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# An evaluation of the effectiveness of midwifery-led services in the health service executive - North Eastern area: the MidU Study - a randomised trial

**Submission date**
04/07/2007

**Recruitment status**
No longer recruiting

**Registration date**
07/09/2007

**Overall study status**
Completed

**Last Edited**
05/04/2012

**Condition category**
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

### Secondary identifying numbers
N/A

# Study information

### Scientific Title

### Acronym
The MidU Study

### Study objectives
No difference between midwifery-led care and consultant-led care for healthy women without risk factors for labour and delivery as measured by rate of interventions, maternal satisfaction and neonatal and maternal morbidity outcomes.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Ethics approval received from the Research Ethics Committee of the School of Nursing and Midwifery Studies, Trinity College, Dublin on the 28th March 2003.

### Study design
Randomised controlled trial

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Hospital

### Study type(s)
Quality of life

### Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

### Health condition(s) or problem(s) studied
Models of maternity care

### Interventions
In this study, the experimental group will receive the experimental intervention of midwifery-led care in a midwifery-led unit while the control group will receive standard care in a consultant-led unit.

Consultant-led care (control group):
For the purpose of this study, consultant-led care refers to care in which the responsibility for the organisation and delivery of care, from initial booking through the postnatal period, is led by a consultant-obstetrician. Women allocated to consultant-led care will receive public care where all pregnancy, birth and immediate postnatal care is provided by a team of midwives and obstetricians. However, it is recognised that some women, having been randomised to consultant-led care will opt for private care whereby a consultant obstetrician sees the woman at each antenatal visit and who may be present for the birth.

Immediate postnatal care is provided by a team of midwives and the consultant obstetrician will usually visit the mother daily for the duration of her postnatal hospital stay. Within either option, antenatal care may be shared between the General Practitioner (GP) and the maternity hospitals within an agreed programme of care, which includes two postnatal visits to the general practitioner.

Midwifery-led care (intervention group):
For the purpose of this study, midwifery-led care refers to care where midwives are, in partnership with the woman, the lead professional with responsibility for assessment of her needs, planning her care with her, referral to other health professionals as appropriate, and for ensuring provision of maternity services. Midwifery-led care will be provided for healthy women without risk factors for pregnancy and labour.

Antenatal care for women randomised to midwifery-led care will primarily be provided by the midwife and shared with the GP who will be the primary source of referral to the Midwifery-Led Units (MLUs) and will, in most instances, have provided the first antenatal visit prior to booking at the MLU. Antenatal care will be provided by midwives in the MLUs and by GPs in GP surgeries. Where complications arise, the woman will be transferred to consultant-led care based on agreed transfer criteria (see 'Midwifery-led Unit (Integrated) Guidelines for Practitioners'). Women transferred to consultant-led care may, dependent on obstetric assessment, be transferred back to midwifery-led care as appropriate during the antenatal and postnatal periods (see 'Midwifery-led Unit (Integrated) Guidelines for Practitioners' for full details of reciprocal transfer arrangements). Women who require transfer to consultant-led care and are unsuitable for transfer back to midwifery-led care will be cared for as per current consultant-led care pathway (see consultant-led care above).

Intrapartum care will be provided by midwives in a MLU, with transfer to consultant-led care from midwifery-led care as appropriate based on agreed transfer criteria. Full details of the services provided by the MLU are detailed in the MLU Booklet titled 'Midwifery-Led Services in the North Eastern Health Board'. To reduce potential psychological impact of an intranatal transfer to consultant-led care, the midwife caring for the woman in the MLU will, wherever possible, accompany and care for the woman during labour in the consultant-led unit.

Postnatal care will be provided by MLU midwives in the MLU up to 48 hours after birth. On discharge from hospital, women will be cared for by a midwife from the MLU who will visit the woman in her home up to and including the seventh day post birth. The frequency of visits after discharge will be determined by the woman and the midwife based on the woman's individual needs. Thereafter care will be transferred to the Public Health Nursing service. Transfer of women and/or neonates to consultant-led care and back to midwifery-led care as appropriate will be based on the agreed transfer criteria (see 'Midwifery-led Unit (Integrated) Guidelines for Practitioners').

