

**PErineal Assessment Repair  
Longitudinal Study (PEARLS):  
*Can we improve perineal assessment  
and repair?***



***Professor Christine Kettle***



# University Hospital of North Staffordshire



# Overview

- Background
- Informing study outcomes
  - National survey of current midwifery practice
  - Delphi study – what's important to women
- PEARLS cluster RCT
- Study progress to date



# Background

- Currently >350,000 women in UK experience perineal suturing after spontaneous vaginal delivery & millions more worldwide
- Consequences of perineal trauma have long lasting and devastating effect on women's physical and emotional wellbeing
- Large variation in practice relating to assessment, management and documentation of perineal trauma



# Training Issues

- Sultan and colleagues (1995) highlighted dissatisfaction with training in perineal anatomy and repair
- Similarly – audit carried out (1995) at the University Hospital of North Staffs (UHNS) highlighted deficiencies with training and lack of supervision
- Locally & nationally – variations in practice
- UHNS structured training programmes: -
  - Episiotomy & 2<sup>nd</sup> degree tears
  - 3<sup>rd</sup> & 4<sup>th</sup> degree tears



# Have you been trained to do that ?



# Appropriate training

- Practitioners – appropriately trained – more likely to provide consistent high standard of perineal repair – reduce associated morbidity
- Need experienced practitioner to facilitate training & provide support & supervision

# What is PEARLS?

- PErineal Assessment and Repair Longitudinal Study (PEARLS)
- National clinical quality improvement initiative
- Aim – to enhance assessment and management of perineal trauma
- Funded by the Health Foundation
- Undertaken by a multi-disciplinary team: -
  - Sue Macdonald (RCM); Debra Bick (KCL); Christine Kettle (Staffs University/UHNS); Khaled Ismail (Keele University/UHNS); Peter Thomas (Poole/Bournemouth); Sue Tohill (Project Midwife); Kenda Crozier (RCM); Judith Ockenden (NCT)
- Trial Steering Group



# Aims & Objective

- Improve clinical care in line with evidence based guidance (RCOG Green-Top Guideline) – using appropriate suture technique & material
- Enhance the assessment and management of perineal trauma – short & long-term
- Improve clinician's knowledge, skills & confidence in providing high quality evidence based perineal care
- Reduce immediate & long-term maternal postnatal morbidity
- Improve women's experience of maternity care



# Details of Study

- National UK survey of midwives – to review current practice and training
- Survey medical schools, leads for midwifery education, deaneries – content of existing training programmes
- Delphi study – identify outcomes important to women
- Matched pair cluster RCT – evaluation of standardised evidence based training package for the immediate and long-term management of perineal trauma



# National Survey

- Aim:
  - To assess current practice and provision of training for clinicians undertaking perineal management
  - To review current practice in relation to knowledge of evidence based management of perineal trauma
- Design:
  - Survey – structured questionnaire
  - Participants – random sample qualified midwives that were members of the RCM
  - Sample size – 1000
  - Inclusion criteria – midwives currently involved in the assessment, repair & supervision of perineal trauma



# Findings

- 405 (40.5%) midwives returned questionnaires
- 322 (80%) met the inclusion criteria
- 83 (20%) were not eligible to take part

<b>Years Qualified</b>	<b>N = 322</b>
> 20 years	113 (35%)
16 – 20 years	85 (26%)
11 – 15 years	34 (11%)
6 – 10 years	39 (12%)
1 – 5 years	39 (12%)
< 1 year	4 (1%)
Missing data	8 (2%)

# Findings – Assessment

Q – Confident to assess perineal trauma (n = 320)

- All of the time - 117 (36%)
- Most of time - 175 (55%)
- Some of time - 28 (9%)

Q – PR as part of initial assessment (n = 319)

- All of time - 133 (42%)
- Most of time - 49 (15%)
- Some of time - 87 (27%)
- Never - 50 (16%)

