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

Submission date	Recruitment status	[_] Prospectively registered
27/01/2016	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
27/01/2016	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
14/11/2022	Cancer	

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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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

Secondary outcome measures
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

Overall study start date
11/01/2016

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

Age group
Adult

Lower age limit
18 Years

Sex

Female

Target number of participants
Planned Sample Size: 180; UK Sample Size: 180

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
England

United Kingdom

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
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CF14 4XW

Sponsor information

Organisation
University of the West of England, Bristol

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Sponsor type
Hospital/treatment centre

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

Publication and dissemination plan
1. Planned publication of the study protocol and results in peer-reviewed, open access journals
2. Planned presentation of results at national and international conferences

Intention to publish date
31/12/2019

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?
Protocol article	protocol	02/10/2017		Yes	No
Other publications	intervention design	01/01/2020	30/01/2020	Yes	No
Other publications	patients' and health professionals' experiences	24/05/2021	25/05/2021	Yes	No
Plain English results			18/05/2022	No	Yes
Results article		15/11/2021	14/11/2022	Yes	No