Author’s response to reviews

Title: Transverse position. Using Rotation to aid Normal birth: OUTcomes following manual rotation (TURN-OUT): study protocol for a randomized controlled trial

Authors:

Bradley S de Vries Dr (bradley.devries@sswahs.nsw.gov.au)
Hala N/A Phipps Mrs (hala.phipps@sswahs.nsw.gov.au)
Sabrina N/A Kuah Dr (sabrina.Kuah@health.sa.gov.au)
John N/A Pardey Dr (john@pardey.com.au)
Joanne N/A Ludlow Dr (Joanne.ludlow@sswahs.nsw.gov.au)
Andrew N/A Bisits Assoc Prof
(Andrew.Bisits@SESIAHS.HEALTH.NSW.GOV.AU)
Felicity N/A Park Dr (felicit@med.usyd.edu.au)
David N/A Kowalski Dr (dkowalski@optusnet.com.au)
Jon A Hyett Prof (Jon.hyett@sswahs.nsw.gov.au)

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Author’s response to reviews:

1st June 2015
Dear Editor,

We thank the reviewer for his comments dated 5th April 2015 and apologise for the delayed response (we missed the original Email).

We agree with the reviewer that it makes sense to have prolonged second stage of labour as an outcome because it may better reflect the underlying pathology (eg presumed cephalopelvic disproportion). We have therefore adjusted the protocol to include a new secondary outcome of prolonged second stage.

However, we would like to keep operative delivery as our primary outcome because (1) It is a clear cut outcome which is not susceptible to measurement error; (2) it is an important outcome for the women themselves; (3) it is the same outcome used for our previous trial of manual rotation for occiput posterior position, which will make the trials more comparable; and (4) we believe many readers will consider this to be a more important clinical outcome. However, the reader will also be able to compare prolonged second stage of labour between the two groups.

For purposes of the TURN-OUT Trial, operative delivery for suspected fetal compromise will be defined as:

“Operative delivery in the presence of a pathological CTG according to NICE guidelines, a fetal scalp lactate > 4.8, or a fetal scalp pH < 7.2.”

Operative delivery for prolonged second stage will be defined as:

“Operative delivery with > 1 hour of second stage (for parous women no
epidural), > 2 hours (for nulliparous women with no epidural or parous women with an epidural), or >3 hours (for nulliparous, women with an epidural).

If the criteria for both operative delivery for suspected fetal compromise and operative delivery for prolonged second stage are both met, then the operative delivery will be classified as “for prolonged second stage”.

If operative delivery occurs and neither criteria are met (eg for “maternal request” or for “maternal exhaustion”) then the reason for operative delivery will be classified as “other”.

We have adjusted the protocol to reflect this.

Yours Sincerely,

Brad de Vries