

Decision aids for breast cancer surgery: a randomised controlled trial

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KEY MESSAGE

In Chinese women who require breast cancer surgery, use of a decision aid booklet reduces decisional conflict, treatment decision-making difficulty, and post-surgery decision regret. Decision aids should be available as part of the routine clinical service, specifically to support post-consultation decision making.

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Introduction

Breast cancer management involves medical, surgical, and radiotherapeutic treatments. Our previous study showed that approximately one in seven of the ~2500 Chinese women diagnosed with breast cancer each year suffer from increased psychological morbidity attributable to treatment decision-making (TDM) difficulty.^{1,2} Two-thirds of the women preferred shared rather than sole responsibility for TDM, with guidance received from doctors.³ However, most women were left to decide on treatment alone, and many opted to have more extensive surgery than necessary, owing to a fear of prolonged treatment and associated social stigmatisation.³ The social and relationship consequences of this choice are often poorly comprehended before treatment and thus compound subsequent psychosocial morbidity. Information and decision-support strategies are needed to optimise women's breast cancer TDM.

Decision aids facilitate decision making by emphasising alternatives, probability of risks and benefits, and personal values.⁴ In a systematic review of the effect of decision aids in women with breast cancer, those who used a decision aid were more likely to choose breast-conserving therapy, were more knowledgeable about breast cancer, and had less decisional conflict and were more satisfied with the decision-making process.⁵ Nonetheless, there is no evidence that decision aids directly benefit health outcomes such as psychological morbidity. Their benefit may be mediated by patient satisfaction with the decision process.

This study assessed the effect of decision aids on the decision-making process, satisfaction with TDM, and psychological morbidity in women undergoing breast cancer surgery.

Methods

This randomised controlled trial was conducted from December 2009 to November 2011 at Kwong Wah Hospital Breast Centre and Tung Wah Hospital Breast Centre. Ethical approval was obtained. Cantonese/Mandarin-speaking Chinese women with early-stage breast cancer who had no other cancer history, were fit for surgery, and consented to be interviewed were invited to participate. Patients were excluded if they were to receive chemotherapy as a neo-adjuvant therapy, came for a second opinion, had metastasis or recurrence of breast cancer, or were cognitively impaired or physically unfit to complete the interview.

Women were block randomised by week to either an intervention (decision aid booklet) or control (standard-information booklet) arm. Procedures and wordings were identical. The corresponding booklet was provided prior to making a decision by telephone about treatment. The decision aid booklet comprised information about (1) the main differences between the available treatment options and their associated probable outcome, (2) benefits and costs of the available treatments, (3) methods for clarifying patients' values, and (4) structured guidance in reaching a decision. The standard-information booklet contained information on diagnosis, treatment, and management of breast cancer in general terms and was not designed to help make a specific, personal treatment decision.

Women were asked to complete questionnaires immediately (baseline: time 1) and within 7 days (time 2) of consultation, and at 4 weeks (time 3), 4 months (time 4), and 10 months (time 5) post-surgery. Face-to-face interviews were conducted at

baseline and follow-up assessments.

Outcome measures included satisfaction with the decision process (scores of TDM difficulty and decisional conflict), psychological morbidity (scores of Chinese Health Questionnaire and Hospital Anxiety and Depression Scale [HADS]), satisfaction with the treatment decision (scores of decision regret), and knowledge of breast cancer.

The two groups were compared using linear mixed effects (LME) models to control the random effects of hospital sites and surgeons. Covariates correlated with outcome measures were also included in the models to adjust for confounders. Intention-to-treat analysis was also used. For repeated measures (decision regret, psychological distress, and realistic outcome expectation), mean differences within and between groups were analysed using LME models, with random subject effects estimated for the intercept, slope for time, time-squared, and time-cubed. The quadratic and cubic effects of time

were included to account for non-linear change over time. The LEM model was adjusted for relevant demographic and clinical variables, and decision-making factors. To assess whether the booklet significantly influenced psychological morbidity, the mediating effect of patient satisfaction with TDM and use of the booklet on psychological morbidity was tested.

Results

A total of 276 women were randomised to the intervention (n=138) or control (n=138) group (Fig 1); 225 (81.5%) women (113 in intervention and 112 in control groups) were offered more than one treatment option (Table 1). Compared with controls, decision aids were associated with lower scores for TDM difficulty ($\beta=1.8, P=0.016$), decisional conflict ($\beta=5.8, P=0.004$), and decision regret ($\beta=4.55, P<0.05$) [Table 2]. Nonetheless, the two groups did not differ significantly in terms of decision regret at 4 weeks,

