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Women-centred interventions to increase vaginal birth after caesarean section (VBAC): A systematic review

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Highlights

- We searched for randomized studies on women-centred interventions designed to improve VBAC rates
- There were only three studies that evaluated interventions in pregnancy, none during the birth
- There were no studies showing any effect on VBAC rates
- Decision-aids and information programmes can help women make decisions on mode of birth
- There is an urgent need to develop women-centred interventions for improving VBAC rates

Introduction

Rising rates of caesarean section (CS) is an issue of particular concern in the global maternity care field (EURO-PERISTAT, 2013), due to the increased adverse maternal and neonatal outcomes associated with CS (Morrison et al., 1995; Guise et al., 2010; Marshall et al., 2011). If rates continue to rise at the same pace as in recent years, the overall CS rate is projected to be 56% by 2020 (Solheim et al., 2011). A key factor contributing to increasing rates is the tendency for women who have had a previous CS to have a repeat CS rather than a subsequent vaginal birth (Cheng et al., 2011). Given the higher incidence of placenta praevia, placenta accreta, hysterectomy, and composite maternal morbidity in women who have increasing numbers of CS births (Marshall et al., 2011), the potential effects this trend will have on women's health in the future warrants immediate attention.

Vaginal birth after CS (VBAC) has favourable outcomes compared with planned elective repeat CS. Maternal mortality has been shown, through a systematic review and meta-analysis of 203 research reports (Guise et al., 2010), to be significantly increased with elective repeat CS (ERCS) compared with elective VBAC (1.34 versus 0.38 per 10,000). Planned VBAC, however, significantly increases perinatal mortality (13 per 10,000) compared with ERCS (5 per 10,000), though it should be noted that absolute rates of both mortalities are low (Guise et al., 2010).

CS performed without a medically indicated reason i.e., for maternal request, is a frequently cited reason for increasing CS rates, with current rates ranging from 2.6% to 26.8% of all CSs (Quinlivan et al., 1999; Jacquemyn et al., 2003). In particular, one Australian study found that the foremost primary indication for elective caesarean section was woman's choice, mostly

due to women refusing to agree to a planned VBAC or to agree an attempt at vaginal breech birth (Quinlivan et al., 1999). In Sweden, the rate of CS without a medical indication increased threefold during the period 1997 to 2006; the most frequently stated reasons for an elective CS, in conjunction with no medical indication, were previous caesarean sections (28%) and childbirth-related fear (13%) (Karlström et al., 2010). Maternal request for CS, both primary and repeat, is strongly associated with fear of childbirth and previous negative birth experience (Karlström et al., 2010; Stjernholm et al., 2010; Nilsson et al., 2012; Størksen et al., 2013).

One qualitative study (Emmett et al., 2006) explored women's views of decision-making around mode of birth following a previous CS. Women's experiences varied, with some making firm decisions and setting goals for themselves and others remaining uncertain about choosing between repeat CS and VBAC. Information given to women was most commonly provided by doctors and related mostly to procedural matters rather than focusing on the risks and benefits linked with VBAC. Women described that information was not provided routinely and they had to seek it actively, which is disappointing given the number of studies showing that education of all women in the antenatal period (including those with a previous CS) improves birth outcome (Maimburg et al., 2010) and is appreciated and requested by nulliparous and multiparous women alike (Mungrue et al., 2010). For example, relaxation and birth preparation classes, which have led to a reduction in CS rates in nulliparous women (Khunpradit et al., 2011), and psycho-educational group sessions for women experiencing an intense fear of childbirth (Salmela-Aro et al., 2012) could also be tried with women following previous CS.

Despite the knowledge that women respond to educational interventions, a recent metasynthesis of eight qualitative studies (Lundgren et al., 2012) found that women with previous CS felt they were "groping through the fog" when it came to trying to access information on VBAC. The authors of this metasynthesis recommend that clinicians should provide women with evidence-based information on both the risks and benefits of VBAC, to assist in their decision-making. A recent Cochrane Review examined randomised trials of interventions designed to support decision-making about VBAC, the acceptability of any such interventions to women and their partners and how feasible their implementation would be (Horey et al., 2013). Their findings, based on three studies involving 2270 women, were that the decision support interventions used had no effect on the women's mode of birth, or their preferences for mode of birth. However, the review was limited to interventions designed to support decision-making only and did not seek information on any other types of intervention designed to assist women to achieve VBAC, nor did it include interventions during birth. In addition, while women liked the decision support there was concern among health professionals about the impact on their time and workload.

