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

Submission date	Recruitment status No longer recruiting	Prospectively registered		
05/07/2006		Protocol		
Registration date 14/07/2006	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited	Condition category	Individual participant data		
19/02/2008	Pregnancy and Childbirth			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number 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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s))

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 percieved their care was bad

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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 5201

Sponsor information

Organisation

Effective Care Research Unit (South Africa)

ROR

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 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

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	30/04/2007		Yes	No