Reviewer's report

Title: Osteopathic manipulative treatment and pain in preterms: study protocol for a randomized controlled trial.

Version: 2 Date: 2 January 2015

Reviewer: Angela Todd

Reviewer's report:

Major Compulsory Revision

1. Sample size difference
Different numbers in study groups. Why only 20 students and 20 professional? Perhaps only do professionals in same sample size as sham and control so as not to affect results.

Sample types may be different and need to be accounted for in results

2. Mean costs will be different based on the acuteness of the illness that has them in NICU?
Are the babies selected and then randomized based on level of illness or age of preterm?
More unwell and preterm babies seeing a less experienced practitioner might affect the results.
More unwell children will potentially have more pain or take longer to improve in health scores.

Discretionary Revisions

1. A "per protocol analysis" envisages determining the biological effect of OMT, but this restriction of analysis to the selected patient population may not show the practical application of OMT across all populations.

2. Last observation carried forward LOCF to handle missing data may bias result in under reporting of side effects or over reporting of benefit of OMT and may over estimate precision and reliability and the power of the trial to assess treatment because the sample size on which estimates are based is lowered and there is a tendency to underestimate the variability of the results.

To minimise bias perhaps collect information on reason for drop outs and include methods that provide type 1 error rates.

Level of interest: An article of outstanding merit and interest in its field

Quality of written English: Acceptable
Statistical review: Yes, but I do not feel adequately qualified to assess the statistics.

Declaration of competing interests:
I declare that I have an interest in paediatric chiropractic care.