

Expressive writing intervention for body image concerns

Submission date 12/05/2010	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 12/05/2010	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 27/07/2022	Condition category Cancer	☐ Individual participant data ☐ 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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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

Primary study design

Interventional

Study design

Single centre randomised interventional process of care trial

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/024mrxd33>

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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[Plain English results](#)

27/07/2022

No

Yes