Reviewer’s report

Title: IDEAS for a Healthy Baby: Rationale and design of a randomized controlled intervention trial of patient navigators to assist low-income pregnant women in using publicly reported pediatric quality data

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Reviewer: Audrey Prost

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I think that the manuscript would benefit from minor revisions along the following lines:

1. Revising the abstract

The objectives of the study are less clearly specified in the abstract than they are in the section entitled 'Study objectives'.
I would encourage the authors to use the section in the main body of the text in the abstract too (especially for objectives 2 and 3), for greater clarity.

2. Giving more background on the US health system and how it might shape the delivery and impact of the intervention

Trials is an international journal and many readers may not be familiar with the US health system and the authors' local context.

The authors may wish to clarify the following issues:

- The article states that 89% of the Baystate prenatal clinic attendees are insured through Medicaid. What are the implications of this for patients' choice of paediatric care providers (and therefore the impact of the intervention)? Are they eligible to go to any of the clinics appraised for quality by MHQP within 25 miles of Baystate? Your comments about barriers seem to suggest that insurance conditions may apply. Are you referring to the mothers on Medicaid or others? What might these restrictions be?
- Does the MHQP website provide quality scores for all paediatric clinics within 25 miles of Baystate? If not, might some of your patients go to clinics without MHQP scores and how would you account for them in your analyses?
- The authors sometimes refer to patients as 'consumers', and sometimes as 'patients'. Again, this may reflect a US understandings of a health system and appear strange to non-American readers. While it is not my place to comment on which term is more suitable, I would suggest using one term consistently throughout the article.

3. Giving more details on the intervention

3a. Who will deliver it and how? While the conceptual framework for the
intervention is clear, the actual delivery needs further description. The protocol does not specify whether the 'patient navigator' is a person or a thing (!). If it is a person, who are they, what level of training and socio-economic background will they have? Will they be from the same background as the patients attending? Just how much influence will they be allowed to have on a patients' thinking in relation to choosing a provider of paediatric care: are they simply showing quality scores, or are they actively discussing scores and individual practices with patients? The section on Support in Table 2 suggests that the 'navigator' will encourage mothers to think about choosing a quality provider with the same importance as other parenting decisions (e.g. Circumcision), but the main manuscript suggests that participants (patients?) will complete a worksheet with tables of scores for the practices they review, which sounds rather more involved. What will the navigators actually do in the Support phase, and how much will they be able to influence patients' choices?

3b. How much will the intervention cost? While I recognise that doing a full cost-effectiveness evaluation of the intervention may be beyond the scope of this trial, presumably any efforts to scale up the intervention if the trial is successful will require understanding (a) who can provide such an intervention – see above – and (b) how much it costs? Shouldn't documenting costs be part of this study? If the authors do not plan to do it, perhaps they could say so in the limitations section?

4. Power of the study to test hypotheses related to secondary objectives
The study design appears adequate to test the primary hypothesis that the intervention will lead to higher mean quality scores for pediatric centres chosen by women who received the intervention compared to those in a control arm. However the ability of the study to test further hypotheses linked to the trial's secondary aims is less clear. Will the research team be able to detect significant differences in quality scores or patient experience ratings in so many sub-group analyses (parity categories; literacy; ethnicity)? This may be worth checking and specifying, and if it is possible that you will have sufficient power to detect differences in sub-groups, the authors could acknowledge this in the limitations.

5. Issues related to the analyses for the main outcomes
• What is the primary outcome of the trial? Is it the mean of two mean scores (clinical quality and patient experience) or one of these two scores? The primary outcome should be clearly stated in the abstract, in the first sentence in 'study objectives' and in the section entitled 'Primary Outcome'.
• How often are the MHQP quality scores revised? If the trial recruitment period extends over 18 months, is it possible that the MHQP scores for individual clinics will change over time? Are the authors intending to use the MHQP score either at the time of delivery or in the neonatal period (which would make sense)? It would be good to pre-specify this.
• Although patients attending the prenatal clinic are randomised individually, there are potential sources of clustering in the outcome data: for example, patients residing within a particular area may be more likely to access clinics
within that area too, reducing the possible variability in responses/quality scores. Has any thought been given to clustering in the data for the analysis? Is area of residence one of the maternal characteristics you would consider adjusting for in the final analyses?

Declaration of competing interests:
I do not have any competing interests in relation to the manuscript.