

# PEGASUS: The effectiveness of an intervention designed to promote shared decision making about breast reconstruction

<b>Submission date</b> 27/01/2016	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 27/01/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 14/11/2022	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

<http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-looking-at-a-new-way-to-help-women-decide-about-breast-reconstructive-surgery-pegasus>

## Contact information

### Type(s)

Public

### Contact name

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## Additional identifiers

### Protocol serial number

19624

## Study information

**Scientific Title**

A multi-centred study of the effectiveness of PEGASUS: An intervention to promote shared decision making about breast reconstruction

**Acronym**

PEGASUS

**Study objectives**

The aim of this study is to evaluate the impact and cost effectiveness of a patient-centred, goal-focused intervention to support shared decision making for women contemplating breast reconstruction.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

National Research Ethics Service Committee South Central - Berkshire B, 01/07/2015, ref: 15/SC/033

**Study design**

Non-randomised; Interventional; Design type: Process of Care

**Primary study design**

Interventional

**Study type(s)**

Treatment

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

Topic: Cancer; Subtopic: Breast Cancer; Disease: Breast

**Interventions**

All participants are invited to take part in PEGASUS. This involves meeting a decision facilitator (specialist nurse/psychologist trained in its use) during which the patient elicits her individual breast reconstruction goals, what would indicate a successful outcome and the importance of each goal. The PEGASUS intervention can last between 20 minutes to an hour, depending on the participant. Participants take the completed PEGASUS sheet into the surgical consultation where it is used to set shared goals and promote concordance between the patient and surgeon so they approach surgery as a shared endeavor. PEGASUS facilitates the disclosure and discussion of expectations, enabling the surgeon to decide the extent to which they are realistic and if necessary take appropriate steps to address unrealistic expectations.

Data will be collected from at the time of decision making, and then 3, 6 and 12 months after surgery. Health professionals and a purposefully selected sample of participants will be interviewed about whether their expectations of reconstruction were met and their experiences of PEGASUS (if appropriate).

**Intervention Type**

Other

**Primary outcome(s)**

Breast Q (reconstruction) is measured pre-operatively and 3, 6 and 12 months post-operatively.

### **Key secondary outcome(s)**

1. Regret is measured using the Decisional Regret Scale at 3, 6 and 12 months post-operatively
2. Health related quality of life is measured using the EQ5DL and ICECAP-A questionnaires pre-operatively and 3, 6 and 12 months post operatively
3. Health economic measures are measured at 3, 6 and 12 months post operatively
4. Shared decision making is measured using the decisional conflict scale, VAS items and CollaboRATE pre-operatively

### **Completion date**

30/06/2019

## **Eligibility**

### **Key inclusion criteria**

1. Women over the age of 18
2. Those who have been offered the option of immediate or delayed breast reconstruction (any type) because they have been diagnosed as having breast cancer or Ductal Carcinoma in Situ (DCIS), or are undergoing risk-reducing mastectomy

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Sex**

Female

### **Total final enrolment**

147

### **Key exclusion criteria**

1. Those who are unsuitable for breast reconstruction
2. Insufficient grasp of English to participate in an intervention and study conducted in English

### **Date of first enrolment**

11/01/2016

### **Date of final enrolment**

31/10/2017

## **Locations**

**Countries of recruitment**

United Kingdom

England

Wales

**Study participating centre****Royal Hampshire County Hospital**

Hampshire Hospitals NHS Foundation Trust

Romsey Road

Winchester

United Kingdom

SO22 5DG

**Study participating centre****Royal United Hospital**

Royal United Hospitals Bath NHS Foundation Trust

Combe Park

Bath

United Kingdom

BA1 3NG

**Study participating centre****Royal Cornwall Hospital**

2 Penventinnie Lane

Treliske

Truro

United Kingdom

TR1 3LQ

**Study participating centre****Southmead Hospital**

North Bristol NHS Trust

Southmead Way

Bristol

United Kingdom

BS10 5NB

**Study participating centre**

**University Hospital Wales**  
Cardiff and Vale University Health Board  
Health Park  
Cardiff  
United Kingdom  
CF14 4XW

## Sponsor information

**Organisation**  
University of the West of England, Bristol

**ROR**  
<https://ror.org/02nwg5t34>

## Funder(s)

**Funder type**  
Charity

**Funder Name**  
Breast Cancer Campaign

**Alternative Name(s)**

**Funding Body Type**  
Private sector organisation

**Funding Body Subtype**  
Other non-profit organizations

**Location**  
United Kingdom

## Results and Publications

**Individual participant data (IPD) sharing plan**  
Not provided at time of registration

**IPD sharing plan summary**  
Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		15/11/2021	14/11/2022	Yes	No
<a href="#">Protocol article</a>	protocol	02/10/2017		Yes	No
<a href="#">Other publications</a>	intervention design	01/01/2020	30/01/2020	Yes	No
<a href="#">Other publications</a>	patients' and health professionals' experiences	24/05/2021	25/05/2021	Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Plain English results</a>			18/05/2022	No	Yes