Accordingly, a systematic review evaluating all types of women-centred interventions during birth as well as pregnancy, for increasing VBAC rates, was proposed. The aim of this paper is to report the conduct and findings of this systematic review.

Methods

Inclusion criteria

Types of participants

Participants were pregnant women who have had at least one previous CS.

Types of interventions

Any women-centred intervention, used during pregnancy or birth, that was designed to increase VBAC rates in women with at least one previous CS. Comparator groups included standard or usual care or an alternative intervention aimed at increasing VBAC rates.

Types of studies

Randomised trials, including cluster randomised trials, were eligible for inclusion.

Types of outcome measures

The primary outcome measure was incidence of VBAC. The secondary outcome measures were maternal satisfaction with mode of birth preference/decision and birth experience, knowledge about birth choices, maternal anxiety levels, compliance with the intervention, rate of decisional conflict, mode of birth (spontaneous vaginal birth, instrumental birth, and emergency CS), maternal mortality, perinatal mortality, length of labour, uterine rupture, baby birth weight, neonatal Apgar scores, and admission to a neonatal intensive care unit.

Search and selection strategy

We searched electronic bibliographic databases of The Cochrane Library, PubMed,
PsychINFO and CINAHL from their inception dates, to 31st July 2014. The following search
string was used: 'Vaginal birth after cesarean' or 'Trial of Labor' or normal birth or ventouse

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or forcep* or instrumental and Cesar* or Caesar* or VBAC or TOLAC AND "Randomized Controlled Trial" [Publication Type] OR "Controlled Clinical Trial" [Publication Type] OR "Randomized Controlled Trials as Topic" [Mesh Terms] OR "Placebos" [Mesh Terms] OR (random* AND trial*[tiab]) OR "randomized" [tiab] OR "randomly" [tiab] or placebo*.

Prior to applying the search strategy, the search string was reviewed for accuracy, by one member of the review team not involved in developing the search strategy (CB), using the Peer Review of Electronic Search Strategies (PRESS) criteria (Sampson et al., 2009). There was no restriction applied to years searched, but retrieval of papers was limited to English language publications only.

Quality assessment of included studies

The Effective Public Health Practice Project (EPHPP) quality assessment tool (2009) was used to assess the methodological quality of the included studies. This tool was chosen because it provides a thorough assessment of potential sources of bias in randomised trials. Methodological components assessed within this tool include selection bias, allocation bias, confounding, blinding, data collection methods, withdrawals and drop-outs and analysis and intervention integrity. A global quality rating of Strong (no weak ratings), Moderate (one weak rating) or Weak (two or more weak ratings) was assigned to each study following the quality assessment procedure. An *a priori* decision was made to exclude studies from the analysis that received a 'Weak' global rating score.

Two members of the review team (VS and JN) independently assessed the quality of included studies. Any disagreements were to be discussed and resolved by consensus. Where disagreements could not be resolved by consensus, recourse to a third member of the review team was planned; this was not required.

Data extraction and analysis

Using a pre-designed data extraction form, data on the outcomes of interest were extracted independently by three members of the review team (KVJ, AB and EvL) and checked for accuracy by a fourth reviewer (VS). For dichotomous data, we planned to perform meta-analyses and present the results using a summary risk ratio with 95% confidence intervals. For continuous data we planned to present the mean difference with 95% confidence intervals. Due to the differing types of interventions evaluated in the individual studies, individual study results could not be pooled statistically in this review. A narrative synthesis of the results is provided instead.

Findings

Results of search and selection strategy

In total, 821 citations were identified using the designed search strategy. After removing duplicates, 799 unique citations were screened by title and abstract by two members of the team, and 784 were excluded. The reference lists of all remaining papers were checked for any additional relevant papers, but none were found. Full-text papers of the remaining 15 citations were read and 12 of these were subsequently excluded (7 had no intervention, 3 did not focus on VBAC, 1 was outside the topic, and 1 was excluded as it focused on clinician-

centered interventions for increasing VBAC rates) (Table 1). This resulted in three papers meeting the inclusion criteria for this review (Figure 1, Table 2). Final decisions on included papers were made by authors CN, IL, VS and CB.