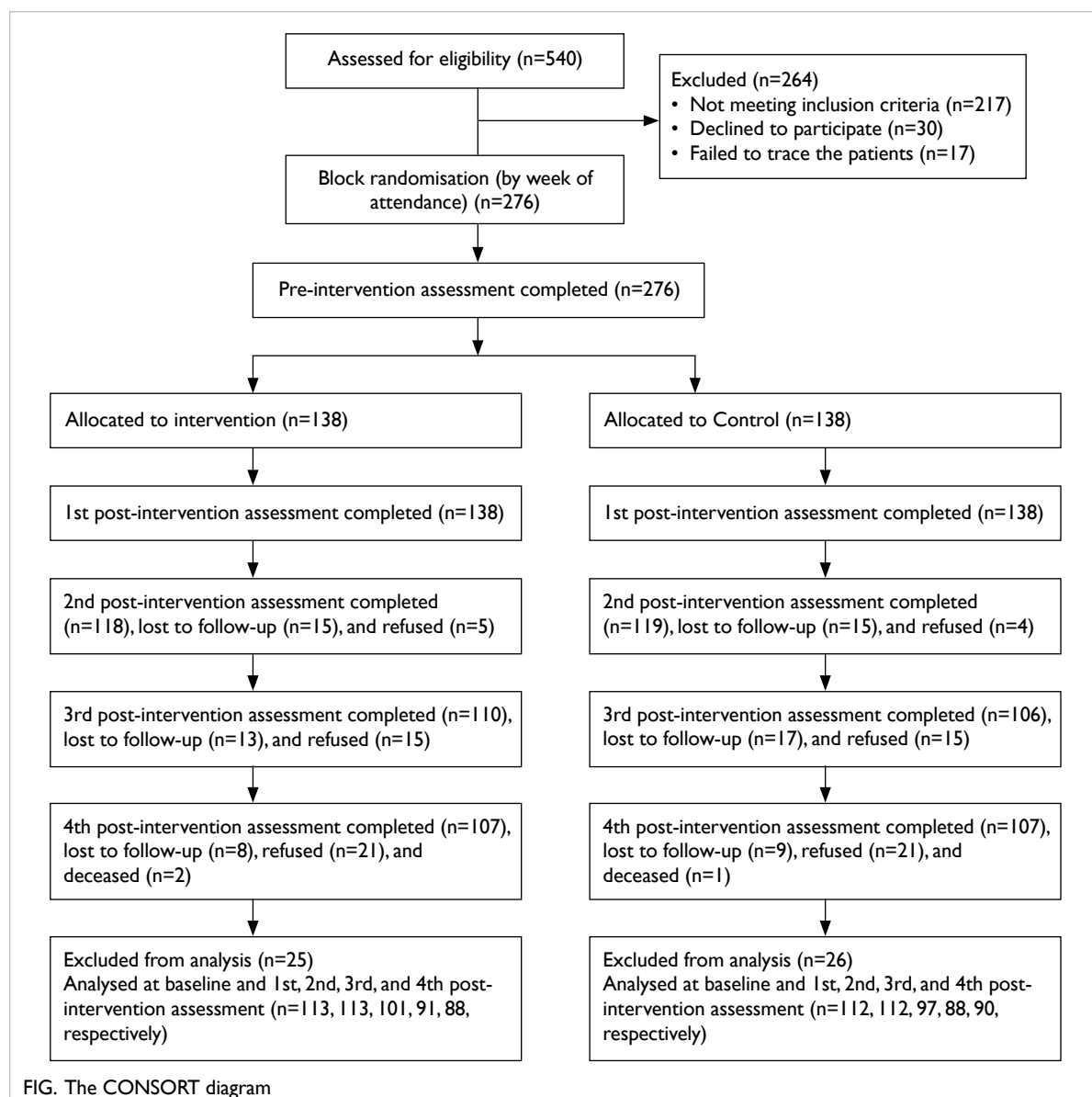


FIG. The CONSORT diagram

TABLE I. Patient demographics*

Variable	Decision aids (n=138)	Controls (n=138)	P value
Age (years)	56.8±10.8	54.6±10.1	>0.05
Marital status			>0.05
Married	85 (61.6)	87 (63)	
Single	21 (15.2)	19 (13.8)	
Divorced	12 (8.7)	12 (8.7)	
Widowed	20 (14.5)	20 (14.5)	
Education level			>0.05
No formal education	8 (5.8)	11 (8.0)	
Primary	44 (31.9)	40 (29.0)	
Secondary	71 (51.4)	73 (52.9)	
Tertiary	15 (10.9)	14 (10.1)	
Occupation			>0.05
Employed	51 (36.9)	63 (45.6)	
Retired	37 (26.8)	27 (19.6)	
Housewife	40 (29)	30 (21.7)	
Unemployed	10 (7.25)	18 (13.0)	
Monthly household income (HK\$)			>0.05
≤10 000	55 (42)	56 (43.8)	
10 001-20 000	43 (32.8)	36 (28.1)	
20 001-30 000	18 (13.7)	20 (15.6)	
30 001-40 000	8 (6.1)	9 (7.0)	
>40 000	7 (5.3)	7 (5.5)	
Family history of breast cancer	14 (10.1)	13 (9.4)	>0.05
More than one treatment choice	113 (83.7)	112 (83.0)	>0.05
Stage of breast cancer			>0.05
0	31 (37.8)	21 (28.8)	
I/II	42 (51.3)	47 (64.4)	
III	9 (11)	5 (6.8)	
Active chemotherapy			
At 1 month	21 (18.1)	19 (22)	>0.05
At 4 months	29 (28.2)	26 (25)	>0.05
At 10 months	0 (0)	0 (0)	>0.05
Active radiotherapy			
At 1 month	9 (8.6)	5 (4.8)	>0.05
At 4 months	9 (8.6)	4 (4.8)	>0.05
At 10 months	2 (2)	1 (1)	>0.05
Active hormonal therapy			
At 4 months	31 (30.1)	33 (31.7)	>0.05
At 10 months	65 (63.7)	64 (62.7)	>0.05

