



ELSEVIER



# A multi-centred sequential trial comparing PEGASUS, an intervention to promote shared decision making about breast reconstruction with usual care

N. Paraskeva, P. Tollow, A. Clarke, P. White, J.E. Powell, D.M. Cox, D.M. Harcourt\*

Centre for Appearance Research, University of the West of England, Coldharbour Lane, Bristol BS16 1QY, UK

Received 3 September 2020; accepted 6 November 2021

## KEYWORDS

Breast reconstruction;  
Shared decision making;  
Intervention;  
Patient expectations

**Summary** Decision making about breast reconstruction (BR) is complex. The Patients' Expectations and Goals: Assisting Shared Understanding of Surgery (PEGASUS) intervention aims to support shared decision making by helping women and clinicians clarify and discuss their expectations around reconstructive surgery.

We conducted a multi-centred sequential trial comparing PEGASUS ( $n = 52$ ) with usual care (UC) ( $n = 86$ ) in women considering reconstruction, who completed outcome measures at baseline, and 3, 6 and 12 months post-surgery. The primary outcome was BR-specific quality of life (Breast-Q) 6 months post-intervention. Secondary outcomes were health-related quality of life (EQ-5D-5L), capabilities (ICECAP-A) and decisional regret, compared using  $t$ -tests and Cohen's  $d$ .

Comparative analyses revealed no significant differences between groups in Breast-Q scores at any time point, except for a favourable effect for UC on psychological well-being at 3 months ( $t = -2.41$ ,  $p = .019$ ,  $d = -0.59$ ). Intervention participants reported significantly higher, therefore improved, ICECAP-A ( $t = -2.13$ ,  $p = .037$ ,  $d = -0.45$ ) and EQ VAS ( $t = -2.28$ ,  $p = .026$ ,  $d = -0.49$ ) scores at 12 months compared to UC. Decisional regret was significantly lower in the

**Work to be attributed to:** The Centre for Appearance Research, Faculty of Health & Applied Sciences, University of the West of England, Bristol, UK.

**Presented at:** This paper was due to be presented as a poster at the UK Association of Breast Surgery annual conference in June 2020, but the conference was cancelled due to COVID-19. The abstract for this conference submission was published in the European Journal of Surgical Oncology (June 2020, vol 46, e37) and a poster submitted to the members' section of the Association of Breast Surgery website.

**Trial Registration:** ISRCTN 18000391 (DOI 10.1186/ISRCTN18000391) 27/01/2016.

**Intervention Condition:** PEGASUS (see Table 1)

\* Centre for Appearance Research, University of the West of England, Bristol, BS16 1QY

E-mail address: [Diana2.Harcourt@uwe.ac.uk](mailto:Diana2.Harcourt@uwe.ac.uk) (D.M. Harcourt).

<https://doi.org/10.1016/j.bjps.2021.11.033>

1748-6815/© 2021 British Association of Plastic, Reconstructive and Aesthetic Surgeons. Published by Elsevier Ltd. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>)

PEGASUS group compared to the UC group at 6 months ( $t = 2.06$ ,  $p = .044$ ,  $d = -0.51$ ), but this was not sustained at 12 months.

In conclusion, the PEGASUS intervention offers some benefits to women considering BR. At times, women experienced less decisional regret, improved health-related quality of life and capability well-being. Findings are discussed in the light of fidelity testing and embedding PEGASUS into practice.

© 2021 British Association of Plastic, Reconstructive and Aesthetic Surgeons. Published by Elsevier Ltd. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>)

## Introduction

Decision making about breast reconstruction (BR) can be challenging and complex.<sup>1</sup> The choices concerning whether to undergo reconstruction, the timing (delayed, immediate) and type (e.g., autologous, implant-based) of surgery are considerable and will depend on each woman's individual needs, preferences and goals.<sup>2</sup> Many women report satisfaction with their choices, yet post-surgical dissatisfaction, decisional regret, decisional conflict and poor psychosocial outcomes have been reported.<sup>3-7</sup> Dissatisfaction can result from a paucity of information and knowledge about BR,<sup>5</sup> unrealistic and unmet expectations regarding surgery,<sup>8,9</sup> and a lack of involvement in the decision-making process.<sup>10-11</sup> Research has demonstrated that taking patients' values and goals into consideration during shared decision making (SDM)<sup>12</sup> is crucial; however, eliciting this information is not standard in cancer care.<sup>12-14</sup> Indeed, decisions regarding BR are not always aligned with patients' preferences, for example, about appearance and recovery.<sup>15-16</sup>

Interventions designed to support and encourage patient decision making can improve decision-related self-reported outcomes for a wide range of cancer treatments, including radiotherapy and chemotherapy.<sup>17</sup> However, research focusing on the rigorous development and evaluation of interventions designed to help women make a choice about BR is in its infancy.<sup>18</sup> Only a handful of interventions are available to women specifically making a decision about BR, and their impact on patient outcomes is mixed.<sup>16,18</sup> Available interventions often provide standard rather than personalised information, and the majority have not been rigorously developed.<sup>16,18</sup>

Identifying the need for a rigorously developed intervention, Patients' Expectations and Goals: Assisting Shared Understanding of Surgery (PEGASUS) was designed to facilitate SDM.<sup>19</sup> PEGASUS helps patients and health professionals clarify each woman's individual expectations and goals for BR, thus promoting concordance so that they approach surgery as a shared endeavour. Building on successful acceptability and feasibility testing<sup>20</sup>, this paper reports on a multi-site trial examining the effectiveness of the PEGASUS intervention.<sup>21</sup>

We hypothesised that in comparison with women receiving usual care (UC), those receiving the PEGASUS intervention would report improved BR quality of life, SDM, reduced decisional conflict (the extent to which women experience uncertainty regarding their BR decision), reduced decisional regret, improved health-related quality of life (HRQoL) and capability well-being (what participants want to be able to

do in various key aspects of life). We also explored the economic costs of delivering the PEGASUS intervention in comparison with UC and conducted fidelity testing to assess the intervention delivery.

## Method

### Study design and procedure

This was a mixed-method, multi-centred time-sequential between subjects, before-and-after design comparing UC with the PEGASUS intervention. Qualitative data are presented elsewhere.<sup>22</sup> Women, aged 18 years or over, offered the option of immediate or delayed BR of any type following a diagnosis of breast cancer, ductal carcinoma in situ (DCIS) or undergoing risk-reducing mastectomy were eligible to participate. Women who were unsuitable for BR or unable to participate in an intervention and study conducted in English were not eligible. Participants were recruited between January 2016 and July 2018 from five NHS sites in the South of England and Wales. Potential participants were identified by clinic staff. After consenting, participants were asked to complete a self-report questionnaire at baseline (i.e., pre-PEGASUS for those in the intervention condition; pre-surgical consultation for those in the UC condition), after their surgical consultation (i.e., before surgery), and 3, 6 and 12 months post-surgery. At each site, the UC group was recruited before training for the intervention was delivered to health professionals and recruitment into the intervention condition commenced.<sup>21</sup> Ethical approval was granted from the NRES Committee South Central - Berkshire B (reference 15/SC/0331) and a Research Ethics Committee at the authors' host institution. R&D approvals were granted by the participating NHS study sites.

### The PEGASUS intervention

**Intervention condition: PEGASUS (see Table 1)** Part 1: Each participant attended an individual pre-surgical consultation (before a decision about treatment was made) with a PEGASUS coach (a specialist nurse or psychologist who had been trained in its use) who carefully elicited the patient's personal BR goals, separating those relating to surgical (e.g., shape, sensation) and psychosocial/lifestyle issues (e.g., self-confidence, clothing) and facilitating a discussion about what the patient considered to be a successful outcome. The patient then rated the importance of each of

**Table 1** PEGASUS intervention.**Part 1: A meeting between the patient and the trained PEGASUS coach:**

Step	Action: What the PEGASUS coach must do:
1-4	Introduce the PEGASUS intervention, gain an overview of patient's pathway to date, explain the structure of the session and check patient's understanding of the session.
5*	Elicit the patient's <b>surgical</b> goals and write them on the PEGASUS sheet.
6*	Explain the rating system and ask the patient to rate each surgical goal (from 0-10) in regards to its importance to them.
7*	Elicit the patient's <b>psychosocial (lifestyle)</b> goals and write them on the PEGASUS sheet.
8*	Ask the patient to rate each psychosocial goal (0-10).
9	Re-cap the patient's surgical and psychosocial goals and ratings. Check PEGASUS sheet is a complete and accurate record of patient's goals and expectations. Edit if necessary and agree with patient.
10	Ask the patient to take the completed PEGASUS sheet into their consultation with the surgeon (Part 2) and explain why this is important.

**Part 2: The meeting between the surgeon and the patient:**

Step	Action: What the Surgeon must do:
1	Look at the completed PEGASUS sheet which contains the patient's surgical and psychosocial/lifestyle goals and use it to <b>facilitate</b> a consultation that is focused around the patient's individual goals.
2	<b>Rank</b> (from 0-10) the probability of achieving each surgical goal and write this on the PEGASUS sheet.
3	<b>Reflect</b> with the patient on the extent to which psychosocial goals are likely to follow. Do not rank the probability of achieving psychosocial goals.
4	Use the PEGASUS sheet, along with their expert knowledge and experience of surgery, to identify if the patient's expectations are realistic. If necessary, take steps to address and manage any considered to be unrealistic.
5	At an appropriate post-surgical appointment, use the PEGASUS sheet again to <b>assist a discussion</b> and reflection on the extent to which goals have been met.

\* Key components of the PEGASUS intervention in the light of fidelity testing.

her goals (from 0 (not at all important) to 10 (extremely important)), and this information was listed on a PEGASUS sheet. These consultations were audio-recorded and assessed against a study-specific checklist to examine the fidelity of the intervention.

Part 2: Women took their completed PEGASUS sheet into their consultation with the BR surgeon (trained to use the sheet), where the patient's goals were used to facilitate the discussion. During this session, surgeons determined the extent to which the patient's goals were realistic and, if necessary, took appropriate steps to address unrealistic expectations (e.g., gave further explanation of the likely outcomes and the limitations of a surgical approach, showed additional photographs). Based on their experience and expertise, the surgeon rated (from 0 (not at all) to 10 (completely)) the likelihood of achieving each surgical goal and recorded this on the patient's PEGASUS sheet. The surgeon also reflected with the patient on the extent to which psychosocial/lifestyle goals were likely to follow. PEGASUS thereby helps women express what they want from surgery and assists health professionals to understand their patient's preferences before a shared decision about surgery is made.

### Intervention training

A standardised 90-minute face-to-face training session was delivered by the authors to the designated PEGASUS coaches at each participating site. Each trainee was given a PEGASUS intervention manual. The training included a Power-

Point presentation and video depicting a PEGASUS intervention being delivered, role plays and opportunities for questions throughout. BR surgeons received a 30-minute training session focussing on how to use the PEGASUS sheet to frame the surgical discussion. Training materials can be accessed at [www.pegasusdecisionmaking.com](http://www.pegasusdecisionmaking.com).

