/352 (4·3)			
Medium	85/356 (23·9)	89/352 (25·3)		1·05	·94–1·16
High	261/356 (73·3)	248/352 (70·5)		1·02	·98–1·06
Satisfaction§					
High	293/356 (82·3)	289/353 (81·9)			
Medium	32/356 (9·0)	35/353 (9·9)		0·91	·58–1·44
Low	31/356 (7·7)	29/353 (8·2)		1·05	·65–1·70

*Ref. 18; RR: High *vs* low plus medium
**Ref. 16; RR: Medium and high *vs* low
†Ref. 21; RR: Low *vs* medium
‡Ref. 20; RR: Medium and high *vs* low
§Postpartum questionnaire; RR: Medium and low *vs* high

are likely to improve this situation. The doula intervention should be recommended as an additional activity to those comprehensive efforts.

The positive results obtained for knowledge about breastfeeding-promoting behaviours and reasons to interrupt or supplement breastfeeding show that a careful discussion about breastfeeding in the immediate postpartum period makes a difference. Women in the control group knew less about recommendations to increase the likelihood of successful breastfeeding. Also, the decision to supplement their milk with a formula was based on popular grounds or was attributed to recommendations by doctors who, we believe, indicate a supplement too often and without foundation. Women in the doula group appear to have been better prepared to ignore this advice; they only added a supplement when health problems arose. Unfortunately, these changes in knowledge did not wield a strong enough influence to substantially modify the most common breastfeeding pattern in Mexico: full breastfeeding or breastfeeding plus formula. This gap between increased knowledge and actual changes in health-related behaviours has also been demonstrated in other studies in the field of perinatal and reproductive health[23].

The positive effects on the length of labour were considered relevant since such a reduction may have an impact on women's wellbeing (shortening the often painful labour experience) and on costs for the health institution. More control over the labour experience was also achieved among women in the intervention group. However, this effect was not

accompanied by other positive effects on emotional conditions nor did it contribute to fewer medical interventions, as was expected.

No statistically significant differences were achieved on the frequency of medical interventions, although there is a trend towards positive effects in the experimental group (Table 4). Possibly, the limited power of the study made these results inconclusive. The decrease in the frequency of caesarean section (3·4%) was similar to that of other studies in which different and more specific interventions were evaluated[24]. However, we would have needed a sample size of 3379 women in each arm in order to demonstrate a statistically significant difference between the two groups. This sample size was impossible to achieve with the budget available for this study.

In addition to the limitations imposed by the sample size, there are at least four possible explanations for the modest effects on medical interventions reached in this trial when compared with previous studies. The first hypothesis refers to the rigid medical and surgical practices at the study site. When a procedure such as epidural anaesthesia is indicated in more than 80% of the cases it is obviously part of hospital routine and, therefore, difficult to modify with an intervention focussed on patients.

A second hypothesis refers to the characteristics of the study population. According to Keirse *et al.*[25], the culturally appropriate care offered by the doula may counteract the negative effects of the hospital environment. This mechanism was considered to have great weight in the studies carried out in Guatemala[2]. However, this was not the case in our study, in which the women came from urban areas, had a medium educational level, and were all rather far removed from their indigenous and/or rural roots. Therefore, they may have been less susceptible to being helped by the intervention.

Other important difference in our study was the shorter duration of the intervention due to the hospital requirements for admitting patients (with not < 5 cm of dilation), and the almost universal use of oxytocin on which our study had no influence. Since a small group of women were admitted with < 4 cm of dilatation (n = 161), we performed a separate exploratory analysis with this subgroup to assess the effect of a longer intervention time. We found a 10% difference in caesarean sections: 26% (18/70) in the intervention group *vs* 36·3% (33/91) in the control group. Unfortunately, we would have needed a sample of 248 women in each group recruited with < 4 cm of dilatation to achieve a statistically significant difference. In this same sub-sample, there was a significant decrease in the application of an epidural block for those women accompanied by a doula (83%) compared with the unaccompanied ones (87%). The results of this exploratory analysis support the hypothesis that the short time available for intervening could have limited the impact of the doula program.

Finally, it is possible that retired nurses may be less effective as doulas than nonmedically trained women. Nurses, particularly those who have worked in large, busy hospitals, may have been desensitised to the feelings of women in labour. The nurse may harbour the sense of professional hierarchy and unwittingly adopt a more patronising attitude, thereby blunting her capacity to communicate empathy.

These results provide grounds to consider that psychosocial support during labour and the immediate postpartum period should be part of comprehensive strategies to promote breastfeeding. These results also indicate that instead of concentrating on changing patients' behaviour as a strategy to decrease indications to perform medical interventions, more efforts should focus on modifying medical norms and health staff routines. In a context of limited resources, priority should be given to interventions of proven effectiveness. Social support, though mandatory from a humane point of view, has important limitations as a strategy to modify health staff behaviour and reproductive outcomes.

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