

Expressive writing intervention for body image concerns

| | | |
|--|---|--|
| Submission date 12/05/2010 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 12/05/2010 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results |
| Last Edited 27/07/2022 | Condition category 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

Mr Simon Pini

Contact details

Level 03, Bexley Wing
St James's Institute of Oncology
Beckett Street
Leeds
United Kingdom
LS9 7TF

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 |