# Findings – Perineal Repair

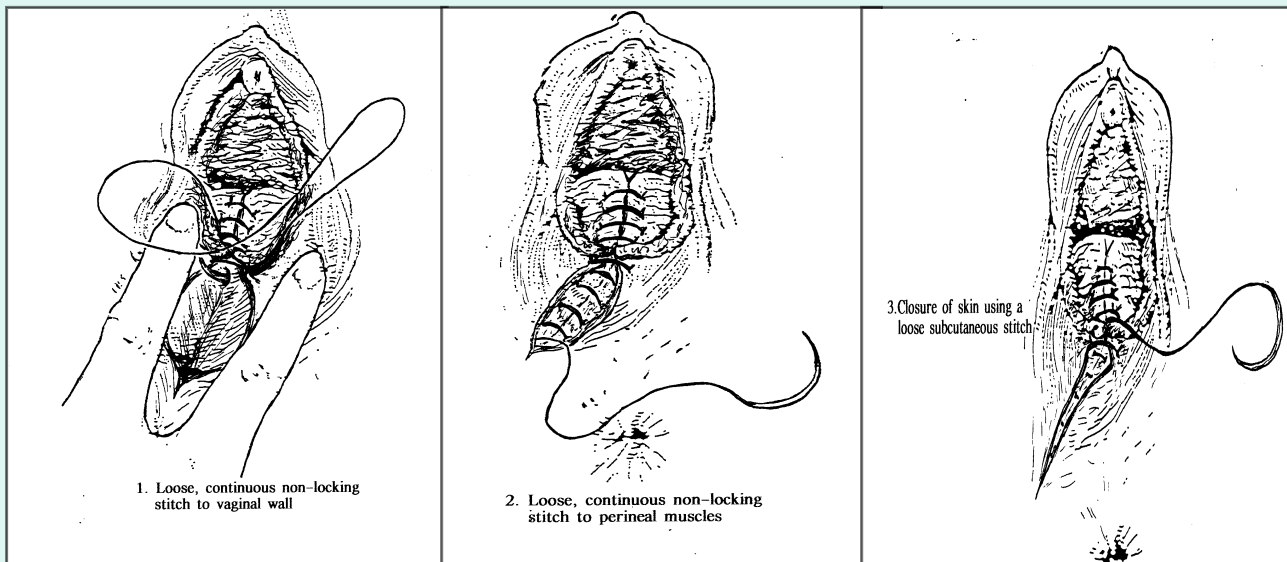
Q – Confidence in performing perineal repair (n=317)

- All of time - 67 (21%)
- Most of time - 185 (58%)
- Some of time - 53 (17%)
- Never - 12 (4%)

Midwives qualified for > 20 years were more likely to be confident 'all' or 'most' of the time to undertake perineal repairs

# Findings – Suturing Technique

- Only 17 (5%) out of 322 midwives used the recommended evidence based suturing technique (continuous non-locking to close vagina and perineal muscles and subcutaneous sutures to close perineal skin)
- More likely to be used by midwives practicing for >20 years (n = 8)



# Findings – Non suturing

Q – Do you leave some second degree tears to heal naturally (n = 308)

- Yes - 176 (57%)
- No - 132 (43%)

## Comments:

- *Against unit policy to leave second degree tears unsutured*
- *Would leave small tear with mothers consent*
- *As a community midwife I have observed that they heal better*
- *Our trust protocol requires that all second degree tears are sutured. However, if it is a small 2<sup>nd</sup> degree tear - it would be best left to heal by nature and it might be re-labelled as 1<sup>st</sup> degree*



# Findings - Training

**Q – Does your unit provide structured training (n=317)**

Yes - 216 (67%)

No - 87 (27%)

Don't know - 14 ( 4%)

**Q – Does your unit provide a training update (n=317)**

Yes - 172 (53%)

No - 131 (40%)

Don't know - 14 ( 4%)

