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A randomised controlled trial of educational counselling on the management of women who have suffered suboptimal outcomes in pregnancy

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Objectives To study whether proactive educational counselling, in addition to routine clinical care, reduces psychological morbidity and improves quality of life and client satisfaction among women who suffer suboptimal outcomes during childbirth.

Design A randomised controlled trial.

Setting Obstetric unit of a tertiary teaching hospital.

Population Women who had unexpected antenatal, intrapartum or postpartum events leading to suboptimal outcomes during pregnancy and childbirth.

Intervention Educational counselling provided by a trained research nurse in the postnatal ward after delivery. Women in the control group received routine clinical care.

Main outcome measures The Hospital Anxiety and Depression Scale, the General Health Questionnaire and the Clinical Global Impression (before and after counselling, at six weeks and six months post-delivery) and the World Health Organisation Quality of Life scale (WHO-QOL) (at six weeks and six months post-delivery).

Results There was no significant difference in psychological morbidity, quality of life or client satisfaction between the counselling group and the control group. Participants who underwent elective caesarean section and who had the educational counselling had significantly lower depression scores [mean 2.6 (SD 2.6)] compared with those receiving routine care [mean 3.9 (SD 3.2)]. On the other hand, educational counselling may have deleterious effect to women's quality of life in those who had instrumental delivery. Participants allocated to the counselling group had a lower mean score 68 (SD 13) in the physical domain of WHO-QOL than those in the intervention group 74 (SD 13).

Conclusion Educational counselling, given on top of routine clinical care, does not give additional beneficial effects on the psychological wellbeing and quality of life of women who encountered suboptimal outcomes during pregnancy.

INTRODUCTION

In most developed countries, normal birth of a healthy baby is the general expectation of pregnant women and their families. Nevertheless, adverse outcomes, which may be unexpected, do occur. Dissatisfaction with the care provided is not uncommon and both the women and their families may become distressed. Adverse events, which are essential suboptimal outcomes, encompass a wide range of conditions including those resulting in additional morbidity or even mortality to the mother or baby. Any condition that leads to, or constitutes, a deviation from a normal vaginal delivery of a healthy infant at term can be considered under the rubric of suboptimal outcomes.

Several studies have demonstrated the detrimental effects of suboptimal outcomes on the women's psychological wellbeing and their satisfaction with the medical care they received. Induction of labour at term for either maternal or fetal indications has been reported to impose deleterious psychological effects on women's experiences of labour and early mother–infant interaction[1]. Women who had operative deliveries and caesarean sections have been noted to have less satisfaction with the delivery and have more maternal psychological morbidity, such as depression and loss of self-esteem[2,3]. Association with increased risk of

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Table 1. Demographic data in both the intervention group and the control group. Values (except for maternal age) are expressed as *n* (%).

		Intervention group ($n = 261$)	Control group ($n = 255$)
Maternal age (SD)		31 (27–34)	30 (27–34)
Parity	0	163 (59)	167 (60)
	1	86 (31)	91 (33)
	2	16 (5.8)	16 (5.7)
	≥3	13 (4.7)	5 (1.8)
Gestational age	<34 weeks	15 (5.4)	6 (2.2)
	≥34 to <37 weeks	34 (12)	28 (10)
	Term	229 (82)	245 (88)
History of infertility	Primary	9 (3.2)	8 (2.9)
	Secondary	9 (3.2)	6 (2.2)
No. of previous miscarriage	1	47 (17)	47 (17)
	2	7 (2.5)	8 (2.9)
	≥3	4 (1.4)	5 (1.8)
Previous psychiatric history	Inactive	5 (1.8)	1 (0.4)
	Active	1 (0.4)	0 (0)
Previous postnatal depression		10 (3.6)	5 (1.8)
Previous history of deliberate self harm		11 (4.0)	9 (3.2)
Previous history of psychosis		4 (1.4)	6 (2.2)
Family history of psychiatric disorders		13 (4.7)	8 (2.9)

postpartum depression was also reported in women with antenatal complications, dissatisfaction with antenatal care and early mother–child separation[4–6]. Notwithstanding a few studies that reported a lack of association between pregnancy complications, operative deliveries and postpartum depressive symptoms[7,8], it appears that some women have increased risk of psychological morbidity following suboptimal outcomes of pregnancy.

