Reviewer's report

Title: PRISM (Program of Resources, Information and Support for Mothers) Protocol for a community-randomised trial [ISRCTN03464021]

Version: 3 Date: 29 August 2003

Reviewer: Ann Oakley

Reviewer's report:

This protocol describes the methodology and scientific rationale of a project aimed at reducing the incidence of an important, and under-researched, public health problem: low emotional well-being among mothers. The rationale is sound, and the authors draw very ably on existing literature relating to interventions in this area and to methods of designing and implementing RCTs of complex interventions in community settings using a cluster approach. There is currently a good deal of interest among health service researchers (and funders) in the scientific and ethical challenges of such studies; this makes PRISM an exciting project with a methodological interest going well beyond the topic field.

The protocol is well written and sufficiently detailed to allow similar studies to be modelled on this basis.

I have these substantive comments.

1. I would like the authors to consider supplementing the 'intention to treat' with an 'on treatment' analysis. Social interventions of this type in this kind of population often have problems of low uptake, which complicates a straightforward intention-to-treat analysis. Using both approaches, the authors would be able to address both pragmatic questions (do women use these strategies in practice?) and scientific questions about effectiveness (do these strategies actually work?)

2. The process evaluation will include the collection of data from mothers. But is there any formal plan to involve a sample of mothers more directly in the design of the evaluation? This is generally regarded to be 'good practice' these days.

3. Issues of consent are complex in a cluster trial. Strictly speaking, individual mothers do not have to consent to participate in the trial; their consent is only needed for the provision of outcome and process data. But there is an ethical argument that individual participants in cluster trials should nonetheless be informed about the design of the trial. I would like to see the authors discuss this issue, and explain / justify their position on it.

None of the above comments should be taken as requiring mandatory revisions.