- Only 10% had received training in the last 12 months
- A third had not received training for over 5 years

# Comments

- *Not heard of RCOG guideline*
- *Not really confident, need more training*
- *As an independent midwife not heard of RCOG guideline, had to do a 'Google' search – now will change practice*
- *Never had the opportunity to learn new technique*
- *Was a student in 1996-1998 when non suturing of second degree tears was practiced therefore I'm not confident*

# Final Comments

- *Student in 1980's – never felt prepared or confident – usually avoid suturing*
- *I need more extensive training, I know midwives that qualified with me who also lack confidence*
- *Many senior midwives do not have the confidence*
- *This questionnaire has highlighted the need for some personal updating*
- *Statement from one midwife currently using the continuous evidence-based technique:*

***“I have been observing others using the interrupted method so I may start using that instead”***



# Delphi Study



## Aim:

To obtain consensus from women who had experienced perineal trauma (experts) regarding outcomes, which they considered to be important up to 3 months following birth

# Participants & Methods

- All women who had experienced a vaginal birth and perineal suturing (up to six months prior to the study taking place) were invited to participate
- Two round Delphi study carried out (April 2006)  $n = 27$  at the University Hospital of North Staffordshire, UK
  - Women were invited to a cheese and wine evening
- One round consensus survey (Nov 2006)  $n = 45$  women at the Royal Berkshire Hospital, Reading, UK
  - Women were invited to a coffee morning
- *Approval was gained through 'Patient Partnership' groups*
- Also repeated in Brazil (Oct 2007)  $n = 17$  women/midwives at a conference at the University of São Paulo, Brazil



# Methods continued -

- Important outcomes identified from focus groups
- Used to generate a list of questions used for the first and second rounds (iterations) of the Delphi studies and consensus survey
- Generated 44 questions – subdivided into: -
  - first week after delivery
  - 2 – 4 weeks postpartum
  - 3 months postpartum
- Women were asked to score the questions & rank them on a scale of 1 – 6 in order of importance
- ‘Who Wants to be a Millionaire’ style key pad were used for scoring



# Comparisons

## *UK*

### ***Week 1***

1. Fear of perineal infection
2. Able to open bowels without pain or fear of stitches bursting
3. Wound breakdown
4. Not being incontinent of urine and faeces

### ***Weeks 2 – 4***

1. Fear of perineal infection
2. Perineal comfort when walking, sitting and feeding baby
3. Wound healed quickly
4. Not experiencing severe pain

### ***3 months***

1. Wound healed quickly
2. Feeling back to normal
3. Perineal comfort when walking
4. Fear of perineal infection

## ***Brazil***

### ***Week 1***

1. Fear of perineal infection
2. Able to open bowels without pain or fear of stitches bursting
3. Provision of consistent information
4. Not experiencing severe pain

### ***Weeks 2 – 4***

1. Fear of perineal infection
2. Perineal comfort when sitting
3. Wound healed quickly
4. Not experiencing severe pain

### ***3 months***

1. Perineal comfort when sitting and walking
2. Not experiencing severe pain
3. Perineal area felt comfortable
4. Resume pain free intercourse



# Delphi study findings

- It is interesting that wherever childbirth takes place that women have similar concerns and fears
- The Delphi and consensus survey - established what outcomes were important to women
- Findings were used in the development of the questionnaires for the PEARLS Cluster RCT – quality improvement project

# PEARLS Cluster RCT

## Aims and objectives:

- To improve clinical care in line with evidence-based guidelines
- To evaluate if enhanced clinical training in perineal assessment and management can reduce short and long-term maternal morbidity
- To improve women's experiences of maternity care relating to perineal trauma following childbirth and perceptions of health & well-being



# Methods

**Design:** Multi-centered, matched pair randomised cluster trial

- Matching criteria includes size and type of unit, number of births, type of perineal repair training and experience of facilitator

