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To assess the effectiveness of psychological counselling in reducing psychological morbidity after miscarriage

Submission date
02/08/2013

Recruitment status
No longer recruiting

Registration date
23/08/2013

Overall study status
Completed

Last Edited
24/02/2015

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Whilst psychological distress after a miscarriage can be significant and enduring, women are not routinely provided with professional psychological support or any follow-up care. The purpose of this study is to find out how well psychological counselling works in reducing psychological distress after miscarriage.

Who can participate?
Miscarrying women in the Prince of Wales Hospital, Hong Kong are eligible to participate in the study.

What does the study involve?
Patients are randomly allocated to one of two groups: either psychological counselling or routine management without psychological counselling. The counselling group receives a psychological counselling programme conducted in two sessions, one when they are still in the hospital and the second, two weeks after the miscarriage. They are asked to fill in some questionnaires at 6 weeks, 3 months and 6 months after the miscarriage to find out how well the counselling has worked.

What are the possible benefits and risks of participating?
The participants do not have any benefit and risks of taking part in the study.

Where is the study run from?
Prince of Wales Hospital, Hong Kong.

When is the study starting and how long is it expected to run for?
This study started in 2005 and finished in 2006.

Who is funding the study?
This study is funded by the Department of Obstetrics and Gynaecology, The Chinese University of Hong Kong.

Who is the main contact?
Dr Grace Wing Shan Kong
gracekong@cuhk.edu.hk

Contact information

Type(s)
Scientific

Contact name
Prof Grace Wing Shan Kong

Contact details
1E, Department of Obstetrics and Gynaecology
Prince of Wales Hospital
Shatin
Hong Kong
HKSAR

Additional identifiers

Protocol serial number
CRE-2000.233

Study information

Scientific Title
A randomised controlled trial of psychological counselling on psychological morbidity after miscarriage

Study objectives
Psychological counselling reduces the proportion of patients with psychological morbidity following miscarriage.

Ethics approval required
Old ethics approval format

Ethics approval(s)
This study is approved by Joint The Chinese University of Hong Kong-New Territories East Cluster Clinical Research Ethics Committee with CREC Ref. No: CRE-2000.233 in 2003

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Miscarriage

Interventions
For the randomization, patients who agreed to participate in the study gave written consent and were then randomised using a set of sealed, opaque, sequentially numbered envelopes, each containing a computer-generated random number denoting the randomisation result. Randomisation was into one of the following two groups:
Group 1 (Counselling group): Patient in this group received psychological counselling from a nurse counsellor after completion of baseline questionnaires in the hospital before discharge. They were then followed up by the nurse counsellor two weeks later by telephone to reinforce the counselling.
Group 2 (Control group): Patient in this group were managed according to our routine clinical practice and attended by the clinical staff as usual. No specific counselling or follow-up care was arranged.

For the intervention, the counselling programme comprised of two sessions.
The first session usually lasted about 60 minutes and was conducted while the patient was still in hospital. The second session usually lasted about 30 minutes and was conducted two weeks after miscarriage. This session thus aimed at reinforcing the previous information given; to allow the patient to discuss her feelings, worries and physical concerns; to discover possible underlying stress factors. We adopted telephone conselling format mainly for the convenience of the patient.

Intervention Type
Behavioural

Primary outcome(s)
The psychological morbidity [General Health Questionnaire (GHQ-12) and Beck Depression Inventory (BDI) questionnaires] following miscarriage
The psychological outcomes (proportion of patients suffering psychological morbidity and the median psychometric scores) at baseline, six weeks, three months and six months after miscarriage of both counselling group and control group were evaluated.

Key secondary outcome(s))
The interaction between time and psychological intervention on the psychometric outcome were assessed.

Completion date
31/01/2005

Eligibility

Key inclusion criteria
Women aged 18-40 admitted with the diagnosis of miscarriage

Participant type(s)
Patient

Healthy volunteers allowed

No

Age group
Adult

Lower age limit
18 years

Upper age limit
40 years

Sex
Female

Key exclusion criteria
1. Patient who were unwilling to participate
2. Patient with psychiatric disease requiring active treatment
3. Patient who were non-Chinese
4. Patient who were visitors to Hong Kong (e.g. tourists for whom arranging follow-up would be difficult)

Date of first enrolment
01/02/2004

Date of final enrolment
31/01/2005

Locations

Countries of recruitment
Hong Kong

Study participating centre
Prince of Wales Hospital
Shatin
Hong Kong
HKSAR

Sponsor information

Organisation
The Chinese University of Hong Kong (Hong Kong)

ROR
https://ror.org/00t33hh48

Funder(s)

Funder type
University/education

Funder Name
Chinese University of Hong Kong

Alternative Name(s)
The Chinese University of Hong Kong, , , Hēunggóng Jūngmàhn Daaihhohk, CUHK,

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Hong Kong

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2014		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes