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Expressive writing intervention for body image concerns

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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

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

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 measure
Evaluation of writing method, measured at each time point

Secondary outcome measures
Moderating effects, measured alongside the writing tasks at baseline.

Overall study start date
26/02/2010

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

Age group
Senior

Sex
Female

Target number of participants
Planned sample size: 60

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
England

United Kingdom

Study participating centre
Level 03, Bexley Wing
Leeds
United Kingdom
LS9 7TF

Sponsor information

Organisation
University of Leeds (UK)

Sponsor details
Woodhouse Lane
Leeds
England
United Kingdom
LS2 9JT

Sponsor type
University/education

Website
http://www.leeds.ac.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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Plain English results			27/07/2022	No	Yes