The potential emotional disturbances associated with suboptimal outcome affect not only the women and their families, but also the staff involved in their care. Complaints and litigation[9], resulting from suboptimal outcomes, also undermine job satisfaction and staff morale. This is especially so if formal complaints and legal actions are initiated in the absence of perceived medical mismanagement. A recent audit of obstetric medical legal claims showed that about half of all litigations were misguided allegation, which could have been resolved in alternative ways, such as improved communications and explanation of the outcomes[10]. Hence, proper psychological management is as important as medical management in the quality care of adverse pregnancy outcomes.

Until recently, little research attention has been focussed on the psychological management of women encountering suboptimal outcome during pregnancy. Two recent randomised control trials on midwife-led postpartum debriefing showed divergent results. Small *et al.*[11] found that providing debriefing after instrumental delivery and caesarean section did not reduce psychological morbidity at six months postpartum. In contrast, Lavender and Walkinshaw[12] reported that psychological debriefing after birth dramatically reduced anxiety and depression scores in women with normal vaginal deliveries. In view of the conflicting findings, further studies are needed to evaluate the utility of psychological intervention in ameliorating dissatisfaction and reducing psychiatric morbidity associated with suboptimal outcomes. It has also been suggested that psychological debriefing can inadvertently increased psychiatric morbidity in post-traumatic stress[13], and not all suboptimal outcomes constitute a traumatic experience. Therefore, the approach and technique of delivering psychological intervention is also a major concern in the evaluation. In cases of suboptimal outcomes, especially if unexpected, women may appreciate being informed about the reason behind the obstetric complications and the rationale for the intervention. We therefore considered that educational counselling is a most appropriate intervention for women with suboptimal outcomes. The objective of this randomised control trial is to investigate the effects of nurse-led educational counselling on the psychological wellbeing, quality of life and client satisfaction of women with suboptimal outcome and complications related to pregnancy and childbirth.

METHODS

Before commencement of the study, two senior research nurses (WL and TL) experienced in psychological aspects

Table 2. Mean (SD) anxiety and depression rating scores in HADS, GHQ scores, CGI, in the intervention and control groups before intervention.

	Intervention group	Control group	*P*
HADS			
Anxiety rating scores	4.2 (3.6)	4.3 (3.6)	0.30
Depression rating scores	3.5 (2.9)	3.5 (2.9)	0.75
GHQ scores	2.2 (2.5)	1.9 (2.3)	0.40
CGI scores	0.48 (1.2)	0.43 (1.2)	0.73

Table 3. Comparison of mean (SD) anxiety and depression rating scores in HADS, GHQ scores, CGI, WHO-QOL scores and CSQ scores between the intervention group and the control group.

	Intervention group	Control group	*P*
HADS			
Anxiety rating scores	3.8 (3.5)	3.9 (3.5)	0.91
Depression rating scores	3.3 (2.9)	3.5 (3.0)	0.34
GHQ scores	1.7 (2.4)	1.8 (2.5)	0.34
CGI scores	0.53 (1.2)	0.55 (1.3)	0.78
WHO-QOL scores			
Overall	6.7 (0.64)	6.8 (0.65)	0.50
Physical health domain	67 (15)	68 (14)	0.24
Psychological domain	67 (16)	67 (16)	0.67
Cultural adjusted psychological domain	69 (15)	69 (15)	0.67
Social relationship domain	64 (13)	64 (14)	0.81
Environment domain	63 (14)	63 (14)	0.57
CSQ	24 (2.7)	24 (3.0)	0.99

of childbirth were trained in midwifery course and psychological counselling for one year. The latter included clinic attachment (women mental health clinic run by a psychiatrist DTS), and workshops on interpersonal psychotherapy, grief counselling and communication skills.

The intervention was 'educational counselling', which consisted of two components. First, our intervention was based on the premise that lack of information, especially on the nature of the 'suboptimal outcome', and misunderstandings could lead to client dissatisfaction, psychological morbidity and impaired quality of life. The 'educational' component entailed a proper explanation of the clinical condition constituting any adverse event, justification the management provided and clarification to any misconceptions. Second, women were encouraged to discuss their feelings in relation to the unexpected events during the antenatal period, labour and puerperium. The psychological component of the intervention is based on the counselling paradigm, and is not equivalent to 'debriefing'. The counselling aims to help the women to come to terms with her losses and find solutions to specific difficulties. Therapeutic relationship and specific facilitating techniques were used to help the women to clarify and release emotions, and to discuss painful issues which otherwise might be avoided. The counselling nurse also encouraged the women to come to terms with the event experienced and, where necessary, made an informed decision based on evidence available.