Table 1. Papers excluded from the systematic review

Barakat, R., Pelaez, M., Lope, z C., Montejo, R., Coteron, J., 2012. Exercise during pregnancy reduces the rate of cesarean and instrumental deliveries: results of a randomized controlled trial. Journal of Maternal-Fetal and Neonatal Medicine 25, 2372-2376.

Bernitz, S., Aas, E., Øian, P., 2012. Economic evaluation of birth care in low-risk women. A comparison between a midwife-led birth unit and a standard obstetric unit within the same hospital in Norway. A randomised controlled trial. Midwifery 28, 591-599.

Cromi, A., Ghezzi, F., Uccella, S., Agosti, M., Serati, M., Marchitelli, G., Bolis, P., 2012. A randomized trial of preinduction cervical ripening: dinoprostone vaginal insert versus double-balloon catheter. American journal of obstetrics and gynecology 207, 125 e121-127.

Crowther, C.A., Dodd, J.M., Hiller, J.E., Haslam, R.R., Robinson, J.S., 2012. Planned vaginal birth or elective repeat caesarean: patient preference restricted cohort with nested randomised trial. PLoS medicine 9, e1001192.

Eden, K.B., Dolan, J.G., Perrin, N.A., Kocaoglu, D., Anderson, N., Case, J., Guise, J.M., 2009. Patients were more consistent in randomized trial at prioritizing childbirth preferences using graphic-numeric than verbal formats. Journal of clinical epidemiology 62, 415-424 e413.

Emmett, C.L., Montgomery, A.A., Murphy, D.J., 2011. Preferences for mode of delivery after previous caesarean section: what do women want, what do they get and how do they value outcomes? Health expectations: an international journal of public participation in health care and health policy 14, 397-404.

Flamm, B.L., Geiger, A.M., 1997. Vaginal birth after cesarean delivery: an admission scoring system. Obstetrics and gynecology 90, 907-910.

Hashima, J.N., Guise, J., 2007. Vaginal birth after cesarean: a prenatal scoring tool. American Journal of Obstetrics & Gynecology 196, e22-23.

Hollinghurst, S., Emmett, C., Peters, T.J., Watson, H., Fahey, T., Murphy, D.J., Montgomery, A., 2010. Economic Evaluation of the DiAMOND Randomized Trial: Cost and Outcomes of 2 Decision Aids for Mode of Delivery among Women with a Previous Cesarean Section. Medical Decision Making 30, 453-463.

Law, L.W., Pang, M.W., Chung, T.K, Lao, T.T., Lee, D.T., Leung, T.Y., Sahota, D.S., Lau, T.K., 2010. Randomised trial of assigned mode of delivery after a previous cesarean section-impact on maternal psychological dynamics. The journal of maternal-fetal & neonatal medicine: the official journal of the European Association of Perinatal Medicine, the Federation of Asia and Oceania Perinatal Societies, the International Society of Perinatal Obstet 23, 1106-1113.

McLachlan, H.L., Forster, D.A., Davey, M.A., Farrell, T., Gold, L., Biro, M.A., Albers, L., Flood, M., Oats, J., Waldenström, U., 2012. Effects of continuity of care by a primary midwife (caseload midwifery) on caesarean section rates in women of low obstetric risk: the COSMOS randomised controlled trial. BJOG: An International Journal of Obstetrics & Gynaecology 119, 1483-1492.

Thubisi, M., Ebrahim, A., Moodley, J., Shweni, P.M., 1993. Vaginal delivery after previous caesarean section: is X-ray pelvimetry necessary? British journal of obstetrics and gynaecology 100, 421-424.

Two studies (Shorten et al., 2005; Montgomery et al., 2007) evaluated the effectiveness of decision aids for mode of birth in women with a previous CS and one evaluated the effectiveness of an antenatal education programme (Fraser et al., 1997).

Figure 1. Flow-diagram of the selection and search process

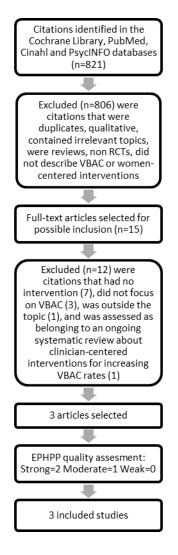


Table 2. Papers included in the systematic review

Fraser, W., Maunsell, E., Hodnett, E., Moutquin, J.M., 1997. Randomized controlled trial of a prenatal vaginal birth after cesarean section education and support program. Childbirth Alternatives Post-Cesarean Study Group. American Journal of Obstetrics and Gynecology 176, 419-425.

