Reviewer’s report

Title: Room 4 Birth - The effect of an adaptable birthing room on labour and birth outcomes for nulliparous women at term with spontaneous labour start: study protocol for a randomised controlled superiority trial in Sweden

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Reviewer: Suneet Chauhan

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Room 4 Birth - The effect of an adaptable birthing room on labour and birth outcomes for nulliparous women at term with spontaneous labour start: study protocol for a randomised controlled superiority trial in Sweden

It is admirable that the investigators are undertaking a randomized clinical trial (RCT) with a "physiologically normal" process. Though their overarching assumptions, as outlined in the introduction, are acceptable, the authors should acknowledge the results of the multicenter RCT called ARRIVE (Grobman et al. NEJM 2008). This RCT rather convincingly noted that the rate of cesarean delivery, hypertensive disorder of pregnancy were significantly lowered with induction at 39 weeks rather than expectant management. Additionlly, the pain score, and satisfaction were substantially better with induction rather than observation. Thus, the very definition of normal labor being "starts spontaneously and ends in vaginal delivery" may be antiquated.

Nonethless, the thought process process behind the RCT is admirable and worth completing.

While revising the manuscript, please address the following:

1. Please reference "the fact that maternity wards all over the world are in need of either reconstruction or new construction of labour wards."

2. Please proived reference for the biological plausibility: "A more adaptable person-centered birthing room will facilitate and enable a healthy process and outcome of labour and birth by reducing stress and facilitating the release of endogenous oxytocin." Even if there was an increase in endogenous oxytocin, it might not translate into cervical dilation.

3. In Table 1, there seems to at least twelve differences between the old and new rooms. Thus, one is uncertain if it's the "new" room or one or a combination of the differences in the place which will translate into the change. Though the design will not change, I beliver that the changes in the new room are excessive and may diminish the generalizability of the RCT.

4. Please clarify what exactly are eligible women informed about the new room before they consent.

5. While it's understandable that if the new room is "not available," a woman cannot be consented and randomized. But, unless there is an objective oversight of "not available," there is a potential for bias. If, for example, a woman with body mass index of 50 kg/m2 is admitted in
labor, screaming, the bias could lead to the new room being unavailable though it would be in 45 min, after it's cleaned.

6. The intent to treat principle of CONSORT guideline will not permit: "If a woman, randomised to the "new room", wants to withdraw from the study at any time, she will be transferred and cared for in a regular room, and her data will be deleted." Once randomized, the outcome data must remain in the assigned group.

7. What if a woman randomized to routine room is adamant about being in the "new room?" Would she be permitted to be in the new room?

8. I have concerns about the composite primary outcome. While some are indisputable (vaginal delivery) others can be swayed in favor of intervention. What if the EBL is 999 ml in the new room and 1000 ml in the old.

9. What is the anticipated lost to follow up at 3 and 12 months? Are there planned measures to ensure the follow-up of these women?

10. For the sample size calculation, how did the investigator arrive at that it is 45% in the control group?

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