### Control condition

Participants in this condition received UC.

### Outcome measures

The primary outcome was BR-specific quality of life at 6 months follow-up, assessed using the Breast-Q<sup>23</sup> - a well validated and widely used breast-surgery specific measure of quality of life, including psychosocial, sexual and physical well-being. It also includes satisfaction with breasts, nipples, abdomen, outcome and care. Scores range from 0-100 with a higher score indicating higher satisfaction or better HRQoL.

Unless stated below, secondary outcome measures were completed at baseline and repeated at 3, 6 and 12 months follow-up. Six months post-surgery was considered the key time point, allowing participants some time to recover from

**Table 2** Participant demographic and clinical characteristics at baseline

Characteristic	PEGASUS intervention n (%)	Usual care n (%)	p
<b>Age</b>			
Mean yrs (SD)	47.4 (10.8)	50.8 (10.4)	0.059
<b>Marital status</b>			
Single	5 (8.9)	7 (7.7)	0.991
Married	34 (60.7)	59 (64.8)	
In a relationship	8 (14.3)	13 (14.3)	
Divorced	6 (10.7)	8 (8.8)	
Separated	3 (5.4)	4 (4.4)	
<b>Ethnicity</b>			
White	53 (94.4)	87 (95.6)	0.999
Mixed/multiple ethnic group	1 (1.8)	2 (2.2)	
Asian/Asian British	1 (1.8)	1 (1.1)	
Black/African/Caribbean/Black British	0 (0.0)	0 (0.0)	
Chinese	0 (0.0)	1 (1.1)	
Missing	1 (1.8)	0 (0.0)	
<b>Employment status</b>			
Working full-time	19 (33.9)	29 (31.9)	0.617
Working part-time	21 (37.5)	25 (27.5)	
Unemployed	1 (1.8)	3 (3.3)	
Retired	6 (10.7)	16 (17.6)	
Student	0 (0.0)	0 (0.0)	
Other	9 (16.1)	18 (19.8)	
<b>Education</b>			
GCSE/O-level or equivalent	14 (25.0)	25 (27.5)	0.566
A level or equivalent	5 (8.9)	11 (12.1)	
Higher education certificate or diploma	8 (14.3)	22 (24.2)	
Undergraduate degree	21 (37.5)	22 (24.2)	
Master's degree	4 (7.1)	4 (4.4)	
PhD or equivalent	1 (1.8)	2 (2.2)	
No qualifications	2 (3.6)	5 (5.5)	
Missing	1 (1.8)	0 (0.0)	
<b>Treatment reasons</b>			
Diagnosis of breast cancer	43 (76.8)	73 (80.2)	0.841
Risk reduction	12 (21.4)	16 (17.6)	
Both	1 (1.8)	1 (1.1)	
Missing	0 (0.0)	1 (1.1)	
<b>Time since diagnosis</b>			
< 1 month	9 (20.5)	29 (38.7)	0.020
1 to 4 months	25 (56.8)	22 (29.3)	
> 4 months	10 (22.7)	18 (24.0)	
Missing	0 (0.0)	6 (8.0)	
<b>Type of breast cancer</b>			
Invasive	16 (36.4)	39 (52.0)	0.218
Non-invasive	16 (36.4)	17 (22.7)	
Not sure	7 (15.9)	11 (14.7)	

(continued on next page)

surgery. All measures have been well validated and widely used in this population:

- Decisional Conflict Scale<sup>24</sup>: 16 items measure personal perceptions of (a) uncertainty in choosing options; (b) modifiable factors contributing to uncertainty such as feeling uninformed, unclear about personal values and unsupported in decision making; (c) effective decision making. This was completed immediately post-intervention/post-consultation only.
- CollaboRATE<sup>25</sup>: 4 items measure SDM in the clinical encounter from the patient's perspective. This was completed post-intervention/post-consultation only.
- Decision Regret Scale<sup>26</sup>: 5 items measure distress or remorse after a health care decision.
- EQ-5D-5L<sup>27</sup>: a measure of HRQoL consisting of five dimensions (mobility, self-care, usual activities, pain/discomfort and anxiety/depression) and a single index value (EQ VAS) for generic health status.

**Table 2** (continued)

Characteristic	PEGASUS intervention n (%)	Usual care n (%)	<i>p</i>
Invasive and DCIS	3 (6.8)	2 (2.7)	
Missing	2 (4.5)	6 (8.0)	
<b>Treatment to date</b>			
Chemotherapy	4 (7.1)	11 (12.1)	0.493
Radiotherapy	2 (3.6)	3 (3.3)	
Hormonal:	1 (1.8)	3 (3.3)	
Chemotherapy and hormonal	0 (0.0)	2 (2.2)	
Chemotherapy, radiotherapy and hormonal	1 (1.8)	3 (3.3)	
Chemotherapy and radiotherapy	3 (5.4)	1 (1.1)	
Radiotherapy and hormonal	1 (1.8)	0 (0.0)	
Missing	44 (78.6)	74.7)	
<b>Decision about BR</b>			
Yes, I definitely want breast reconstruction	43 (76.8)	63 (69.2)	0.548
Yes, I definitely do not want breast reconstruction	1 (1.8)	3 (3.3)	
I am undecided	10 (17.9)	22 (24.2)	
Missing	2 (3.6)	3 (3.3)	
<b>Surgery</b>			
Immediate BR	35 (62.5)	47 (51.6)	0.125
Delayed BR	5 (8.9)	18 (19.8)	
Mastectomy only	4 (7.1)	14 (15.4)	
Other	3 (5.4)	9 (9.9)	
Missing	9 (16.1)	3 (3.3)	

- e. ICECAP-A<sup>28</sup>: a measure of capability well-being consisting of five attributes linked to key aspects of the participant's life; stability, attachment, autonomy, achievement and enjoyment.

