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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

Registration date
09/10/2002

Overall study status
Completed

Last Edited
02/07/2009

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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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
-
Hong Kong
-

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