



An economic evaluation alongside a randomised controlled trial on psycho-education counselling intervention offered by midwives to address women's fear of childbirth in Australia



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ARTICLE INFO

Article history:

Received 17 September 2015

Revised 21 August 2016

Accepted 25 August 2016

Keywords:

Childbirth fear

Health-related quality of life

Health services use

Psycho-education

Healthcare cost

Postpartum

ABSTRACT

Objective: The rate of caesarean section continues to increase, and there is evidence that childbirth fear is a contributing factor. Insufficient evidence is available on the impact of reducing childbirth fear on health-related quality of life and health service use. We undertook an economic evaluation of a psycho-education counselling intervention offered by midwives to address women's fear of childbirth in Australia. **Methods:** Pregnant women (n = 339) with high childbirth fear were randomised to a midwife-led psycho-education intervention for childbirth fear or to usual care. This paper presents the economic evaluation of the intervention based on health-related quality of life and health service use from recruitment to six weeks postpartum (n = 184).

Results: The changes in health-related quality of life after birth (EQ-5D-3L: 0.016 vs. 0.010, p = 0.833, for usual care and intervention) and total health care use cost (AUS\$10,110 vs. AUS\$9980, p = 0.819) were similar between groups. The intervention did not increase costs; however, in a post hoc analysis, the interventions might be cost-effective for those women with very high childbirth fear.

Conclusion: This brief psycho-education intervention by midwives did not improve the health-related quality of life of women, and had no impact on overall cost.

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Introduction

Childbirth fear is common in developed countries, with a prevalence of severe childbirth fear reported between 4 and 15 percent [1]. Australia has similar levels of childbirth fear, with approximately 24% of pregnant women in Australia reporting high childbirth fear and 4.8% reporting severe fear [2].

Researchers consistently report fear of pain and complications as predominant predictors of severe fear of childbirth. In nulliparous women, lack of confidence to birth, fear of the unknown, and concerns about perineal tearing and labour pain are common [3]. Childhood abuse [1] and anxious personality [4] also place women at risk. However, a previous negative birth experience and previous

caesarean section are commonly reported by multiparous women [3,5]. Increased childbirth fear in pregnancy has also been associated with expectations of lower confidence during childbirth [6,7]. Sjogren identified lack of trust in maternity staff and the system as the most common reasons women were fearful of childbirth [8]. Mental health problems, unrelated to pregnancy, have also been seen as an important issue for women who have severe childbirth fear. For example, in a Finnish retrospective study, depression and anxiety were twice as common in fearful women as in non-fearful controls [9]. A large cross-sectional Norwegian study also reported a clear association between anxiety/depression and childbirth fear [10].

In resource rich countries, such as Australia, the rate of caesarean section (CS) has increased dramatically over the last two decades [11]. While the issues are complex, there is some evidence that this rise may be associated with an increase in women requesting a CS where there is no medical indication [12,13]. Although CS has come to be seen as somewhat routine in the mind of some health professionals and birthing women [14,15], it is a major surgical operation that exposes women and their unborn baby to potential harm. Maternal and neonatal mortality and morbidity are significantly higher in women who give birth by CS [16,17].

Abbreviations: GP, general practitioner; BELIEF, Birth Emotions: Looking to Improve Expectant Fear; CS, caesarean section; EQ-5D-3L, EuroQol 5-dimensional scale, three dimensions; EQ-5D-5L, EuroQol 5-dimensional scale, five dimensions; WDEQ-A, Wijma Delivery Expectancy/Experience Questionnaire version A.

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Although results are mixed, some studies report that a proportion of elective CS is due to childbirth fear. A recent large cohort study with 6422 Northern European women found that both primiparous and multiparous women reporting severe fear of childbirth were more likely to give birth by elective caesarean [18]. An earlier Swedish intervention study reported that women with childbirth fear requested elective CS more frequently than women in the matched reference group [19]. In this study, psychosomatic support resulted in a reduction of CS rates for psychosocial indications with vaginal birth rates similar to the reference group. Similarly, work undertaken by Rouhe demonstrated a reduction in CS rates using a two hour group psycho-education intervention six times from 26 weeks of gestation, with no change in overall health care cost [20].

A recent Cochrane review of interventions for reducing unnecessary CS indicated that only two of the six randomised controlled trials targeting pregnant women reduced caesarean section rates. The first study offered birth preparation sessions for nulliparous Iranian women and the second study was a nurse-led relaxation training program in young nulliparous Iranian women suffering anxiety during pregnancy. The authors concluded there was insufficient evidence that prenatal education and support programs, computer patient decision-aids, decision-aid booklets and intensive group therapy were effective in reducing CS rates [12]. Nevertheless, our previous study has shown that highly distressed women giving birth have higher health care use and reduced health-related quality of life in the first year after birth [21]. Therefore, reducing the distress during pregnancy in women with high childbirth fear could improve health-related quality of life, reduce health care use, and reduce associated costs.

