

# Labour support and evidence based medicine: a randomised controlled trial of implementation

<b>Submission date</b> 05/07/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 14/07/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 19/02/2008	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data

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

## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

**Secondary identifying numbers**  
M960512

## Study information

## **Scientific Title**

### **Study objectives**

Providing women with evidence based maternity care, with provision of labour support as a focus, will improve the care of women during childbirth.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Ethics approval received from the Committee for Research on Human Subjects (Medical), University of the Witwatersrand on the 1st August 1998 (ref: M960512).

### **Study design**

Cluster randomised controlled trial

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Hospital

### **Study type(s)**

Treatment

### **Participant information sheet**

### **Health condition(s) or problem(s) studied**

Support during labour and evidence based medicine

### **Interventions**

Two educational interventions for maternity staff: one focused on provision of labour support and the other on accessing evidence based maternity care information.

### **Intervention Type**

Other

### **Phase**

Not Specified

### **Primary outcome measure**

Whether women had a labour support person with them during labour.

### **Secondary outcome measures**

Whether women during labour were:

1. Offered food or fluids

2. Left alone for long periods of time
3. Allowed to move during labour and delivery
4. Given an episiotomy
5. Given an enema
6. Shouted at
7. Struck or slapped
8. Unhappy with their care or perceived their care was bad

**Overall study start date**

01/10/1998

**Completion date**

01/03/2000

## Eligibility

**Key inclusion criteria**

Maternity units within Gauteng Province, South Africa, that delivered a minimum of 150 women per month.

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Female

**Target number of participants**

10 maternity units

**Key exclusion criteria**

Maternity units within Gauteng Province, South Africa, that were directly linked to a university teaching scheme.

**Date of first enrolment**

01/10/1998

**Date of final enrolment**

01/03/2000

## Locations

**Countries of recruitment**

South Africa

**Study participating centre**

**Effective Care Research Unit**

East London

South Africa

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## Sponsor information

**Organisation**

Effective Care Research Unit (South Africa)

**Sponsor details**

University of the Witwatersrand/University of Fort Hare/East London Hospital Complex

P Bag X9047

East London

South Africa

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**Sponsor type**

Research organisation

**ROR**

<https://ror.org/03rp50x72>

## Funder(s)

**Funder type**

Research organisation

**Funder Name**

Department for International Development (UK)

**Funder Name**

Medical Research Council (South Africa)

**Alternative Name(s)**

Medical Research Council (United Kingdom), UK Medical Research Council, MRC

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

**Funder Name**

International Childbirth Educators Association (USA)

**Funder Name**

Johnson and Johnson (South Africa)

**Alternative Name(s)**

Johnson & Johnson, johnson & Johnson Services, Inc., Johnson&Johnson, , Johnson & Johnson Private Limited, , J&J, JNJ

**Funding Body Type**

Government organisation

**Funding Body Subtype**

For-profit companies (industry)

**Location**

United States of America

## 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?
<a href="#">Results article</a>	Results	30/04/2007		Yes	No