Author’s response to reviews

Title: The ELSIPS trial: Evaluation of Lay Support In Pregnant women with Social risk: a randomised controlled trial.

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Reviewer: Edwin van Teijlingen

We thank the reviewer for his helpful comments. We addressed them point by point below.

The researchers provide generally a good outline for the research with appropriate justification why multiparae women are excluded.

1. Abstract: The sentence about why the trial has a qualitative research element is vague / not explaining why this method has been chosen.
We have added more detail:
Qualitative research will explore the POWs’ daily work in context. This will complement the findings of the RCT through a triangulation of quantitative and qualitative data on the process of the intervention, and identify other contextual factors that affect the implementation of the intervention.

2. Abstract: Not sure what to envisage for the expression ‘women from a multi-ethnic background’? Does it refer to women with more than one ethnic background hence ‘multi’? For example, White mother and Afro-Caribbean father? It is obviously different from women from an ethnic-minority background, otherwise surely the researcher would have used the expression ethnic minority women, or the more common in the UK and more politically correct ‘women from BME communities’ (Black and Minority Ethnic groups). This expression multi-ethnic background is probably unclear for the international readerships of BMC Pregnancy & Childbirth.
We have clarified the background to the abstract. We have re-written the section so that it refers to women from black and ethnic minority groups, but have retained the reference to multi-ethnic populations to describe the setting where the research took place. The section now reads:

Maternal, neonatal and child health outcomes are worse in families from black and ethnic minority groups and disadvantaged backgrounds. There is little evidence on whether lay support improves maternal and infant outcomes among women with complex social needs within a disadvantaged multi-ethnic population in the UK.


Thank you – we have made this correction.


This is now spelled out in full at the top of page 4.

5. Page 6: Give in full BMI & DNA

These are both given in full on page 6.

6. Page 12: The researchers make a rather sweeping statement about the limitations of formal interviews: “tends to reproduce the ‘theory’ about the role, idealised accounts and retrospective explanations about action…” without providing a reference to a methodological text to back up this statement.

We have toned down the statement and included a reference about the value of observational data in relation to other forms of data collection in the health research field (now on page 13).

We have chosen to avoid formal interviews of the POWs about their work these can reproduce the ‘theory’ about the role, idealised accounts and retrospective explanations about action (Pope 2005, Diefenbach 2009) and is therefore less likely to be able to fully uncover any disjunction between the process information collected about their work and the complexity of daily practice.

7. Page 13: It is unclear from the ‘Data collection statement’ whether two researchers together will observe /shadow one POW at the time, to benefit from their combined professional perspectives, or whether the social researcher and the clinical researcher will each separately shadow different POW at the same time. The former could lead to overcrowding (two people shadowing one POW), the latter could mean different researchers interact differently with different POW they shadow. I assume the procedure is the latter as under ‘Recruitment’ is a statement “..accompanied by a researcher…”

Only one researcher will observe any one POW/client interaction. We have clarified this by stating that the researchers will singly observe the POWs. The section now reads:

Two researchers (one social scientist, one clinical researcher) will singly observe
POWs undertaking their daily work, including meetings with clients, until theme saturation is achieved. It is anticipated that this will take approximately 100 hours.

8. Figure 1 needs legend for abbreviations; MW and POW
   These have now been added.

9. Check list of abbreviations for completeness, I noticed that BMI, MW are missing.
   We have added BMI, MW and NIHR to the list of abbreviations.