Demographics and clinical characteristics (including age, education, marital status, time since diagnosis) were collated for sample description.

### Statistical Analysis

Primary analyses were performed on an available case basis, utilising all data available. Data validity checks and missing values analysis were undertaken prior to descriptive and inferential analysis. Measures did not have distributions that were overly skewed and mean values were the best measures of central location, so parametric analyses were conducted. All statistical tests were performed as two-sided tests with a nominal significance level of standard alpha level of 0.05. Cohen's *d* was used as a measure of effect size. Confidence intervals for standardised and unstandardised effects are reported. An a priori power analysis indicated that at least 90% power would be achieved with a sample size of  $n = 90$  per group.

### Results

One hundred and forty-seven (76.17%) of 193 eligible patients were enrolled, 91 into the UC group and 56 to the PEGASUS intervention. At baseline, there were no differences between the two groups on demographic or clinical characteristics (Table 2) apart from 'time since diagnosis', where the intervention group had disproportionality more women

who had been diagnosed between 1 and 4 months before study entry. An exploratory two-way analysis showed no significant statistical interaction between 'group' and 'time since diagnosis' on outcomes.

### Primary outcome: Intervention effects on BR-specific Quality of life (Breast-Q)

Table 3 depicts the means and standard deviations on each domain of the Breast-Q at baseline, 3, 6 and 12 months follow-up. Table 4 summarises comparative between-group analyses summarising mean difference, unstandardised effect size (95% CI for mean difference) and standardised effect size (Cohen's *d* and 95% CI for Cohen's *d*). These comparative analyses do not show statistically significant differences between the two groups on Breast-Q domains at any time point, except for a marginal favourable effect for UC on psychological well-being at 3 months ( $t = -2.41$ ,  $p = .019$ ,  $d = -0.59$ ).

**Secondary outcomes: Intervention effects on HRQoL (EQ-5D-5L), generic health status (EQ VAS), capabilities (ICECAP-A), decision regret (Decision Regret Scale), decisional conflict (Decisional Conflict Scale) and shared decision making (CollaboRATE).**

Comparative analyses revealed no significant differences between groups in ICECAP-A or EQ-5D-5L scores at 3 or 6 months follow-up. The intervention group reported significantly higher, and therefore improved, ICECAP-A ( $t = -2.13$ ,  $p = .037$ ,  $d = -0.45$ ) and EQ VAS ( $t = -2.28$ ,  $p = .026$ ,  $d = -0.49$ ) scores at 12 months compared to UC, as shown in Table 5 and Table 6.

Analyses revealed no significant differences between groups in decisional regret scores at 3 months. It was sig-

**Table 3** Primary outcome: Mean and standard deviation on each domain of the Breast-Q at baseline, 3 months, 6 months and 12 months.

Breast-Q domain	Control			Intervention		
<b>Baseline</b>						
Satisfaction	84	62.08	19.866	51	67.18	22.863
Psychological	83	66.58	18.732	48	71.00	16.356
Chest	86	79.05	16.782	52	79.29	19.238
Abdomen	85	88.96	16.871	51	90.61	15.372
Sexual	76	55.38	22.367	46	57.26	17.669
<b>3 months</b>						
Satisfaction	37	64.97	16.868	21	66.05	14.915
Psychological	38	74.97	19.522	27	64.15	16.606
Chest	37	72.89	15.712	28	70.14	18.149
Abdomen	10	81.20	22.260	12	82.33	20.029
Sexual	31	56.48	25.406	24	46.33	23.900
Information	35	78.91	17.044	25	74.76	23.763
Surgeon	36	96.08	7.236	27	90.48	21.988
Medical team	37	93.00	17.941	28	92.61	20.595
Office staff	37	95.65	8.479	28	93.11	19.960
<b>6 months</b>						
Satisfaction	31	60.84	20.466	20	61.95	20.229
Psych well-being	33	70.70	23.115	25	68.76	16.846
Chest	34	71.85	17.441	25	74.28	16.395
Abdomen	7	76.43	18.769	10	77.30	16.139
Sexually	30	52.67	27.906	22	46.73	19.037
Information	33	75.24	20.843	22	75.73	22.943
Surgeon	34	90.03	17.997	25	94.60	16.457
Medical team	34	93.00	14.824	25	93.12	12.411
Office staff	34	94.09	12.662	25	97.24	8.141
<b>12 months</b>						
Satisfaction	40	64.75	14.870	26	69.12	17.065
Psychological	47	72.06	21.324	28	73.54	17.304
Chest	45	72.18	18.496	28	75.61	12.032
Abdomen	10	75.60	24.047	8	79.25	15.554
Sexual	42	53.86	24.465	23	54.00	21.971
Information	43	76.42	19.000	27	73.33	26.217
Surgeon	44	92.32	15.409	25	90.72	22.399
Medical team	45	91.47	19.620	27	91.52	22.545
Office staff	45	92.49	17.922	27	91.56	22.478

nificantly lower in the PEGASUS group compared to UC at 6 months ( $t = 2.06$ ,  $p = .044$ ,  $d = -0.51$ ), but this was not sustained at 12 months.

