

# The ON TRACK Network

April 2018



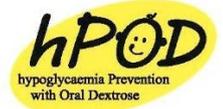
Edition 20



Welcome to the April edition of the ON TRACK Network newsletter

## ON TRACK News

- ❖ Welcome to Joy Marriot as the new Site Network Leader at Waikato Hospital
- ❖ PSANZ IMPACT Network Concept Development Workshop in Sydney in the first week in August.  
<https://impact.psanz.com.au/meetings-and-events/impact-network-workshops/>
- ❖ Congratulations to all involved in hPOD – April was your best month ever 62 babies recruited, over half way to your final target!



## Feature Trial

### Does the use of a mobile phone app improve maternal awareness and reporting of decreased fetal movements leading to a reduction in stillbirth?



This is a big question to answer but this is what the **My Baby's Movement (MBM) Study** is designed to do.

MBM is a stepped-wedged, cluster randomised trial, collecting data on approximately 260,000 births in New Zealand and Australia over three years. The aim of the study is to evaluate the impact of a personalised interactive mobile phone software program, using smart phones or SMS, on maternal awareness of fetal movements and reporting of decreased fetal movements (DFM) and subsequent hospital wide stillbirth rates. MBM has the ability to detect a reduction in stillbirths at  $\geq 28$  weeks by 30%, from 3/1000 to 2/1000 births.

The effects of the MBM package will be compared to routine antenatal care alone (prior to use of the MBM app) on:

- stillbirth at 28 weeks or more
- maternal psychosocial outcomes
- knowledge of fetal movements
- neonatal morbidity
- health services utilisation/economics
- the acceptability of MBM

Hospitals across Australia and New Zealand are contributing anonymised routine clinical data about births and stillbirths over the three year study period. Groups of hospitals are then assigned randomly to time-periods to introduce the MBM

app into routine care for all women. Snapshots of women's attitudes and understanding are taken by survey in a one month period before the MBM app is introduced and after six months of use. At these same time-points each hospital will undertake an audit of all women presenting to hospital with DFM.

**New Zealand hospitals participating:** National Women's Health, Christchurch Women's and Middlemore. **App use goes LIVE Monday 11<sup>th</sup> June.**

**ALL CLINICIANS** Even if you are not taking part in the MBM you can still access and use the PSANZ Clinical Practice Guideline for women with DFM <https://psanz.com.au/guidelines/> download patient information brochures <https://sanda.psanz.com.au/parent-centre/pregnancy/> and use the e-learning package <http://perinatal.matereducation.qld.edu.au/login/index.php> to upskill yourself on the care of women with DFM.



## Update Your Practice

This month we have selected a slightly different topic away from our usual 'maternal and perinatal health'. At first glance it may not seem to be of interest to those of you who are paediatricians, neonatal nurses and midwives.

However, this paper describes a very practical New Zealand approach to providing an answer to a worldwide unknown clinical question. These Auckland researchers have used a gold standard randomised controlled trial in a very pragmatic way to find out if intrauterine insemination for women with unexplained infertility will increase the number of livebirths compared to expectant management. Randomising care has so many advantages over random care!

**Intrauterine insemination with ovarian stimulation versus expectant management for unexplained infertility (TUI): a pragmatic, open-label, randomised, controlled, two-centre trial**

**Farquhar Lancet 2018; 391: 441-50**  
doi.org/10.1016/S0140-6736(17)32406-

**THE LANCET**

Intrauterine insemination (IUI) is a widely used low-cost, less-invasive alternative to in-vitro fertilisation (IVF). The vast majority of UK fertility specialists (96%) still offer this as a first-line treatment to couples with unexplained fertility despite NICE guidelines recommending against it as it remains unknown whether it increases livebirth rates compared to expectant management alone.

The TUI trial was designed to answer this question. Women with unexplained infertility and an unfavourable prediction score for conceiving within the next 12 months (<30%) and attending Fertility Plus and ReproMed clinics in Auckland were invited to participate. They were randomly allocated to IUI (with ovarian stimulation by clomiphene or letrozole, luteal phase support & insemination with fresh or frozen prepared sperm sample) OR expectant management. The primary outcome was cumulative livebirth rate after 3 completed treatment cycles. ACTRN12612001025820.

**Results:** 201 women were included in the trial. Livebirth rates were higher for those women assigned to IUI compared to expectant management; 31% vs 9% livebirth rate RR 3.41, 95% CI 1.71-6.79; p=0.0003. Two sets of twins were born in the IUI group.

**What does this mean?** IUI with ovarian stimulation is a safe and effective treatment for women with unexplained infertility and an unfavourable prognosis for natural conception. It is much cheaper than IVF and so likely to be a good alternative first-line therapy.

## Multicentre Trials

currently recruiting in NZ

GEMS

hPOD

HINT2

DIAMOND

MBM

OBLIGE

PROVIDE

PAEAN

## Trial Development Workshop - Concept Summary

The ON TRACK Network hosted our second trial development workshop in February of this year. Each two day workshop is designed to help groups of investigators develop promising concepts for clinical trials into collaborative, multicentre proposals suitable for submission for competitive grant funding. Over the next few months we will tell you a little about each of the four concepts worked on this year.

Jennifer Barrowclough, an Auckland based midwife, presented her proposal for the **Management of Occipito-posterior Position in Labour (MOFIL) trial**. Her team aim to investigate the use of maternal posture and gravity to enhance the rotation of fetuses in the occipito-posterior (OP) position in labour, thereby reducing the need for operative birth.

25% of women present in labour with a fetus in the OP position; of these 60-70% require operative delivery, mostly caesarean section, usually due failure to progress in labour and obstruction. Maternal and fetal trauma and the economic costs of operative birth associated with OP position make compelling reasons to investigate how best to facilitate rotation.

The MOFIL trial will compare standard care for OP labours to the use of a specified maternal lateral prone posture. The primary outcome will be the rate of operative/instrumental delivery. Secondary outcomes include caesarean section rate, labour duration, perineal trauma, neonatal resuscitation and maternal satisfaction.

Jennifer writes 'The MOFIL trial is in its early stages of development and has benefited tremendously from the timely guidance provided at the OTN Workshop in February. We have planned our next steps to include a pilot study of 80 women to gauge acceptability; a survey of midwives to gauge compliance with the study protocol following teaching sessions; focus groups with Māori and other cultural representatives to gauge cultural acceptability and efficacy; and our working group will develop a trial protocol using the templates and guidelines provided by the Liggins Central Coordinating Research Hub (CCRH) that supports the ON TRACK Network. This work will inform our future funding submission to the Health Research Council and ethics and locality approval applications.'



Jennifer Barrowclough (right) and her team with expert facilitator Lucille Sebastian (second left)