* Data are presented as mean±SD or No. (%) of patients

realistic outcome expectation, knowledge of breast cancer, or scores of Chinese Health Questionnaire, HADS-Anxiety and HADS-Depression.

Discussion

Decision aids decreased TDM difficulty, decisional conflict, and decision regret, without increasing anxiety. Decision aids could be an adjunct to post-consultation support in TDM. The effect of decision

aids on psychological morbidity was not mediated by patient satisfaction with the decision process. Psychological distress was associated with TDM difficulty, decision regret, and lack of treatment recommendation from the surgeon. Decision aids minimised TDM difficulty. This highlights the importance of reducing the level of TDM difficulty for women considering breast cancer surgery. Future study is needed to identify the optimal strategy

TABLE 2. Comparison of outcomes

Variable	Decision aid (n=113) Mean±SD	Controls (n=112) Mean±SD	Adjusted β±SE (95% CI) [decision aid as reference]	P value (95% CI)
Treatment decision-making difficulty	17.5±6.3	19.1±6.4	1.8±0.7 (0.34-3.24)	0.016 (0.34-3.24)
Decisional conflict	15.8±15.5	19.9±16.3	5.8±1.9 (1.85-9.71)	0.004 (1.85-9.71)
Knowledge of breast cancer	6.1±2.1	5.9±2.1	-0.17±0.2 (-0.65-0.31)	>0.05 (-0.65-0.31)
Chinese Health Questionnaire				
4 weeks	7.8±4.8	8.3±5.8	0.5±0.6 (-0.71-1.70)	>0.05 (-0.71-1.70)
4 months	7.6±5.3	7.3±5.6	0.21±0.69 (-1.17-1.57)	>0.05
10 months	6.7±4.9	7.5±5.6	1.4±0.7 (-0.07-2.86)	>0.05
Hospital Anxiety and Depression Scale (HADS)-Anxiety				
4 weeks	2.5±3.2	2.6±3.3	-0.1±0.4 (-0.94-0.67)	>0.05 (-0.94-0.67)
4 months	2.2±3.2	2.1±3.1	-0.08±0.38 (-0.85-0.68)	>0.05
10 months	2.7±3.5	2.8±3.6	0.28±0.47 (-0.65-1.22)	>0.05
HADS-Depression				
4 weeks	2.3±2.7	2.3±2.7	0.1±0.3 (-0.58-0.61)	>0.05 (-0.58-0.61)
4 months	2.1±3.3	1.9±2.4	0.07±0.32 (-0.56-0.71)	>0.05
10 months	1.4±1.9	2.5±3.4	1.38±0.41 (0.58-2.19)	0.001
Decision regret				
4 weeks	21.4±17.2	23.1±18.3	1.6±2.4 (-3.19-6.47)	>0.05 (-3.19-6.47)
4 months	18.8±15.8	24.4±18.9	5.9±2.5 (0.95-10.84)	0.02
10 months	20.1±14.5	24.6±18.8	6.1±2.4 (1.28-10.94)	0.014
Realistic outcome expectation				
4 weeks	-0.01±0.64	-0.11±0.56	-0.04±0.08 (-0.20-0.11)	>0.05 (-0.20-0.11)
4 months	-0.19±0.64	-0.20±0.56	0.05±0.09 (-0.13-0.24)	>0.05 (-0.13-0.24)
10 months	-0.28±0.56	-0.22±0.57	0.15±0.09 (-0.21-0.33)	>0.05
Surgical decision				
No. (%) of patients having breast-conserving therapy (BCT) as an option	Out of 73	Out of 86		>0.05
BCT	29 (43)	41 (51)		
Modified radical mastectomy (MRM)	31 (46)	32 (39)		
MRM plus reconstruction	7 (10)	7 (10)		
No. (%) of patients not having BCT as an option	Out of 40	Out of 26		>0.05
BCT	3 (7.9)	1 (4.3)		
MRM	30 (78.9)	14 (60.9)		
MRM plus reconstruction	5 (13.2)	8 (34.8)		

to integrate decision aids into routine clinical practice.

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