Unfortunately, the small sample of data collected at immediately post-intervention/post-consultation precluded planned analyses to meaningfully examine the impact of the intervention on the Decisional Conflict Scale and Collaborative scores.

### Fidelity

Intervention consultations with the PEGASUS coach (i.e., Part 1) were audio-recorded, with permission, for the purpose of assessing provider adherence. Out of 56 PEGASUS interventions conducted, 45 were recorded (mean duration: 47.61 minutes, range: 10-120 minutes) at four of the participating sites, with nine subsequently excluded due to problems with the recording. Two independent reviewers checked the remaining 36 (64.3%) recordings for fidelity. A

study-specific template was created, which instructed reviewers to check for inclusion of the 10 steps outlined in the PEGASUS intervention manual (see Table 1). A rating of 'overall adherence' (on a scale from 0 (no adherence) to 5 (excellent adherence)) focused on four key components (see Table 1) essential to the decision-making theory underpinning the development of PEGASUS.<sup>19</sup> The mean score was 3.85 (SD=1.08, range 1-5), suggesting generally 'good' to 'very good' adherence. Indeed, 92.97% of the key components were delivered. The average interclass correlation between raters across the 'overall adherence' ratings was .53 ( $p=0.14$ ).<sup>29</sup>

### DISCUSSION

This study examined the impact of the PEGASUS intervention amongst women considering BR following a diagnosis of breast cancer or DCIS or having risk-reducing mastectomy. Of primary interest was the impact on BR-specific quality of life scores at 6 months post-surgery, measured by the

**Table 4** Primary outcome: Breast-Q domains. Mean difference, 95% confidence interval for mean difference (95% CI), t-statistic (t), degrees of freedom (df), p-value, Cohen's d and 95% confidence interval for Cohen's d (95% CI d) for comparing intervention with usual care.

	Mean difference	95% CI	t	df	p	d	95% CI d
<b>Baseline</b>							
Satisfaction	5.09	-2.58, 12.77	1.317	94	.191	-0.24	-0.59, 0.11
Well-being	4.42	-1.78, 10.63	1.412	109	.161	-0.25	-0.60, 0.11
Chest	0.24	-6.16, 6.64	0.075	96	.940	-0.01	-0.36, 0.33
Abdomen	1.64	-3.95, 7.24	0.582	113	.562	-0.10	-0.45, 0.25
Sexual	1.88	-5.37, 9.12	0.514	112	.608	-0.09	-0.46, 0.28
<b>3 months</b>							
Satisfaction	1.08	-7.53, 9.68	0.251	46	.803	-0.07	-0.60, 0.47
Well-being	-10.83	-19.82, -1.83	-2.406	61	.019	0.59	0.08, 1.09
Chest	-2.75	-11.36, 5.86	-0.640	53	.525	0.16	-0.33, 0.65
Abdomen	1.64	-17.98, 20.24	0.124	18	.902	-0.05	-0.89, 0.79
Sexual	-10.15	-23.56, 3.26	-1.520	51	.135	0.41	-0.13, 0.94
Information	-4.15	-15.38, 7.07	-0.747	41	.459	0.21	-0.31, 0.72
Surgeon	-5.60	-14.59, 3.38	-1.273	30	.213	0.36	-0.14, 0.86
Medical team	-0.39	-10.19, 9.40	-0.080	54	.936	0.02	-0.47, 0.51
Office staff	-2.54	-2.28, 8.59	-0.632	34	.532	0.17	-0.32, 0.66
<b>6 months</b>							
Satisfaction	1.11	-10.66, 12.88	0.850	41	.850	-0.05	-0.62, 0.51
Well-being	-1.94	-12.45, 8.58	-0.713	56	.713	0.09	-0.43, 0.61
Chest	2.43	-6.47, 11.33	0.547	53	.587	-0.14	-0.66, 0.38
Abdomen	0.87	-18.22, 19.96	0.100	12	.922	-0.05	-1.01, 0.92
Sexual	-6.14	-19.22, 6.95	-0.943	50	.350	0.24	-0.31, 0.79
Information	0.49	-11.81, 12.77	0.080	42	.937	-0.02	-0.56, 0.52
Surgeon	4.57	-14.59, 3.38	1.013	54	.316	-0.26	-0.78, 0.26
Medical team	0.12	-7.00, 7.24	0.034	56	.973	-0.01	-0.52, 0.51
Office staff	3.15	-2.29, 8.59	1.161	56	.250	-0.29	-0.80, 0.24
<b>12 months</b>							
Satisfaction	4.37	-3.86, 12.59	1.067	48	.850	-0.28	-0.77, 0.22
Well-being	1.47	-7.54, 10.48	0.326	66	.745	-0.07	-0.54, 0.39
Chest	3.43	-3.70, 10.56	0.960	71	.341	-0.21	-0.68, 0.27
Abdomen	3.65	-16.30, 23.60	0.389	15	.703	-0.18	-1.10, 0.76
Sexual	0.14	-11.78, 12.07	0.024	50	.981	-0.01	-0.51, 0.50
Information	-3.09	-14.82, 8.65	0.530	43	.599	0.14	-0.34, 0.62
Surgeon	-1.60	-11.82, 8.63	0.317	37	.753	0.09	-0.40, 0.58
Medical team	0.05	-10.46, 10.57	0.010	49	.992	0.00	-0.48, 0.47
Office staff	-0.93	-11.17, 9.30	-0.184	46	.855	0.05	-0.43, 0.52

Breast-Q. Contrary to our hypothesis, participants who received the PEGASUS intervention did not improve across any of the domains of the Breast-Q at any time point. A marginal improvement in psychological well-being was found at 3 months for participants receiving UC but was not sustained. These findings are consistent with previous research. Luan and colleagues<sup>30</sup> found that a decision aid designed to provide support to BR patients had no significant effect on quality of life 3-5 months postoperatively as measured by the Breast-Q. This may be because other psychological factors such as coping skills, social factors (e.g., partner and family involvement) and issues related to the surgery (e.g., complications experienced) may play an equally or more powerful role in relation to patient satisfaction with outcome and BR quality of life.<sup>30</sup> Future research could benefit from measuring potential moderating or confounding factors.

