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

Submission date	Recruitment status No longer recruiting	Prospectively registered		
09/10/2002		☐ Protocol		
Registration date 09/10/2002	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited 02/07/2009	Condition category Pregnancy and Childbirth	[] 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

Hong Kong

long i

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.

Study design

Randomised controlled trial

Primary study design

Interventional

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

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