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

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

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
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 percieved 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
5201

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
5201

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?
Results article	Results	30/04/2007		Yes	No