Reviewer's report

**Title:** The TURN-OUT Trial: Transverse position. Using Rotation to aid Normal birth: OUTcomes following manual rotation.

**Version:** 3  
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**Reviewer:** Ben Willem Mol

Reviewer's report:

Thanks you for providing me the opportunity to review the manuscript entitled “The TURN-OUT Trial: Transverse position. Using Rotation to aid Normal birth: OUTcomes following manual rotation.” by De Vries et al.

I am aware of the POP-out trial, and this seems to be the successor. I missed a referral to the POP-out trials, and when I searched the PDF, I found POP-out on page 6, 8, 15. Apparently, the authors have started from their previous protocol, which makes sense. I would suggest to add some experiences with POP-out in the protocol. Otherwise, I applaud that groups do similar trials one after the other; it will make studies better in design and execution.

The study is as expected well designed and fulfills major requirements for a modern trial. The discussion that I want to have with the authors is the clinical problem they are attacking.

Fetal occiput transverse (OT) position in the form of deep transverse arrest has long been associated with caesarean section and instrumental vaginal delivery 1. OT position incidentally found in the second stage of labour is also associated with operative delivery in high risk cohorts 2-3. Caesarean section is now a major contributing factor to maternal mortality and morbidity following childbirth in developed countries 4-5. Obstetric intervention by forceps and vacuum delivery is associated with complications to the maternal genital tract and neonate respectively 6-8.

So what actually is the disease. Is it Caesearean section or vaginal instrumental delivery? If that is the case, then simply do not those interventions. Just go to the beach, and count the outcomes at the end of the day. Not true obviously, as we do these interventions for a reason. I think in this category of women (laboring, singleton, cephalic) there are two main reasons for doing a C. Section, i.e. non-progressive labour and suspected fetal distress.

This is what I miss in the protocol. I think the protocol must contain a description of the indications for Caesarean and instrumental delivery, in terms of non-progressive labour and suspected fetal distress. Please define exactly when non-progressive labour and suspected fetal distress occur, according to what criteria; i.e. lack of progress in relation to syntocinon, CTG abnormalities, fetal blood sampling, ST-analysis.
This is important, as in other parts of the world Caesearean section rates are much lower. I have worked in a clinic where in a similar population (induction of labour) 1 in 3 women had the fetus in OP position at start of induction, while the SC rate in the end was below 10%. Nobody in that study did a manual rotation. So what is the clinical problem we are talking about? (Eur J Obstet Gynecol Reprod Biol. 2012 Oct;164(2):133-7.

Verhoeven CJ1)

Other suggestions

Primary objectives is defined as “to determine differences between intervention and control groups in. “ I would replace that by “to assess whether rotation reduces instrumental delivery with 18% from …. To %. An objective of a study is not to determine a difference, it is to test an hypothesis.


For table 1; please calculate Relative Risks and 95% CI, not P-values

Explain how the sham procedure is carried out.

“ However, if the doctor is intending to perform an operative delivery or a manual rotation, the woman will not be randomised.” I would propose to ban manual rotation outside the trial. How can you perform an invasive and potentially hazardous intervention if at the same time you question its effectiveness and do a trial.

Page 12: time from intervention or sham until delivery (median); I would suggest time from randomisation until delivery (median)

Leave out all the questionnaires as endpoint; unnecessary effort for the women and the team. If the intervention reduces CS, you should do it, independent on the outcome of the questionnaires.

6 and 12 months will never be different; as tis will be unrelated to the intervention; I would suggest to leave them out. RCTs should be slim.

Consider to follow the whole cohort that gets an ultrasound

As randomisation is stratified, analysis must be stratified, too.

I would reconsider the logistic regression analysis. Groups will be comparable for baseline characteristics. The building of a prognostic model is another issue. If the authors aim subgroup analysis, than limit the number of variables.

Assessment of effectiveness due to operator ability based on the distribution of success of the operator in the study will be a self fulfilling prophecy. Those with a low success rate will be less effective.
I would leave the statements on interim analysis and stopping rules out of the protocol, and formulate them in an independent statistical addendum. It is a bit unspecific.

Reference 12 is J Matern Fetal Neonatal Med; not AJOG