Reviewer's report

Title: The impact of a computerized decision aids on vaginal versus cesarean section delivery - Study protocol for a randomized controlled trial

Version: 2 Date: 10 November 2014

Reviewer: Dell Horey

Reviewer's report:

Major compulsory revisions
1. This protocol seeks to test a decision aid that intends to “help pregnant women in making decisions about vaginal versus caesarean section delivery”. The primary outcomes are decisional conflict and knowledge, with the sample size calculation based on a decrease in decisional conflict of 15%. The implied purpose of the study is to address the rising caesarean birth rates in Iran. The authors attribute maternal request as the main reason for the increase in caesarean sections citing a Chilean study (Angeja et al 2006) that doesn’t actually support this claim; yet the cited survey showed the majority of Chilean women do not prefer caesarean section to vaginal delivery and offers no evidence to show that maternal request is a major contributor to high caesarean delivery rates. Systematic and other reviews have concluded that only a minority of women indicate preference for caesarean delivery, particularly in the absence of clinical indicators. See Mazzoni 2010, Kaimal 2012, McCourt 2007, Gamble 2007, Weaver 2007 and Kingdon 2006. The authors need to find evidence to support their claim.

2. The proposed trial faces challenges in addressing the hypothesis that the authors have posed. They assume that maternal demand and high levels of decisional conflict correspond to high rates of caesarean delivery but have not provided evidence to support either assumption. Women asking for caesarean delivery may be certain that they have made the right decision and so their decisional conflict will be low. Introducing a decision aid may increase knowledge and may also increase decisional conflict if women become more uncertain about their preference. An important clinical outcome would be to reduce unnecessary caesareans without increasing decisional conflict. Based on the criteria used in the Cochrane review, the proposed intervention would be described as an independent decision support. Evidence is needed on the use of shared decision support interventions. The authors contend that based on decision theory the intervention will encourage discussions between women and their care providers but it is not clear whether they intend to assess whether this actually occurs. It would useful to establish if, and how, decision aids change behaviours related to decision-making. The authors need to consider how they will address their hypothesis if existing decisional conflict levels are low and how they will demonstrate the relationship between decisional conflict and caesarean delivery rates.
3. There is insufficient information to determine whether the trial is feasible. The authors propose a sample size of 400 women requesting a caesarean delivery without clinical indication. The authors refer to a cross-sectional study but do not include enough information to determine the feasibility of achieving the required sample size. We are not told how many births occur annually across the four proposed study sites or given any baseline data relating to either demands for caesarean delivery without clinical indication or prevalence of decisional conflict about mode of birth decisions. The authors need to provide information so that these assessments can be made.

Minor essential revisions

4. The protocol needs copy-editing. Apart from issues with English expression the use of tenses is inconsistent, and changes from future to past tense throughout. This makes it unclear at time as to whether events have occurred or not.

Discretionary revisions

5. The authors allude to shared decision-making between women and their health care providers or practitioners but there is no provision in the trial to determine if shared decision-making occurs. The proposed decision-aid is to be used by women in their homes. In the Cochrane review on decision support for mode of birth after caesarean, we classified these as “independent” decision support (see Horey 2013). We found no studies that assessed “shared” decision support, which would be a useful area to study. The decision aid described in this protocol would not be considered a form of shared decision support as clinicians are not involved in the decision-making to be assessed. The protocol does not indicate any intention to determine whether women in the intervention group use information from the decision aid in their discussions with their health practitioner. It would be useful to know if the use of independent decision aids actually facilitates discussions between women and their care providers. This may require a cluster RCT to overcome potential contamination. It is useful to remember that Shorten (2005) found that even if women’s preferences changed when they used a decision aid, other factors, such as the hospital where they gave birth, were more likely to determine actual mode of birth.

References


Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Needs some language corrections before being published

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

I declare that I have no competing interests