**Setting:** 22 maternity units in the UK

**Participants eligibility criteria:** All women who sustain a second degree tear or episiotomy in the participating units and give informed written consent

**Exclusion criteria:** Under 16 years of age; non-English speaking or suffered a pregnancy loss

All births during the pre-specified periods will contribute to the analysis

**Ethical approval:** Thames Valley Ethics Committee



## Primary outcome

**Experience of perineal pain** when walking or sitting down during the previous 24 hours – reported at 10 to 12 days



## Secondary outcomes

**10 – 12 days**

Use of analgesia

Wound dehiscence & infection

Sutures requiring removal

Breast feeding rates

**3 months**

EPDS score

Resumption of intercourse

Women's satisfaction with the repair

# Intervention

Reading material for independent study and self directed learning

*The Second Degree & Episiotomy Workshop*

Interactive DVD

OSAT  
Objective Structures Assessment of Training

Postnatal information leaflet for women  
to promote self management

# Facilitators Training

- Local facilitators attended a two day ‘hands on’ perineal management workshop with project team to help them to deliver the intervention:
  - Lectures – anatomy; basic surgical skills; recognition of perineal trauma; evidence based practice (suture materials and technique); postnatal management and leadership programme
  - Hands-on-workshop
  - Training materials (DVD, lectures, training equipment including Keele and Staffs Episiotomy Repair Trainer, Instruments etc)
  - Ongoing support
  - Site visits – to ensure standardisation of training