Suboptimal outcomes were categorised into seven groups: (1) antenatal complications resulted in hospital admission (e.g. gestational diabetes mellitus, antepartum haemorrhage or placenta praevia), (2) elective caesarean section, (3) emergency caesarean section, (4) instrumental vaginal delivery, (5) labour induction at term for maternal or fetal indication, (6) postnatal maternal complications: postpartum haemorrhage, manual removal of placenta or perineal tear, (7) admission to neonatal special care unit. To ensure that subjects could be contacted up to six months from the delivery, women who did not have permanent residential rights (about 20% of women delivered in the unit did not have a permanent residential rights) and those who would leave the territory within six months of delivery were not included in the study. Informed written consent was obtained from all participants. The study was approved by the institutional review board.

Pregnant women who had suboptimal outcome during pregnancy were recruited from the postnatal ward within 48 hours after delivery. Once the woman was identified and allocated into a subgroup, randomisation was carried out by one research nurse (WL) according to the computer generated number in sealed, opaque, sequentially numbered envelopes. A quota of 80 participants was set in each subgroup as we want to address to the role of educational counselling on each individual problem. The number of 80 in each subgroup was based on the assumption of a standardised effect size of 0.7 at a power of 80% and two-tailed alpha of 0.05 and an attrition rate of 20%. Thus, altogether 560 participants (280 cases and 280 controls) were recruited. In case a participant had more than one suboptimal outcome, she was allocated to the subgroup that had the most prominent and troublesome condition.

Participants randomised into the intervention group were interviewed by another research nurse (TL) for educational counselling. The number of counselling sessions required

Table 4. Comparison of anxiety rating scores and depression rating scores in HADS between the intervention group and the control group in different subgroups.

	Anxiety rating scores (SD)			**Depression rating scores (SD)**		
	Intervention group	Control group	*P*	Intervention group	Control group	*P*
Antenatal complication	3.0 (2.9)	3.9 (3.3)	0.097	2.9 (2.5)	3.5 (2.8)	0.25
Elective caesarean section	3.3 (3.2)	4.1 (3.8)	0.16	2.6 (2.6)	3.9 (3.2)	0.009
Instrumental delivery	3.9 (2.9)	3.8 (3.5)	0.91	3.2 (2.5)	3.1 (2.7)	0.74
Emergency caesarean section	4.0 (3.5)	3.3 (3.0)	0.27	3.5 (2.8)	3.5 (3.1)	0.95
Induction at term	4.4 (3.9)	3.9 (3.6)	0.51	3.9 (3.0)	3.2 (2.7)	0.14
Postnatal maternal complication	3.7 (3.7)	3.7 (3.5)	0.91	3.0 (3.2)	3.2 (3.1)	0.67
Postnatal neonatal complication	4.7 (3.8)	4.3 (3.6)	0.59	4.1 (3.2)	4.1 (3.1)	0.93

Table 5. Comparison of WHO-QOL between the intervention group and the control group in different subgroups: physical and psychological domains.

	Physical domain (SD)			Psychological domain scores (SD)		
	Intervention group	Control group	*P*	Intervention group	Control group	*P*
Antenatal complication	69 (14)	68 (13)	0.82	70 (15)	67 (17)	0.35
Elective caesarean section	68 (15)	65 (15)	0.33	68 (17)	66 (14)	0.36
Instrumental delivery	68 (13)	74 (13)	0.04	68 (14)	69 (17)	0.80
Emergency caesarean section	67 (14)	68 (13)	0.75	67 (16)	68 (14)	0.83
Induction at term	65 (15)	69 (15)	0.20	65 (16)	69 (16)	0.26
Postnatal maternal complication	65 (16)	65 (15)	0.99	66 (17)	68 (15)	0.57
Postnatal neonatal complication	63 (14)	67 (13)	0.23	63 (15)	66 (17)	0.37

and the time of counselling were decided by the research nurse herself. In case of any doubt on the management, attending doctors were called to discuss about the obstetric management plan. An interview between the attending doctor and the participants was arranged if deemed necessary especially when the patient had expressed dissatisfaction with the obstetric or neonatal management. The total time of counselling delivered, either in specific interventionist format by counselling nurse or in the course of normal routine care by ward staff during the study period, was quantified. The medical and nursing staff in the postnatal ward were allowed to provide psychological support and counselling to participants in both arms as required.