As predicted, women in the PEGASUS intervention reported less decisional regret at 6 month follow-up in com-

parison with UC. This is an encouraging finding given that regret is experienced by a considerable proportion of women following BR<sup>5</sup> and is associated with dissatisfaction, anxiety and distress.<sup>4,31</sup> Women who participated in the PEGASUS intervention experienced lower levels of distress and remorse following their decision 6 months postoperatively. Although this was not sustained at 12 months (given UC levels dropped towards those of PEGASUS), a non-significant trend indicated that levels of regret in the PEGASUS group remained lower than UC overall. These findings contribute to the broader literature demonstrating that decision aids can effectively reduce decisional regret at least in the short term<sup>32</sup>, and a growing evidence base showing interventions designed to support patient decision making about BR can reduce levels of regret.<sup>6,30</sup>

Contrary to our hypothesis, there were no differences between groups in HRQoL and capability well-being at 3 or 6 months follow-up. However, at 12 months, the inter-

**Table 5** Mean and standard deviation for secondary outcomes.

Measure	Control			Intervention		
	N	Mean	SD	N	Mean	SD
<b>Baseline</b>						
ICECAP-A	89	0.90	0.106	52	0.91	0.113
EQ-5D-5L	90	0.83	0.150	32	0.83	0.119
EQ- VAS	90	74.66	18.886	52	77.50	19.44
<b>3 months</b>						
ICECAP-A	35	0.86	0.188	28	0.87	0.190
EQ-5D-5L	36	0.81	0.128	32	0.83	0.119
EQ- VAS	37	81.22	12.18	27	81.00	14.926
Decision regret	35	7.67	12.91	27	10.18	15.780
<b>6 months</b>						
ICECAP-A	33	0.91	0.106	23	0.91	0.132
EQ-5D-5L	34	0.82	0.133	25	0.81	0.176
EQ- VAS	33	78.48	20.370	25	77.12	23.017
Decision regret	33	14.39	22.387	24	4.583	13.426
<b>12 months</b>						
ICECAP-A	44	0.91	0.108	27	0.95	0.047
EQ-5D-5L	42	0.83	0.123	28	0.85	0.092
EQ- VAS	44	82.71	14.958	28	88.89	8.015
Decision regret	42	10.12	15.519	27	7.59	12.813

**Table 6** Secondary outcomes: Mean difference, 95% confidence interval for mean difference (95% CI), t-statistic (t), degrees of freedom (df), p-value, Cohen's d and 95% confidence interval for Cohen's d (95% CI d) for comparing intervention with usual care.

	Mean difference	95% CI	t	df	p	d	95% CI d
<b>Baseline</b>							
ICECAP-A	-0.00	-0.04, 0.34	-0.202	102	.841	-0.04	-0.38, 0.31
EQ-5D-5L	-0.01	-0.06, 0.39	-0.408	114	.684	-0.07	-0.41, 0.27
EQ- VAS	-2.84	-9.49, 3.80	-0.849	104	.398	-0.15	-0.49, 0.19
<b>3 months</b>							
ICECAP-A	-0.01	-0.11, 0.09	-0.198	58	.844	-0.05	-0.55, 0.44
EQ-5D-5L	-0.02	-0.08, 0.04	-0.796	66	.429	-0.19	-0.67, 0.29
EQ- VAS	-0.22	-6.82, 7.25	0.062	49	.951	0.02	-0.48, 0.51
Decision regret	-2.52	-10.03, 4.99	-0.674	50	.504	-0.18	-0.68, 0.33
<b>6 months</b>							
ICECAP-A	-0.00	-0.08, 0.07	-0.109	47	.913	-0.02	-0.56, 0.51
EQ-5D-5L	0.01	-0.07, 0.10	0.268	43	.790	0.07	-0.45, 0.59
EQ- VAS	1.36	-10.32, 13.05	0.235	48	.815	0.06	-0.46, 0.58
Decision regret	9.81	0.26, 19.36	2.059	53	.044	0.51	0.01, 1.04
<b>12 months</b>							
ICECAP-A	-0.04	-0.08, -0.01	-2.127	64	.037	-0.45	-0.93, 0.01
EQ-5D-5L	-0.02	-0.07, 0.03	-0.619	67	.493	-0.16	-0.64, 0.32
EQ- VAS	-6.19	-11.61, -0.78	2.278	68	.026	-0.49	-0.96, -0.01
Decision regret	2.53	-4.34, 9.40	0.735	63	.465	0.17	-0.31, 0.66



vention group reported preferable scores in both domains. Regarding capability well-being, women in the intervention group reported improved ‘capability to do and be the things that are deemed valuable in their life’ (p.174)<sup>28</sup> compared to those receiving UC. Similarly, intervention participants reported improved health status at 12 months. These findings highlight the importance of a longer-term follow-up. To date, the majority of studies assessing the effectiveness of interventions to support patient decision making about BR have included relatively short-term follow-up, usually less than 12 months.<sup>18</sup> It is likely that the impact of BR on well-being more broadly is not evident for some time after surgery.