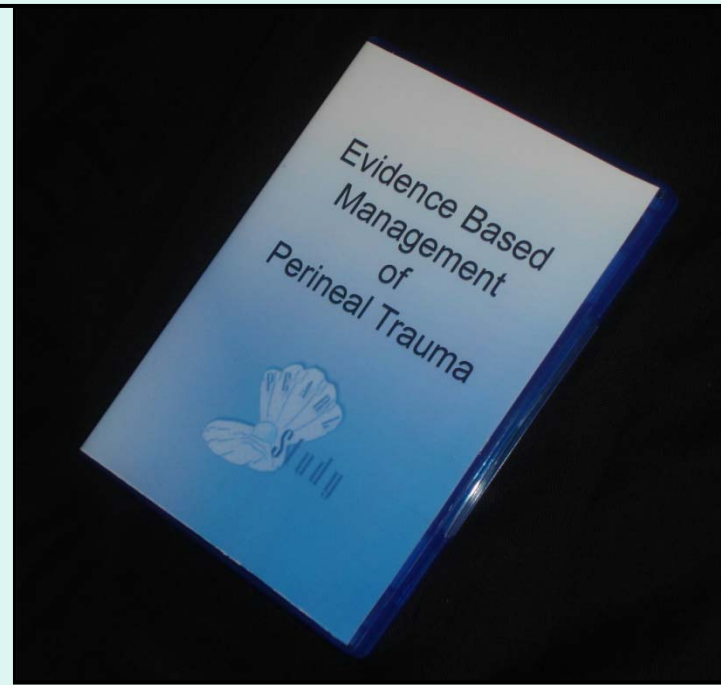


# Training equipment

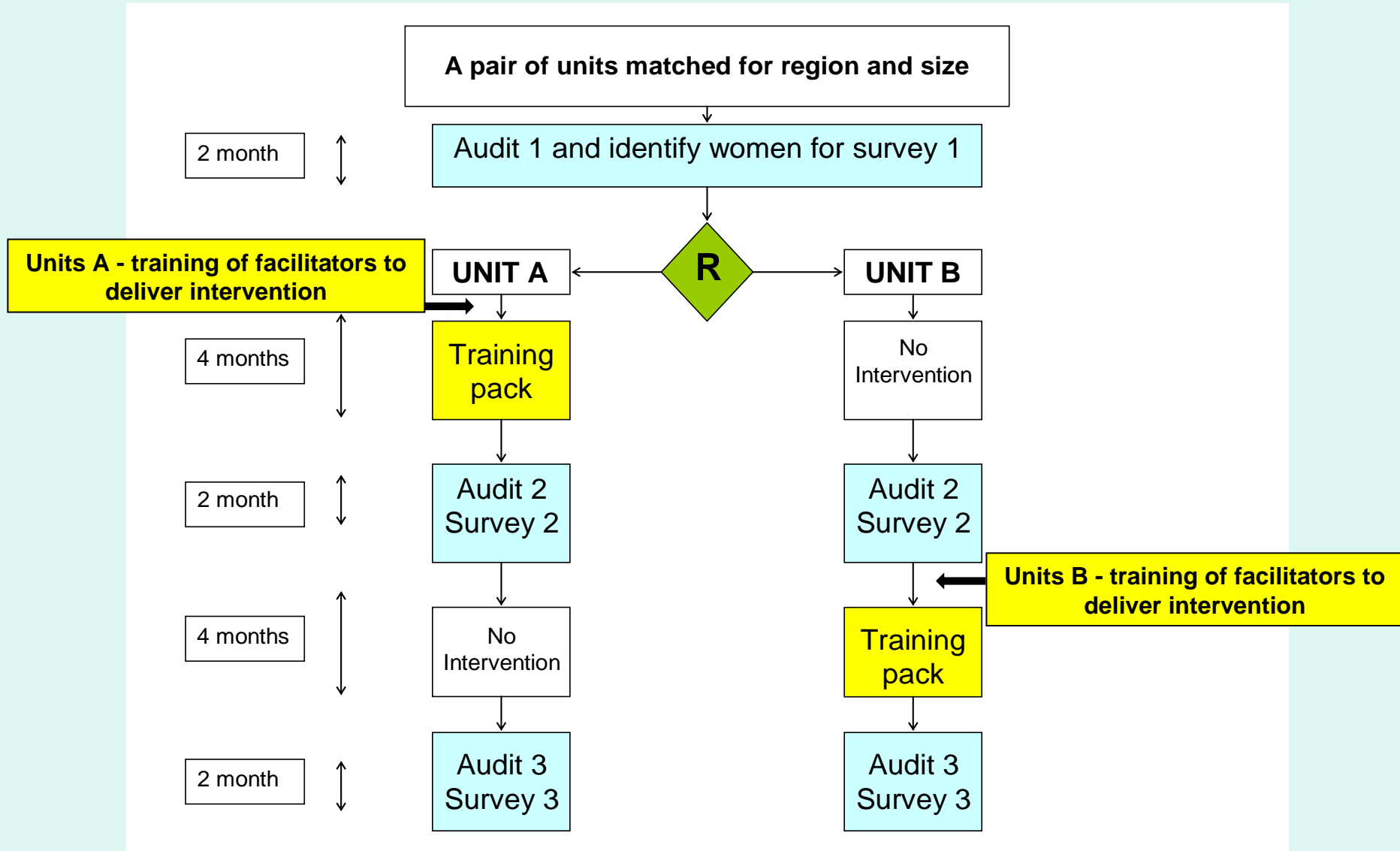


***Keele & Staffs Episiotomy Repair Trainer – developed with Limbs & Things UK Ltd***

***DVD – anatomy, basic surgical skills, identification of trauma, suturing techniques & postnatal care***



# Plan of investigation for pair of matched units (n = 22 units)



# Audit 1 & Survey 1

- **Audit 1** – prospective clinical audit over one a month period to collect baseline data from each pair of units (cluster)
- **Aim:** To assess practice prior to implementing the intervention against quality standards for perineal management
- **Survey 1** – women who sustained episiotomy or second degree tear were asked to complete questionnaire at 10-12 days & 3 months postpartum
- **Aim:** To assess impact on short and long term maternal morbidity prior to implementation of the intervention