The participants in the control group were attended by clinical staff without any additional input from the nurse counsellor. All participants were followed up at the postnatal clinic six weeks postpartum. Although a blinded study was not possible in this setting, the ward staff was primed in the beginning of the study to avoid being selective during their routine care to women in either group.

Socio-demographic, obstetric and previous psychiatric data were collected. Pre-counselling psychological assessment was performed using Clinical Global Impressions (CGI)[14], General Heath Questionnaire (GHQ)[15] and Hospital Anxiety and Depression Scale (HADS)[16]. The CGI provides global rating, whereas the GHQ identifies probably psychiatric morbidity and the HADS measures the level of depression and anxiety of the participants.

The same set of psychological rating assessment was repeated before discharge, at six weeks post-delivery during postnatal follow up and at six months by postal questionnaires. Client satisfaction was assessed using the Client Satisfaction Questionnaire (CSQ)[17] at six weeks. The quality of life was also measured using the Chinese version of World Health Organisation Quality of Life (WHO-QOL)[18] at both six weeks and six months. Formal complaints and litigation during the study period were documented. Participants who were found to be suffering from complicated grief or psychiatric morbidity were offered a referral to a medical social worker, clinical psychologist or liaison psychiatry outpatient service where appropriate. All psychometric instruments used in the study were in Chinese and had been validated, showing good reliability and validity[19,20].

Statistical analysis was conducted using SPSS for Windows version 10.0 on PC computer. The socio-demographic, obstetric and psychiatric characteristics of both groups were compared using Mann–Whitney *U* test. The mean baseline psychometric rating scale before counselling

Table 6. Comparison of WHO-QOL between the intervention group and the control group in different subgroups: cultural adjusted, social and psychological domains.

	Cultural adjusted psychological domain scores (SD)			Social domain score (SD)			Environment domain (SD)		
	Intervention group	Control group	*P*	Intervention group	Control group	*P*	Intervention group	Control group	*P*
Antenatal complication	72 (13)	69 (16)	0.30	68 (14)	64 (14)	0.19	66 (15)	63 (14)	0.46
Elective caesarean section	71 (15)	67 (13)	0.16	65 (14)	63 (13)	0.47	64 (14)	60 (14)	0.15
Instrumental delivery	69 (13)	71 (15)	0.45	66 (12)	66 (15)	0.90	64 (13)	67 (13)	0.33
Emergency caesarean section	70 (14)	71 (12)	0.77	65 (14)	66 (14)	0.63	63 (13)	64 (13)	0.59
Induction at term	68 (14)	70 (14)	0.59	63 (12)	62 (12)	0.76	61 (13)	62 (13)	0.91
Postnatal maternal complication	69 (15)	71 (14)	0.47	64 (14)	65 (10)	0.80	63 (15)	66 (13)	0.36
Postnatal neonatal complication	63 (14)	67 (17)	0.19	60 (13)	64 (15)	0.25	59 (13)	63 (14)	0.13

was compared using Student's *t* test after log transformation as the rating scores were not normally distributed. Repeated-measure analysis of variance was used in the comparison of psychometric rating scale scores after the counselling. The analysis was first conducted for individual subgroups, and subsequent with all subgroups aggregated.

RESULTS

A total of 560 patients were invited during the period from December 1998 to September 2000 of whom 180 declined to participate. One case in the control group was excluded from the study because it was subsequently determined that the case did not fall under our inclusion criteria. Two hundred and sixty-one participants in the counselling group and 255 in the control group completed the study. Their socio-demographic data and psychiatric history are shown in Table 1.

Counselling by the research nurse was confined to the intervention group. The number of sessions ranged from 1 to 4, the median (interquartile range) total time of counselling was 35 minutes (25–50 minutes). The pre-intervention scores for HADS, GHQ and CGI scores are shown in Table 2. The post-delivery scores for the whole sample are shown in Table 3. Twenty-six (9.8%) and 35 (14%) women in the intervention group and in the control group met the criteria of 'possible case' of postnatal depression using a cutoff of 4/5 in GHQ according to our previous study[21]. There was no significant statistical difference between the two groups.

The HAD scores for the various subgroups are shown in Table 4 and the WHO-QOL scores are shown in Tables 5 and 6. There was no formal complaint against the unit from the study cases during the study period. There were 24 patients in the intervention group who needed explanation by doctors.

