Reviewer's report

Title: Involving seldom-heard groups in a PPI process to inform the design of a proposed trial on the use of probiotics to prevent preterm birth: a case study

Version: 0 Date: 02 Mar 2017

Reviewer: Gill Norman

Reviewer's report:

This is clearly written and provides a good summary of the PPI activity undertaken. I would have liked to see a more specific discussion of the impact of the PPI on the trial; I kept waiting for the impacts to be detailed and reached the end of the paper without feeling that I really knew precisely what the outcome was in terms of design and implementation of the trial protocol. The issues raised would clearly affect recruitment of pregnant women and a point by point discussion of how the presentation of the trial recruitment will be tailored would make this paper significantly more relevant. At the moment it has methodological and qualitative interest but it has the potential to also provide additional value to the design of quantitative trials, at the moment it doesn't guide a reader who wishes to find this information. If protocol/participant information and recruitment amendments have not yet been made then a paragraph outlining potential alterations/methods of incorporating the valuable information from this exercise could be provided.

In terms of the participants it was good to see their interest in continuing involvement - were any other impacts of involvement on the participants documented?

I was interested in the concept of safety concerns in pregnancy and would have been interested to know whether there was any exploration of the ways in which adverse pregnancy outcomes would be perceived by women in the trial. The intervention begins early in pregnancy and a significant proportion of pregnancies would therefore be expected to end in miscarriage. Women often look for explanations of pregnancy loss and engage in self-blame for all kinds of behaviours which almost certainly have no causal link to the loss - I would have anticipated that taking tablets in a trial may be one of these scrutinised behaviours. (I'd also wondered if the issue of PNV impacting adherence had arisen?)

Very minor point: There is a typo on line 264 - "women of West African women" should I think read "women of West African origin/background"?
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I am employed by the university of manchester; my research is funded by an NIHR grant to Cochrane Wounds. I am an unpaid director of Antenatal Results and Choices (ARC); this charity receives a small payment from UCL for my role as a PPI advisor to the GIFTsurg project (funded by Wellcome).

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