Montgomery, A.A., Emmett, C.L., Fahey, T., Jones, C., Ricketts, I., Patel, R.R., Peters, T.J., Murphy, D.J., 2007. Two decision aids for mode of delivery among women with previous caesarean section: randomised controlled trial. BMJ (Clinical research ed) 334, 1305.

Shorten, A., Shorten, B., Keogh, J., West, S., Morris, J., 2005. Making choices for childbirth: a randomized controlled trial of a decision-aid for informed birth after cesarean. Birth (Berkeley, Calif) 32, 252-261.

Description of included studies

Decision aids for women

Montgomery et al. (2007) compared two computer-based decision-aids with usual care. Participants were pregnant women (n=742) with a caesarean section in their last pregnancy and expecting to birth their babies at or after 37 weeks gestation. The intervention groups received either an information programme or individualised decision analysis via a laptop. The information programme provided women with evidence-based information on the probabilities of outcomes for the mother and baby associated with planned vaginal, and elective and emergency caesarean births. Women allocated to the individualised decision analysis also received information on the outcomes for mother and baby associated with the different modes of birth but probabilities were not explicit. The control group received usual care given by the obstetric and midwifery team and both intervention groups also continued to receive usual care. Women rated the value they attached to each outcome and these ratings were combined with the outcome probabilities to derive a preferred mode of birth. The primary outcomes were women's decisional conflict and mode of birth.

Shorten et al. (2005) evaluated the effectiveness of a decision-aid booklet for pregnant women with one previous caesarean section. Women allocated to the intervention group received a 'decision-aid booklet' at 28 weeks gestation containing evidence-based information. As in the information programme in Montgomery et al. (2007), the decision-aid included explicit probabilities and women's value ratings on the risks and benefits of possible modes of birth. The control group received usual care. Primary outcome measures were knowledge, decisional conflict, postnatal satisfaction and mode of birth.

Antenatal education programme for women

Fraser et al. (1997) compared written information with an antenatal education programme. Participants were pregnant women with one previous caesarean section who were at less than 28 weeks gestation (n=1301) on recruitment. Women in the written information group received information on the benefits of vaginal birth over elective repeat caesarean section. Women in the education programme received two individualised sessions focusing on predisposing, enabling, and reinforcing factors for VBAC. Enabling factors, for example, included informing women of recommendations favouring VBAC and of probability of planned VBAC at her local centre. The primary outcomes were VBAC and attempted VBAC.

Methodological quality of included studies

The nature of the intervention made it impossible, practically, to blind either the clinician or the participating woman to her allocation. Therefore, a lack of blinding was not considered to undermine the quality of the included studies. Montgomery et al. (2007) had a high rate of recruitment and a low loss to follow-up, resulting in a relatively large sample of 742 (although

data were only available on 713). Participants were slightly older and less deprived than women who did not consent to join the study, which affects the ability to generalise. Although the study was rated as methodologically strong, implementation issues meant that the decision aid could not be provided through the internet, but had to be accessed through a computer held by the researcher, which may have limited the participants' access and affected the results. The study by Shorten et al. (2005) had a smaller sample size (n=227) but a high response rate (90%), and overall received a 'strong' methodological quality rating. Fraser et al.'s study (1997) had the largest sample size (n=1301), but the withdrawal of 26 women's data for various reasons led to an increased risk of selection bias. Despite this, the study rated as 'moderate', as all other key methodological aspects were of a high standard. Table 3 below provides the overall category scores and global quality rating for each individual included study. Following the quality assessment procedure, all studies remained eligible for inclusion.

Table 3. Results of the methodological quality appraisal of the included studies

Component	Montgomery	Shorten	Fraser
Selection Bias	Strong	Strong	Weak
Allocation Bias	Strong	Strong	Strong
Confounders	Strong	Strong	Strong
Blinding	Weak	Strong	Weak
Data Collection Methods	Strong	Strong	Strong
Withdrawals & Drop-outs	Strong	Strong	Strong
Analysis: Intention to treat	Strong	Moderate	Strong
Intervention integrity: % of participants that received	Strong Strong		Strong
allocated intervention			
Global Quality Score	Strong	Strong	Moderate
Include Study	Yes	Yes	Yes

Effects of interventions

Interventions evaluated in the studies included decision-aids with information and explicit probabilities of outcomes with value exercises (Shorten et al., 2005), information and explicit probabilities of outcomes without value exercises (Montgomery et al., 2007), information and value exercises without explicit probabilities (Mongomery et al., 2007) and an antenatal education programme (Fraser et al., 1997). We did not therefore regard interventions to be sufficiently similar to ensure meaningful conclusions from a statistically pooled result.