## Intervention Type

Other

## Phase
Not Specified

## Primary outcome measure
1. Rate of interventions
2. Maternal satisfaction
3. Neonatal and maternal morbidity outcomes

All outcomes are measured in the postnatal period by review of records as and when such records become available.

## Secondary outcome measures
1. Antenatal (measured postnatally):
1.1. Number of antenatal visits: midwife, GP and consultant
1.2. Number of prenatal ultrasound examinations
1.3. Tests of foetal well-being: non-stress test; biophysical profile
1.4. Antenatal transfer to consultant-led care
1.5. Antenatal admission
1.6. Pregnancy complications: pregnancy related hypertensive disorders; antepartum haemorrhage; gestational diabetes (insulin, non-insulin)
1.7. Foetal loss before 24 weeks: spontaneous and induced abortion
1.8. Foetal loss after 24 weeks: prior to labour
1.9. Induction of labour
1.10. Women's experiences of and satisfaction with antenatal care: measured by postnatal questionnaire

2. Labour (measured postnatally):
2.1. Labour onset: spontaneous; induced (prostaglandins, amniotomy, oxytocin, reason for induction); not in labour, caesarean section
2.2. Spontaneous rupture of membranes
2.3. Amniotomy
2.4. Acceleration during labour: amniotomy; oxytocin
2.5. Artificial oxytocin during labour (1st to 3rd stage)
2.6. Analgesia/anaesthesia: none; pharmacological (pethidine, nitrous oxide, pudendal block, spinal anaesthetic, general anaesthetic, local analgesia postpartum, epidural analgesia); non-pharmacological (Transcutaneous Electrical Nerve Stimulation [TENS], hydrotherapy)
2.7. Labour length (1st to 3rd stage)
2.8. Foetal heart rate monitoring: intermittent auscultation only; intermittent auscultation then continuous electronic Cardiotocography (CTG) (commenced with intermittent auscultation then reverted to continuous electronic CTG); admission CTG plus intermittent auscultation only; admission CTG plus intermittent electronic plus intermittent auscultation (admission CTG plus additional CTG at intervals with intermittent auscultation between CTG recordings); continuous electronic CTG (cardiotocography greater than 75% of time from admission to labour ward to delivery); foetal scalp/spiral electrode; foetal scalp blood sampling
2.9. Perceived control during labour: measured by the Labour Agentry Scale within the women's postnatal questionnaire
2.10. Mobility during labour
2.11. Type of pushing during labour: spontaneous pushing; directed, sustained breath-holding
2.12. Incidence of vaginal examinations

2.13. Cord prolapse
2.14. Intrapartum transfer to consultant-led care

3. Delivery and immediate postpartum (measured postnatally):
3.1. Mode of delivery: spontaneous vaginal delivery; instrumental vaginal delivery (ventouse, forceps); caesarean delivery (elective, emergency)
3.2. Malpresentation
3.3. Position for delivery
3.4. Incidence of vaginal examinations
3.5. Incidence of urinary catheterisation
3.6. Method of management of the third stage of labour: incidence of active management; incidence of physiological management
3.7. Known carer present for delivery: determined by woman within postnatal questionnaire
3.8. Continuity of carer during labour: defined as the same midwife present during labour, at delivery and immediately after delivery (determined by review of records)
3.9. Perineal trauma: intact; episiotomy; 1st to 3rd degree tear; episiotomy extended by tear; perineal repair required
3.10. Postpartum haemorrhage greater than or equal to 500 ml: Estimated Blood Loss [EBL] to be recorded
3.11. Shoulder dystocia: as documented by clinicians
3.12. Blood transfusion: postpartum
3.13. Serious maternal complications: intensive care unit admission; septicaemia; organ failure; hysterectomy; pulmonary embolism
3.14. Maternal death: defined as 'deaths of women while pregnant or within 42 days of delivery, miscarriage or termination of pregnancy, from any cause related to or aggravated by the pregnancy or its management, but not from accidental or incidental causes' (from Confidential Enquiry into Maternal Deaths [CEMD])
3.15. Women's experiences of and satisfaction with intrapartum care: measured by postnatal questionnaire