The purpose of the trial (*Birth Emotions: Looking to Improve Expectant Fear, BELIEF*) was to test an antenatal psycho-education intervention by midwives in reducing women's childbirth fear [22]. The key results have been published elsewhere: psycho-education by trained midwives was effective in reducing high childbirth fear levels and increasing childbirth confidence in pregnant women [2]. Further, there was a clinically meaningful but not statistically significant reduction in overall CS rates after a brief antenatal midwifery psycho-education intervention for childbirth fear. Six weeks postpartum more women in the intervention group indicated a preference for vaginal birth for a future pregnancy and had less psychological sequelae [23]. Whether the midwifery-led psycho-education intervention for childbirth fear is cost-effective or a good use of resources is until now unknown. In this paper, we present an economic evaluation analysis of the BELIEF trial.

Methods

BELIEF was a non-blinded randomised controlled trial [22]. In summary, BELIEF was a telephone psycho-education counselling intervention offered by midwives who had been specifically trained to deliver this intervention. Participants were randomised to the intervention group or usual care, stratified by hospital site and parity, and allocated to study groups using a web-based randomization service in blocks for groups of ten [2]. The intervention aimed to review women's current expectations and feelings around fear of childbirth, support the expression of feelings, and provide information and a framework for women to identify and work through distressing elements of childbirth. This intervention was provided in addition to usual care offered by publicly funded maternity services in Australia. Women in the control group received usual care only. All women received a decision-aid booklet about pregnancy and birth choices. Ethical approval was obtained from the university and participating hospitals. The primary outcome measure was reduction in childbirth fear according to the Wijma Delivery Expectancy/Experience Questionnaire version A (WDEQ-A) [24]. Secondary outcome measures included the EuroQol 5-dimensional scale,

three dimensions (EQ-5D-3L) and health service use. The EQ-5D-3L is a standardised measure of health status, designed for self-completion, and consists of five dimensions (mobility, self-care, usual activities, pain/discomfort and anxiety/depression; each measured on three levels: no problems, some problems, and extreme problems) and an overall self-rated measure of health on a visual analogue scale. It is designed to describe the health status with a single index value. For the purpose of this study we considered a minimum clinically important difference in the EQ-5D-3L of 0.05, based on the lower estimate of a recent study by Kohn et al. [25].

We recruited women in their second trimester attending antenatal clinics of three hospitals in South-East Queensland, Australia, who were able to communicate sufficiently in English, and aged 16 years or older. Participants were screened for high childbirth fear using the WDEQ-A. Participants ($n = 1410$) were recruited from May 2012 to June 2013. Three hundred and thirty-nine women (339/1410, 24%) reporting high childbirth fear (defined as a score of ≥ 66 on the WDEQ-A) were allocated to the intervention ($n = 170$) or control ($n = 169$) groups. Women in the intervention group received psycho-education sessions at 24 and 34 weeks by telephone at a scheduled time convenient to them. Psycho-education sessions were around one hour duration (first session range: 22–125 minutes; second session range: 10–104 minutes) [2]. Participants who received at least one intervention (telephone call) were considered as having received the intervention. As-treated analyses were performed (i.e. participants in the intervention group who did not actually receive any intervention were analysed with the control group) which allowed a slightly more accurate cost comparison for this economic evaluation. The confounding bias potentially introduced with this analysis method appeared limited as the quality of life was similar in both study groups. The study was designed to require 140 participants per group to detect a 10-point difference in WDEQ-A scores from baseline to 36 weeks' gestation (two-tailed, $\alpha = 0.05$, $\beta = 0.20$) [2].

Baseline characteristics of participants were collected at approximately 16–21 weeks gestation. Systematic differences between those followed-up and dropped out before the final data collection point were assessed. Statistically significant (using Wilcoxon rank-sum or t-tests, at $p < 0.05$) differences were observed as follows: women who did not complete the trial were younger, had a lower level of education, less likely to be employed and had a lower yearly income, with no differences between the women in the intervention or control group (see Toohill et al. [2]). At baseline and six weeks postpartum health-related quality of life was collected using the EQ-5D-3L and associated health states valued using the Australian weights [26]. The birth method outcome was categorised into “normal vaginal” (i.e. spontaneous vaginal birth), “vaginal assisted” and CS. CS included both planned and unplanned events. Health care use included self-reported visits to GP, midwives, obstetricians, nurse, home visits, ultrasound scans, hospital emergency department visits, hospital admissions (pre- and post-birth), special care nursery and mode of birth. This paper reports on the economic evaluation of those women who returned data at six weeks postpartum.

Costs were calculated and reported in 2013 Australian Dollars (AUD). Cost of healthcare use was calculated from baseline until six weeks post-partum using Medicare Benefit Scheme Schedule items (GP visit, obstetrician, ultrasound), the 2013–2014 National Efficient Price weights which were applied to weighted Australian Refined Diagnosis-Related Groups separations (hospital admissions antenatal or postnatal, hospital emergency department visit, special care nursery, birth) and Queensland Health nursing/midwifery wages (midwife or nurse visit, intervention telephone calls). Detailed costs are provided in Appendix A. Comparison of health care use and costs between groups were performed using Wilcoxon rank-sum and nonparametric bootstrap testing. EQ-5D-3L scores were compared between groups at baseline and follow-up

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