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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

Contact name
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Contact details
Department of Psychiatry
The Chinese University of Hong Kong
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Hong Kong
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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 measure
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.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/12/1998

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

Age group
Adult

Sex
Female

Target number of participants
180

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)

Sponsor details
Health Welfare and Food Bureau
Government Secretariat, HKSAR
20th floor Murray Building
Garden Road
-
Hong Kong
-

Sponsor type
Government

Website
http://www.fhb.gov.hk/grants/english/funds/funds_hhsrf/funds_hhsrf_abt/funds_hhsrf_abt.html

ROR
https://ror.org/03qh32912

Funder(s)

Funder type
Research organisation

Funder Name
Hong Kong Health Services Research Fund (Hong Kong)

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	01/09/2003		Yes	No