

A randomised controlled trial of educational counseling on the management of women who have suffered suboptimal outcomes during childbirth

Submission date 09/10/2002	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 09/10/2002	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 02/07/2009	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr DTS Lee

Contact details

Department of Psychiatry
The Chinese University of Hong Kong

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Hong Kong

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Additional identifiers

Protocol serial number

811019

Study information

Scientific Title

Study objectives

Unexpected outcomes of pregnancy is commonly associated with client dissatisfaction and psychological morbidity.

Aims and objectives:

To study whether proactive, systematic and interventionist educational counselling in addition to routine clinical care is effective in reducing psychological morbidity and in improving quality of life and client satisfaction among parturients who suffer from suboptimal outcomes during childbirth.

Ethics approval required

Old ethics approval format

Ethics approval(s)

This information was not required at time of registration.

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Obstetrics and gynaecology

Interventions

Educational counselling which consists of:

1. Education on the nature, etiology, management and prognosis of suboptimal outcomes
2. Counselling on the adverse emotions associated with suboptimal outcomes using techniques such as listening, clarification, debriefing, facilitation of affect expression and encouragement of positive coping mechanisms
3. Bereavement counselling, when the suboptimal outcomes involve fetal or neonatal death

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

A longitudinal assessment on the psychological well being using the Hospital Anxiety and Depression Scales, General Health Questionnaire, Clinical Global Impression, and Client Satisfaction Questionnaire.

Key secondary outcome(s)

Not provided at time of registration

Completion date

01/09/2000

Eligibility

Key inclusion criteria

Parturients who developed suboptimal outcomes during pregnancy. Suboptimal outcomes are defined as:

1. Perinatal deaths (intra-uterine death, stillbirth and neonatal death)
2. Treatment in the neonatal intensive care unit and special care unit
3. Unexpected obstetric events, which include significant antenatal complications, such as hypertension and ante-partum haemorrhage, and intra-uterine and post-partum events, such as emergency caesarean deliveries, operative vaginal deliveries and haemorrhage

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

Does not meet exclusion criteria

Date of first enrolment

01/12/1998

Date of final enrolment

01/09/2000

Locations

Countries of recruitment

Hong Kong

Study participating centre

Department of Psychiatry

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Hong Kong

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Sponsor information

Organisation

Hong Kong Health Services Research Fund (Hong Kong)

ROR

<https://ror.org/03qh32912>

Funder(s)

Funder type

Research organisation

Funder Name

Hong Kong Health Services Research Fund (Hong Kong)

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	01/09/2003		Yes	No