# Data Collection: Audit 1 & Survey 1

- **Audit 1:** carried out over one month period during March to August 2008 (depending on commencement date for each paired cluster)
  - Received total 1534 completed audit forms
- **Survey 1:**
  - 708 women recruited (over one month period)
  - 463 returned 10 day questionnaire
  - 366 returned three month questionnaire



# Audit 2 & Survey 2

- The Intervention commenced in Units A
- Training period of 2 months - facilitators trained midwives and doctors during April – August 2008 (depending on commencement date for each paired cluster)
- Followed by 2 months consolidation period
- **Audit 2** – second prospective clinical audit was undertaken in Units A & B following 4 month period
- **Survey 2** – women who sustained episiotomy or second degree tear were asked to complete questionnaire at 10 - 12 days & 3 months postpartum
- **Aim:** To compare data from previous Audit 1 and Survey 1 – to assess the impact that the intervention may have on units that had receive the intervention (Units A)



# Data Collection: Audit 2 & Survey 2

- **Audit 2:** carried out over 2 month period during August to November 2008 (depending on commencement date for each paired cluster)
  - Received total 1570 completed audit forms
- **Survey 2:**
  - 1428 women recruited (over 2 month period)
  - 772 returned 10 day questionnaire
  - 496 returned three month questionnaire



# Audit 3 & Survey 3

- The Intervention commenced in Units B
- Training period of 2 months - facilitators trained midwives and doctors during October 2008 – June 2009 (depending on commencement date for each paired cluster)
- Followed by 2 months consolidation period
- **Audit 3** – third prospective clinical audit was undertaken in Units A & B following 4 month period
- **Survey 3** – women who sustained episiotomy or second degree tear were asked to complete questionnaire at 10 - 12 days & 3 months postpartum
- **Aim:** To compare data from previous audits and surveys – to assess the impact and sustainability of the intervention in Units A and B



# Data Collection: Audit 3 & Survey 3

- **Audit 3:** carried out over 2 month period during February to October 2009 (depending on commencement date for each paired cluster – most units finished in May 2009)
  - Received total 1600 completed audit forms
- **Survey 3:**
  - 1236 women recruited (over 2 month period)
  - 800 returned 10 day questionnaire
  - To date - 300 returned three month questionnaire
- Data collection Audit 3 and Survey 3 ongoing – one unit still completing training period



# Challenges

- Obtaining ethical approval – quality improvement project
- Site Specific R & D approval for each individual unit with own requirements – very time consuming
- Facilitators needed extra support due to delay in starting main study
- Huge pressures on NHS Trusts – reduced staffing levels, financial problems, deployment of facilitators which had major impact on capacity to deliver training and collect data



# Study Milestones

- ✓ Delphi and consensus study completed
- ✓ National survey completed
- ✓ Recruitment of units
- ✓ Facilitator training completed
- ✓ Health Foundation leadership training scheme for facilitators
- Data collection ongoing
- Papers prepared for publication
- Results should be available 2010

# Conclusion

- First RCT to assess the impact of an ‘hands-on’ training package for the assessment and management of childbirth associated perineal trauma
- Findings may have implications for the development of national standards for pre and post-reg education
- Likely to produce the largest data set to date on aspects of clinical management and women’s health outcomes
- Implications for women’s health globally



# Acknowledgements

- The Health Foundation for funding PEARLS
- The PEARLS Central Project Team:
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  - Professor Chris Kettle (UHNS & Staffordshire University)
  - Ms Sue McDonald (Royal College of Midwives)
  - Mrs Sue Tohill (Staffordshire University)
  - Professor Peter Thomas (Bournemouth University)

*And finally*

A big thank-you to all the women who kindly agreed to take part in the study



# Thank-you

PEARLS - [www.rcm.org.uk](http://www.rcm.org.uk)

Current Controlled Trials Registry: International Standard Randomised  
Controlled Trial Number Register (ISRCTN) – 28960026

