Reviewer's report

Title: Randomised controlled trial evaluating the effectiveness and cost-effectiveness of 'Families for Health V2', a family-based childhood obesity treatment intervention: Study Protocol and implementation

Version: 1 Date: 18 February 2013

Reviewer: Bijan Borah

Reviewer's report:

This protocol describes a very timely and important randomized clinical trial aimed at reducing childhood obesity. The authors have done a commendable job of putting together a complex trial, which will potentially provide evidence on whether family-mediated intervention leads to weight reduction in children of age 6 to 11.

Having read the paper, it is clear that the "usual care" arm is actually not usual care in its true sense; most of the sites had one or more different weight-reduction programs that are concurrently going on, which the control subjects could potentially avail. It would be helpful to a non-UK reader to understand how each of those programs was different from the "Families for Health" program, and the participation rate in those programs by families of overweight/obese kids. It is likely that the treatment effect of the "Families for Health" program might be potentially diluted. The authors mention in the discussion section that usual care that the control subjects receive will be carefully documented. Will this information be accounted/adjusted for while estimating the treatment effect?

A key feature of the RCT was that the families are not blinded to the treatment assignment, that is, families will be aware as to whether they belong to the treatment arm or the control arm. Given this feature, I would think that attrition of subjects in the control arm is a potential concern - how are the authors going to deal with this?

The intervention is through group-based delivery with parallel session for adults and kids from 8-12 participating families. Note that the age range for kids is 6 to 11, and it is not clear from the protocol whether the instruction materials or its delivery is going to be age-appropriate. I could imagine that when there are 8-12 kids of that age range in a class for two and half hours, there could potentially be good amount of distraction. This is specifically so because the level at which the instruction/intervention might be delivered may be too advanced or too simple for some kids. Some discussion around how the authors plan on overcoming this will be helpful.