4. Postpartum (measured postnatally):
4.1. Postpartum transfer to consultant-led care
4.2. Postnatal complications: none; urinary tract infection; wound infection; hypertension; postpartum haemorrhage greater than or equal to 500 ml: EBL to be recorded
4.3. Length of hospital/MLU stay
4.4. Continuity of carer during the postnatal period: defined as the same professional or small group of professionals providing care throughout a woman's postnatal contact with the maternity services (measured by postal questionnaire)
4.5. Breastfeeding: initiation rates; breastfeeding on discharge; breastfeeding at 6 - 8 weeks (determined via postnatal questionnaire)
4.6. Quality of life: measured by Short Form health survey (SF - version two) instrument included in the postnatal questionnaire
4.7. Women's experiences of and satisfaction with postnatal care: measured by postnatal questionnaire

5. Outcomes of interest to the neonate (measured postnatally):
5.1. Paediatrician/Neonatologist present at delivery
5.2. Need for paediatric review
5.3. Cord prolapse
5.4. Apgar score less than 7 at five minutes
5.5. Neonatal resuscitation: none; tactile; suction (oral/pharyngeal); facial oxygen; bag and mask; Intermittent Positive Pressure Ventilation (IPPV) via mask; IPPV via Endotracheal Tube (ETT);

suction of meconium via ETT; narcotic antagonist (e.g. naloxone); external cardiac massage
5.6. Preterm birth (less than 37 weeks gestation)
5.7. Very premature delivery (less than 34 weeks' gestation)
5.8. Birth weight
5.9. Small for gestational age (birth weight less than 10th centile)
5.10. Large baby (birth weight more than 10th centile)
5.11. Transfer to consultant-led care (neonate)
5.12. Admission to special care nursery/neonatal intensive care unit
5.13. Length of neonatal hospital stay
5.14. Hypoxic ischaemic encephalopathy (incidence and severity)
5.15. Neonatal seizures: either apparent clinically (defined as clonic movements which cannot be stopped by holding the limb, occurring on two or more occasions before 72 hours of age, regardless of cause) or detected by electro-encephalographic recordings
5.16. Meconium aspiration
5.17. Neonatal trauma (fracture or palsies)
5.18. Neonatal jaundice
5.19. Other neonatal complications
5.20. Neonatal death

All outcomes are measured in the postnatal period by review of records as and when such records become available.

### Overall study start date
01/02/2005

### Completion date
17/11/2006

## Eligibility

### Key inclusion criteria
Women are eligible for trial entry if they are:
1. Healthy with an absence of risk factors for complications for labour and delivery as identified in the Midwifery-led Unit (Integrated) Guidelines for Practitioners
2. Aged between 16 and 40 years of age
3. Within 24 completed weeks of pregnancy

### Participant type(s)
Patient

### Age group
Adult

### Sex
Female

### Target number of participants
1500 excluding pilot participants

### Key exclusion criteria

Women who do not meet the above criteria.

### Date of first enrolment
01/02/2005

### Date of final enrolment
17/11/2006

## Locations

### Countries of recruitment
Ireland

### Study participating centre
School of Nursing and Midwifery
Dublin
Ireland
Dublin 2

## Sponsor information

### Organisation
Trinity College Dublin (Ireland)

### Sponsor details
College Green
Dublin
Ireland
Dublin 2

### Sponsor type
University/education

### Website
http://www.tcd.ie/

### ROR
https://ror.org/02tyrky19

## Funder(s)

### Funder type
Government

**Funder Name**
Health Services Executive - Dublin North East (Ireland) - formerly the North Eastern Health Board

# Results and Publications

### Publication and dissemination plan
Not provided at time of registration

### Intention to publish date

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary
Not provided at time of registration

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 29/10/2011 | | Yes | No |