DISCUSSION

Our findings show that the psychological wellbeing, depressive and anxiety symptomatology, quality of life and client satisfaction of women who received educational counselling, the experimental intervention, were not different from those of the control arm who did not. The findings were based on rigorous methodology, including a randomised control design. Our data included a wide spectrum of psychosocial outcomes, measured with validated and widely used psychometric instruments. The sizeable study population and the low attrition rate also ensured reasonable statistical power in detecting differences. Our research nurse was experienced with perinatal and reproductive mental health research, and was carefully trained and closely supervised to deliver the psychological intervention. Hence, in the context of suboptimal outcomes of childbirth, educational counselling, given on top of routine clinical care, does not appear to offer additional benefits.

Several methodological issues have to be considered when evaluating the utility of educational counselling in this context. Firstly, although randomised control trial is generally regarded as the best design to infer causality, we found that conducting a randomised control trial on educational counselling in the context of suboptimal outcomes was fraught with difficulties. There was insurmountable bias in the recruitment process as distressed women were less likely to participate. It was extremely hard for them to agree to be 'tested' amid a time of difficulties and immense emotions. As we found up to 25% of the subjects refused to participate in the study, it was possible that only the less emotionally disturbed women were recruited. This hypothesis is supported by the observation that the baseline GHQ mean scores were around 2 only, and the CGI mean scores were below 1, suggesting relatively good psychological functioning at recruitment. It would thus be more difficult to demonstrate the therapeutic effects of counselling among our study population.

Secondly, women with suboptimal outcomes may have already received adequate psychosocial care in the course of routine care. This study was conducted in a department committed to provide quality psychosocial care and research. The department provided universal postnatal depression screening, and most midwives of the unit were trained to provide counselling for emotionally disturbed mothers[22]. It also has an enthusiastic grief counselling team, one of the first in the region[23]. Hence, the level and quality of psychological care provided by the clinical staff may well have been very high. Compounded with the fact that suboptimal outcomes naturally attract more attention from the clinical staff, this may mean that the women in the control arm received a great deal of attention and the incremental nature of the experimental intervention's effect might have been diminished.

Thirdly, given the nature of experimental intervention, it was impossible to blind the clinical and nursing staff to the experimental status of the subject. In addition, the attending staff was aware that patients' psychological outcomes, including complaints and litigations, were being monitored during the study period. This might have influenced the care given in an unconscious but positive manner, elevating the level of psychological care in the control group.

Finally, these negative findings may simply mean that educational counselling was not potent enough to counteract the adverse effects of unexpected outcomes. Education counselling provides informational and emotional support in the immediate days after unexpected suboptimal outcomes. These forms of support would be useful if the patients want to know more about the unexpected outcomes as well

as receive some emotional support. However, education counselling during inpatient stay may not be potent enough to address more complicated issues, such as entrenched marital conflicts, many of which may confound patients' response to unexpected outcomes.

Although in general we did not find additional therapeutic effects when educational counselling was delivered on top of routine care, it appears that elective caesarean section may be an exception. Women who had an elective caesarean section may have been regarded as comparatively uncomplicated cases and consequently have been neglected compared with the attention that the others received. Educational counselling in this instance may have been effective in improving communication between the women and the clinical staff. Nonetheless, women who had instrumental delivery allocated to the counselling group were found to have lower scores in one out of the five domains in the Quality of life assessment. It was well known that instrumental deliveries were associated with more physical morbidity than spontaneous vaginal delivery[24]. This result was similar to the finding by Small *et al.*[11] who concluded that debriefing might indeed have detrimental effects to women after operative childbirth. They found that women allocated to debriefing had significant lower role functioning (emotional) subscore. Educational counselling may potentially reduce the psychological morbidity. On the other hand, it may also heighten their awareness of physical symptoms during their postpartum period. Nonetheless, as these were the only two significant findings out of a great number of non-significant findings, there was a possibility that it might have been a spurious finding.

CONCLUSION

Educational counselling provided on top of routine clinical care does not give additional beneficial effects on the psychological wellbeing, quality of life and client satisfaction of women who encountered suboptimal outcomes. Although it has always been assumed that communication would automatically lead to better psychological outcomes, when this assumption was subjected to experimental examination, it failed to show the effect expected.

However, concluding that counselling is useless may be premature. It runs counter to common clinical sense. The challenge is to explain why these negative results were obtained and also in the process, hopefully to gain greater understanding of the interaction between caregivers and parturients. We may wonder whether the experimental model was wrong. It could not be blinded and because it required informed consent, the recruitment may have been biased. The Hawthorne effect may well have been observed in this study. These issues need consideration when planning future research on the matter.

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Competing interests

None declared.

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