The PEGASUS intervention appears to offer some benefits over UC; participants experienced less regret in the shorter term and improved HRQoL and capability well-being in the longer term. Crucially, no adverse effects were reported as a result of the intervention. However, there were a number of unexpected findings, including improvements in psychological well-being in the UC group 3 months postoperatively and a lack of effects more generally. Potential reasons for these are considered; first, although training in the PEGASUS intervention was standardised across sites to ensure consistency, fidelity testing showed that adherence varied within and across sites. One site was unable to record any of the sessions, and sites were not asked to record sessions with the surgeon, limiting our ability to assess fidelity with Part 2 of the intervention. Given the nature of the intervention, some flexibility in the delivery and content of PEGASUS was expected (for example, it is likely that health professionals’ prior experience may have influenced how they used it). However, varied approaches and use of the intervention may have contributed to the mixed findings. Second, sites that chose to participate in the trial may be more invested in SDM than others and may therefore already be providing good decision-making support. Indeed, participants across all time points scored highly on satisfaction with care, including satisfaction with the information provided (e.g., “what you could expect your breasts to look like after reconstructive surgery”), satisfaction with their surgeon (e.g., “involved you in the decision-making process”) and medical team (e.g., “made time for your concerns”) as measured by the Breast-Q. Third, participants may have still been recovering from, or undergoing, additional procedures at the point of follow-up data collection which could have impacted satisfaction and quality of life scores. Finally, BR is a complex surgical procedure, taking place in the context of other worries and treatment. It is likely that many factors in addition to pre-surgical decision making about BR influence the outcomes experienced.

This study has limitations. Despite efforts, recruitment was challenging. Some surgical protocols changed during the trial, reducing the number of patients eligible to take part in the intervention phase, and drop out was high, despite reminder emails and phone calls. This resulted in a small sample size, limiting the power of our study and precluding planned analyses to examine the impact of the intervention on decisional conflict and ColaboRATE scores immediately post-intervention. Furthermore, the majority of participants in this study identified as White and were well-educated, limiting the ability to generalise the effectiveness of this intervention to women

from different backgrounds. Going forward, it is crucial to consider women’s socio-economic and ethnic backgrounds, literacy levels and culture, given that these factors are likely to influence their decisions about and preferences for BR.

Use of the PEGASUS intervention as part of SDM in BR consultation is low cost. Once PEGASUS training is completed, there is a very low average running and maintenance cost, and it is possible that greater structuring of the consultation process saves time and resources in the medium and long term.

To conclude, the PEGASUS intervention was developed to support SDM around BR. The findings of this study suggest it may offer some benefits to women considering BR in comparison with UC. At times, intervention participants experienced less decision regret, improved HRQoL and capability well-being. Given these findings, we believe that the PEGASUS intervention can be offered as a useful, free resource to health professionals working with women making difficult and complex decisions about BR surgery.

## Ethical approval

Granted from the NRES Committee South Central - Berkshire B (reference 15/SC/0331) and a Research Ethics Committee at the authors’ host institution. R&D approvals were granted by the participating NHS study sites.

## Declaration of Competing Interest

n/a

## Acknowledgements

This research was supported by Breast Cancer Now (grant no: 014NovPR415).

Most importantly, we thank all the women who took part in this study. We are also very grateful to the staff at the study sites, particularly the PEGASUS coaches and the local PIs (Iain Brown, Olivia Donnelly, Siobhan Laws, Richard Sutton and Nicola West), the study steering committee members (Nicola Walsh (Chair), Elisabeth Baker, Amanda Bond, Simon Cawthorn, Jennifer Finnegan-John, Esther Hansen, Fiona Kennedy, Caroline Oates, Karen Scanlon) and our patient representatives Sarah Sawyer and Nicola Carson.

## References

1. Myckatyn TM, Parikh RP, Lee C, Politi MC. Challenges and solutions for the implementation of shared decision-making in breast reconstruction. *Plast Reconstr Surg Global Open* 2020;8(2):e2645.
2. Flitcroft K, Brennan M, Spillane A. Making decisions about breast reconstruction: a systematic review of patient-reported factors influencing choice. *Qual Life Res* 2017;26:2287-319.
3. *NHS Information Centre for Health and Social Care*. . London: National Mastectomy and Breast Reconstruction Audit; 2011.
4. Sheehan J, Sherman KA, Lam T, Boyages J. Association of information satisfaction, psychological distress and monitoring