Therefore a narrative synthesis of results is reported by presenting the major outcomes and results, organised by intervention categories. All studies reported on VBAC rates as the primary outcome. In this review, we report on our primary outcome of interest (i.e. incidence of VBAC) and on our secondary outcomes of rate of decisional conflict and knowledge about birth choices only. For our remaining pre-specified secondary outcomes, data were reported variously, not measured in the included studies, or too limited to allow us to report in the review.

Decision-aids versus usual care

Montgomery et al. (2007) compared an information programme and an individualised decision analysis with usual care. There was no statistically significant difference in the proportion of women giving birth vaginally between women allocated to decision analysis (37%) and women allocated to usual care (30%) or between women allocated to the information programme (29%) and usual care (30%) (Figure 2).

Figure 2. Intervention effects for outcome 'vaginal birth after caesarean section (VBAC)' (comparison with usual care)

	Experimental		Control		Risk Ratio	Risk Ratio		
Study or Subgroup	Events	Total	Events	Total	M-H, Fixed, 95% CI	M-H, Fixed, 95% CI		
1.1.1 Information programme								
Montgomery et al 2007	70	201	72	201	0.97 [0.75, 1.27]	 		
1.1.2 Individualised decision analysis								
Montgomery et al 2007	88	198	72	201	1.24 [0.97, 1.58]	 		
						0.5 0.7 1 1.5 2		
						Favours control Favours experimenta		

Compared with usual care, women in both intervention groups had significantly lower decisional conflict scores (information group -6.2, 95% CI -8.7 to -3.7; decision analysis group -4.0, 95% CI -6.5 to -1.5).

Shorten et al. (2005) evaluated the effectiveness of a decision-aid booklet with usual care. Women in the decision aid group had significantly higher mean changes in knowledge scores (1.73, 95% CI 1.08–2.37) and significantly lower decisional conflict scores (-0.32, 95% CI - 0.50, -0.14) than women in the control group.

The authors report that there were no significant differences between groups on 'rate of uptake' of trial of labour or elective repeat CS; however, data are not presented on these outcomes in a format that allows identification of effects between the groups to which women had been randomised.

Antenatal education programme versus written information

Fraser et al. (1997) compared written information with an antenatal education programme. There was no significant difference between the written information and antenatal education groups in the proportion of women having a VBAC (49% and 53% respectively, relative risk (RR) 1.08, 95% confidence interval (CI) 0.97 to 1.21) or attempting a VBAC (67% and 73% respectively, RR 1.05, 95% CI 0.97 to 1.12).

Discussion

The general strengths of the systematic review method are that it synthesises all the available research information in one area for the convenience of readers and for a greater understanding of the totality of the evidence on that topic. The main weaknesses are that reviewers are dependent on the quality of the data that exist, the way in which they were gathered, and on the study researchers' interpretation. Our search strategy led to a large number of hits, indicating good sensitivity. However, only three studies were found that met our inclusion criteria, limiting the conclusions that could be drawn from the review. A further limitation of the review was that, because the interventions in the three studies were not sufficiently similar to ensure meaningful conclusions from a statistically pooled result, only a narrative synthesis could be reported.

There are few studies evaluating the effects of interventions focused on women to increase VBAC rates. The findings demonstrate that the use of decision aids and information programmes do not have a significant effect on VBAC rates. Nevertheless, decision-aids and information programmes significantly decrease women's decisional conflict about mode of

birth, and significantly increase their knowledge about the risks and benefits of possible modes of birth, and are thus of value.

Our findings are consistent with those of a recent systematic review on interventions to support women's decision-making about VBAC (Horey et al., 2013), which includes the same three studies from UK, Canada and Australia. It is notable that we did not find any additional studies focusing on childbirth, rather than pregnancy, and none from outside those three English-speaking developed countries. In addition, we found no research looking at any method of increasing VBAC rates other than by supporting women's decision-making. These findings highlight the need for a wider research agenda, that includes research on other women-centred methods aimed at improving VBAC rates. Horey et al. (2013) promote the need for more research focusing on interventions intended to help with shared decision making between pregnant women and their health professionals. We support this conclusion and would also recommend studies from different countries with different decision-making processes.

