Author’s response to reviews

Title: The M@NGO (Midwives @ New Group practice Options) Study: a randomised controlled trial of caseload midwifery care

Authors:

Sally K Tracy Prof (sally.tracy@sydney.edu.au)
Donna Hartz Ms (donna.hartz@sydney.edu.au)
Bev Hall Ms (beverley.hall@sydney.edu.au)
Jyai Allen Ms (jyai.allen@mater.org.au)
Amanda Forti Ms (amanda.forti@mater.org.au)
Anne Lainchbury Ms (anne.lainchbury@sesiahs.health.nsw.gov.au)
Jan White Ms (jan.white@sesiahs.health.nsw.gov.au)
Alec Welsh Prof (alec.welsh@unsw.edu.au)
Mark Tracy Dr (mark.tracy@swahs.health.nsw.gov.au)
Sue Kildea Prof (sue.kildea@acu.edu.au)

Version: 2 Date: 15 August 2011

Author’s response to reviews: see over
15th August 2011

The Editor
BMC Pregnancy and Childbirth

Please find our paper attached - a Protocol – outlining the methods and conduct of a randomised controlled trial of caseload midwifery care in Australia.

The following details are now submitted for your approval.

Requesting Proofs of Funding and Ethical Approval

Provide a list of any manuscripts that are under submission with other journals based on this study protocol?

No other submissions have been made or are under review based on this study protocol.

The trial is funded through a Project Grant from the National Health and Medical Research Council of Australia: 2007-2011 NHMRC 510207 Tracy SK Chapman M Peek M Tracy MB Homer C Kildea S. Project Grant. A randomised controlled trial of caseload midwifery care. Total: $572,000.00

The Trial is registered with the Australian New Zealand Clinical Trials Registry: ACTRN12609000349246

The following Human Research Ethics Committee (HREC) approvals have been given:

University HREC approvals

University of Technology Sydney HREC approval received 8th April 2008: UTS HREC REF NO. 2008-53A

University of Sydney HREC approval received 27th July 2009 REF NO 12068

Hospital HREC Approvals

Hawkesbury NSCCAHS approval (covering RHW) received 25th September 2008 REF NO 0805072M
Northern Network: SSA approval (for RHW) received 27th October 2009 REF NO SSA 08/127 AU RED Ref N/A
HREC Reference: 08/HAWKE/34
Amendments with the addition of questionnaires
Lead HREC site Hawkesbury NSCCAHS 30th April 2009
Lead HREC site Hawkesbury NSCCAHS 7th July 2009
Northern Network amendment 24th July 2009 REF NO SSA 08/G/127

The project is significant because it will be the first such trial of women of all risk categories who will be randomised to receive caseload midwifery care compared to women who receive standard care.

The proposed trial meets the criteria of the *Cochrane Systematic Review Protocol of midwifery caseload care in methods; randomisation; definitions of the intervention and control arms; outcome measures and statistical analysis, the results will contribute to a wider inquiry and meta-analysis in the future.

With thanks,

Sally Tracy

Sally K Tracy DMid MA BNURS Adv Dip Mid RGON RM