- coping style with post-decision regret following breast reconstruction. *Psychooncology* 2007;16:342-51.
5. Flitcroft K, Brennan M, Spillane A. Decisional regret and choice of breast reconstruction following mastectomy for breast cancer: a systematic review. *Psychooncology* 2018;27:1110-20.
  6. Lam WW, Chan M, Or A, Kwong A, Suen D, Fielding R. Reducing treatment decision conflict difficulties in breast cancer surgery: a randomized controlled trial. *J Clin Oncol* 2013;31:2879-85.
  7. Lee BT, Chen C, Yueh JH, Nguyen MD, Lin SJ, Tobias AM. Computer-based learning module increases shared decision making in breast reconstruction. *Ann Surg Oncol* 2010;17:738-43.
  8. Snell L, McCarthy C, Klassen A, Cano S, Rubin L, Hurley K, et al. Clarifying the expectations of patients undergoing implant breast reconstruction: a qualitative study. *Plastic Reconstr Surg* 2010;126:1825-30.
  9. Denford S, Harcourt D, Rubin L, Pusic A. Understanding normality: a qualitative analysis of breast cancer patients concepts of normality after mastectomy and reconstructive surgery. *Psychooncology* 2011;20:553-8.
  10. Lantz PM, Janz NK, Fagerlin A, et al. Satisfaction with surgery outcomes and the decision process in a population-based sample of women with breast cancer. *Health Serv Res* 2005;40:745-67.
  11. Katz SJ, Lantz PM, Janz NK, et al. Patient involvement in surgery treatment decisions for breast cancer. *J Clin Oncol* 2005;23:5526-33.
  12. Kunneman M, Marijnen CA, Baas-Thijssen MC, et al. Considering patient values and treatment preferences enhances patient involvement in rectal cancer treatment decision making. *Radiother Oncol* 2015;117:338-42.
  13. Henselmans I, Van Laarhoven HW, Van der Vloodt J, De Haes HC, Smets EM. Shared decision making about palliative chemotherapy: a qualitative observation of talk about patients' preferences. *Palliat Med* 2017;31:625-33.
  14. Größl I, McMullen CK. Barriers to eliciting patient goals and values in shared decision-making breast cancer surgery consultations: An ethnographic and interview study. *Psychooncology* 2019;28:2233-9.
  15. Lee CN, Deal AM, Huh R, Ubel PA, Liu YJ, Blizard L, Hunt C, Pignone MP. Quality of patient decisions about breast reconstruction after mastectomy. *JAMA Surgery* 2017;152:741-8.
  16. Politi MC, Lee CN, Philpott-Streiff SE, Foraker RE, Olsen MA, Merrill C, Tao Y, Myckatyn TM. A randomized controlled trial evaluating the BREASTChoice tool for personalized decision support about breast reconstruction after mastectomy. *Ann Surg* 2020;271:230-7.
  17. Zdenkowski N, Butow P, Tesson S, Boyle F. A systematic review of decision aids for patients making a decision about treatment for early breast cancer. *Breast* 2016;26:31-45.
  18. Paraskeva N, Guest E, Lewis-Smith H, Harcourt D. Assessing the effectiveness of interventions to support patient decision making about breast reconstruction: A systematic review. *Breast* 2018;40:97-105.
  19. Clarke A, Paraskeva N, White P, Tollow P, Hansen E, Harcourt D. PEGASUS: the Design of an intervention to facilitate shared decision-making in breast reconstruction. *J Canc Educ* 2020;28 1-1. doi:10.1007/s13187-019-01656-6.
  20. Harcourt D, Griffiths C, Baker E, Hansen E, White P, Clarke A. The acceptability of PEGASUS: an intervention to facilitate shared decision-making with women contemplating breast reconstruction. *Psychol Health Med* 2016;17(21):248-53.
  21. Harcourt D, Paraskeva N, White P, Powell J, Clarke A. A study protocol of the effectiveness of PEGASUS: a multi-centred study comparing an intervention to promote shared decision making about breast reconstruction with treatment as usual. *BMC Med Inform Decis Mak* 2017;17:143. doi:10.1186/s12911-017-0543-0.
  22. Tollow P, Paraskeva N, Clarke A, White P, Powell J, Cox D, Harcourt D. "They were aware of who I was as a person": Patients' and health professionals' experiences of using the PEGASUS intervention to facilitate decision-making around breast reconstruction. *Euro J Cancer Care* 2021 In press. doi:10.1111/ecc.13464.
  23. Pusic AL, Klassen AF, Scott AM, Klok JA, Cordeiro PG, Cano SJ. Development of a new patient reported outcome measure for breast surgery: The BREAST-Q. *Plast Reconstr Surg* 2009;124:345-53.
  24. O'Connor AM. Validation of a decisional conflict scale 4. *Med Decis Making* 1995;15:25-33.
  25. Elwyn G, Barr P J, Grande SW, Thompson R, Walsh T, Ozanne EM. Developing CollaboRATE: a fast and frugal patient-reported measure of shared decision making in clinical encounters. *Patient Educ Couns* 2013;93:102-7.
  26. Brehaut JC, O'Connor AM, Wood TJ, Hack TF, Siminoff L, Gordon E, Feldman-Stewart D. Validation of a decision regret scale. *Med Decis Mak* 2003;23:281-92.
  27. EQ-5D Products. EQ5D-5L. <http://www.euroqol.org> (accessed 6 October 2015).
  28. Al-Janabi H, Flynn TN, Coast J. Development of a self-report measure of capability wellbeing for adults: the ICECAP-A. *Qual Life Res* 2012;21:167-76.
  29. Koo TK, Li MY. A guideline of selecting and reporting intraclass correlation coefficients for reliability research. *J Chiropractic Med* 2016;15:155-63.
  30. Luan A, Hui KJ, Remington AC, Liu X, Lee GK. Effects of a novel decision aid for breast reconstruction: a randomized prospective trial. *Ann Plast Surg* 2016;76 S249-S242.
  31. Sheehan J, Sherman KA, Lam T, Boyages J. Regret associated with the decision for breast reconstruction: The association of negative body image, distress and surgery characteristics with decision regret. *Psychol Health* 2008;23:207-19.
  32. Stacey D, Légaré F, Lewis K, et al. Decision aids for people facing health treatment or screening decisions. *Cochrane Database Syst Rev* 2017;4. doi:10.1002/14651858.CD001431.pub5.