Another Cochrane Review on interventions for reducing unnecessary caesarean sections (both primary and repeat) (Khunpradit et al., 2011), also demonstrated a lack of high-quality evidence on how to increase VBAC rates. In this review, Khunpradit et al. (2011) found that most studies were targeted at health personnel, with limited evidence of women-focused interventions for improving VBAC rates. Few studies on women's experiences of VBAC appear to have been performed. Of those that have been conducted, most are of Anglo-American origins where VBAC rates generally are low: 33% in England, Wales and Northern Ireland (Thomas and Paranjothy, 2001) and below 10% in the US (ACOG and SMFM, 2014),

compared with countries such as Sweden, the Netherlands and Finland, with rates from 45-55% (EURO-PERISTAT, 2008). Australia has a similarly low rate of 25%, based on a five-year review of statistics from 11 major obstetric units (Appleton et al., 2000).

Findings from a metasynthesis on studies from the UK, US and Australia (Lundgren et al., 2012), show that women felt uncertainty and anxiety in relation to their choice of VBAC, and experienced professionals as mostly non-supportive towards VBAC. The findings indicate that women tend to be alone in their expectations for a vaginal birth, and unsupported with their decisions around childbirth. This might, in part, explain the generally low VBAC rates in these countries. A qualitative study from Australia (Godden et al., 2012) that explored the experiences of women participating in a midwife-led service during pregnancy, with the purpose of promoting VBAC, demonstrated that women felt supported by midwives in the team. However, the women stated their need to have supportive midwives and physicians also during birth as an important factor for whether a VBAC was actually accomplished and this was dependent on the admitting staff on a given day (Godden et al., 2012). Other contributory factors for achieving a VBAC were to offer special birth preparation classes for women with a history of CS, opportunities to meet other women with experience of VBAC, empower women's partaking in decision-making, stimulate women to write a birth plan, and make sure that all maternity caregivers promote VBAC (Godden et al., 2012).

Moreover, other women-focused interventions shown to be effective in reducing CS rates (even though the randomised controlled trials were small in size), were nurse-led relaxation classes and birth preparation classes targeted towards women with fear of childbirth in their first pregnancies (Khunpradit et al., 2011). In some of the Nordic countries where the VBAC

rates generally are high (e.g., Finland and Sweden), special 'fear clinics' have, for the past 20 years, been available to pregnant women with intense fear of childbirth (Ryding et al., 2003). At these clinics women can discuss their fears and mode of birth during face-to-face meetings with specially educated midwives. The clinics are known well to both women and care providers. For women requesting a repeat CS because of fear related to a previous negative birth experience that ended up in an emergency CS, individualised meetings can be of help and result in a withdrawal of CS requests (Ryding et al., 2003; Wiklund et al., 2012). The evidence demonstrates an obvious reduction of requests for CS in various kinds of support programmes for women with fear of birth (Sjögren and Thomassen, 1997; Nerum et al., 2006). However, the actual effects on women's fear are, as yet, unclear (Hildingsson et al., 2011). These studies demonstrate that successful women-centred interventions do exist, extend beyond just supporting women in their decision-making, and need to be researched. In addition, an on-going study from Australia will show if continuity of care during pregnancy and childbirth will impact decision making in the next birth after caesarean section (Homer et al., 2013); this will provide information on a women-centred intervention during birth, which at present is lacking.

Conclusions

Few studies have evaluated the effectiveness of women-centred interventions designed to improve VBAC rates, and all interventions were applied in pregnancy only, none during the birth. Decision-aids and information programmes should be provided for women as, even though they do not affect the rate of VBAC, they decrease women's decisional conflict and increase their knowledge about possible modes of birth. There is an urgent need to develop

and evaluate the effectiveness of all types of women-centred interventions during pregnancy and birth designed to improve VBAC rates.

Competing interests

The authors declare that they have no competing interests.

Details of ethics approval

As this review was based on data from published literature, ethical approval was not required.

Authors' contributions

All authors have made substantial contributions to all of the following: (1) the conception and design of the study, or acquisition of data, or analysis and interpretation of data, (2) drafting the article or revising it critically for important intellectual content, (3) final approval of the version submitted.

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