

# Expressive writing intervention for body image concerns

<b>Submission date</b> 12/05/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 12/05/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 27/07/2022	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

<https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-writing-experience-women-after-surgery-breast-cancer>

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

### Protocol serial number

8075

## Study information

### Scientific Title

Feasibility of an expressive writing intervention for older women's body image concerns following surgery for breast cancer

**Study objectives**

The primary aim of this feasibility study is to assess the efficacy and limitations of an expressive writing intervention for body image concerns of older women who have received surgery for breast cancer. The effect of the writing intervention on improving self-esteem, body image, and physical health will be examined using patient-reported outcome measures (PROMS). The secondary aim of the study will be to determine whether individual factors, such as alexithymia and ambivalence over emotional expression moderate any intervention effects.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Leeds East REC, 25/01/2010, ref: 09/H1306/114

**Study design**

Single centre randomised interventional process of care trial

**Primary study design**

Interventional

**Study type(s)**

Quality of life

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

Topic: National Cancer Research Network; Subtopic: Breast Cancer; Disease: Breast

**Interventions**

We have baseline measure and a 2 week and 3 month follow up. Consenting patients will be randomised to intervention (expressive writing [EW]) or control (factual writing [FW]) arms. Both arms will complete three twenty minute writing sessions. The intervention arm will write about their deepest thoughts and concerns about cancer and the impact of their disease and treatment on how they feel about their body. The control arm will be given a factual writing task in which they are asked to document how they spent their time the previous day. Alexithymia, ambivalence over emotional expression, physical well-being, and psychological health including self-esteem and body image will be documented by patient self-report using validated instruments.

Study entry: single randomisation only

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome(s)**

Evaluation of writing method, measured at each time point

**Key secondary outcome(s))**

Moderating effects, measured alongside the writing tasks at baseline.

**Completion date**

01/09/2010

## Eligibility

**Key inclusion criteria**

Eligible are all patients who:

1. Are aged 50 and over, female only
2. Have received surgery for breast cancer (mastectomy with or without reconstruction) in the last 5 years
3. Are currently disease free
4. Are English literate
5. Are able to give informed consent

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Senior

**Sex**

Female

**Total final enrolment**

32

**Key exclusion criteria**

1. Overt exhibition of psychopathology or serious cognitive dysfunction which would impede their being able to take part in the study
2. Patients who are deemed too ill by oncology staff

**Date of first enrolment**

26/02/2010

**Date of final enrolment**

01/09/2010

## Locations

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Level 03, Bexley Wing**  
Leeds  
United Kingdom  
LS9 7TF

## Sponsor information

**Organisation**  
University of Leeds (UK)

**ROR**  
<https://ror.org/024mrx33>

## Funder(s)

**Funder type**  
Charity

**Funder Name**  
Breast Cancer Campaign (UK)

**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**  
Not provided at time of registration

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
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<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Plain English results</a>			27/07/2022	No	Yes