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# A psychosocial group intervention to address fear of recurrence in women with cancer: a randomized controlled clinical trial

**Submission date**
31/07/2014

**Recruitment status**
No longer recruiting

**Registration date**
03/09/2014

**Overall study status**
Completed

**Last Edited**
27/04/2016

**Condition category**
Cancer

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

## Plain English summary of protocol

Background and study aims
The most frequently named unmet need in cancer survivors is fear of cancer recurrence (FCR). More than half of all cancer survivors will report moderate to high levels of FCR and is most often reported by women. Cancer survivors who experience recurrent thoughts that their cancer will come back tend to have higher distress levels, lower quality of life and have difficulty building future goals. The aim of the study is to reduce FCR, cancer distress, uncertainty level and improve quality of life.

Who can participate?
Women who have had a diagnosis of breast cancer or gynaecological cancer.

What does the study involve
Participants will be randomly allocated to receive one of two psychological group therapies. They receive psychological therapy for six weeks for 120 minutes each and will be put in a group of six to eight women with either breast cancer or gynecological cancer.

What are the possible benefits and risks of participating?
Benefits to participation include improved quality of life, reduction in the fear of cancer recurrence, cancer distress and learning new relaxation techniques. Possible risks include having difficulty facing your fear of cancer recurrence and not feeling relief from cancer distress or fear of cancer recurrence.

Where is the study run from?
Study is run at three sites.
1. The Princess Margaret Cancer Centre in the ELLICSR in Toronto, Ontario, Canada
2. The University of Ottawa in Ottawa, Ontario, Canada
3. Jewish General Hospital, Montreal, Quebec, Canada

When is the study starting and how long is it expected to run for?
The study will start in October 2014 and is expected to run for three years.

Who is funding the study?
Canadian Cancer Society (Canada)

Who is the main contact?
Dr Christine Maheu
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### Study website
http://ellicsr.ca/content/research-education/dr-christine-maheu/fear-cancer-recurrence-group-intervention-study

## Contact information

### Type(s)
Scientific

### Contact name
Dr Christine Maheu

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## Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
Canadian Cancer Society grant # 702985

## Study information

### Scientific Title
Efficacy of a cognitive-existential (CE) group intervention to address fear of recurrence in women with cancer: a randomized controlled clinical trial

### Acronym
CE

## Study objectives
Compared to a structurally equivalent control group, breast cancer or gynecological cancer survivors participating in the CE group intervention will:
1. Have lower levels of FCR
2. Show improvements in the following secondary outcomes: cancer-specific distress, quality of life, illness uncertainty, intolerance of uncertainty, perceived risk of cancer recurrence, and coping skills.

We further postulate that group differences will be maintained over the six-month period following completion of the intervention.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Ethics Committees of:
1. McGill University - pending approval
2. University Health Network - pending approval
3. University of Ottawa - pending approval

## Study design
Multicentre prospective randomized controlled trial

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Other

## 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
Breast cancer and gynecological cancer

## Interventions
This study involved the comparison of two group intervention approaches to test the effectiveness at reducing fear of cancer recurrence. Upon meeting eligibility criteria that includes scoring a medium level of fear of cancer recurrence and cancer distress, women with breast or women with gynecological cancers will be randomized to either receive one of the two psychosocial group therapies. Each group will be comprised of either breast or gynecological cancer and will have six to eight women per group. Groups will be weekly for 6 weeks for 120

minutes each. All women who consent to participate will complete a questionnaire package before the start of the first session, at the end of the six sessions, at 3 and 6 months post-intervention.

### Intervention Type
Other

### Phase
Not Applicable

### Primary outcome measure
Fear of cancer recurrence will be measured using the Fear of Cancer Recurrence Inventory (FCRI) (Simard & Savard, 2009). The FCRI is a 42-item questionnaire that includes a global score as well as seven subscales including triggers, severity, psychological distress, functional impairment, insight, reassurance, and coping strategies. A score of 13 or greater on the nine-item severity subscale (range 0-36) indicates clinical level of FCR (54).

### Secondary outcome measures
1. Cancer-specific distress with the Impact of Event Scale (IES) (Horowitz, Wilner, & Alvarez, 1979); The IES is a 15-item questionnaires that assesses cancer distress. It has two subscales, intrusive thoughts and avoidance, which provide a total score. Perceived risk of cancer recurrence will be assessed using a one-item question where respondents indicate their level of perceived personal risk for a cancer recurrence over the last two days (Bish et al., 2002).
2. Intolerance of uncertainty with be measured with the Intolerance of Uncertainty Scale (IUS) (Buhr & Dugas, 2002). The IUS is a 27-item four-factor questionnaire that represents uncertainty as stressful and upsetting, uncertainty as leading to the inability to act, uncertain events as being negative and to be avoided, and being uncertain as unfair (Buhr & Dugas, 2002).
3. Uncertainty in Illness will be measured by the Mishel Uncertainty in Illness Scale (MUIS-C) (Mishel, 1981). The MUIS-C consists of 23 items rated on a five-point Likert scale. Coping will be measured with the following three coping scales: (1) Cognitive Avoidance Questionnaire (Sexton & Dugas, 2008), that contains 25 items that measure avoidance coping; (2) the Reassurance-Seeking Behaviours subscale of the Health Anxiety Questionnaire (Lucock & Morley, 1996), that contains three items that pertain to body-checking and reassurance-seeking from loved ones; and 3) the Reassurance Questionnaire (Speckens, Spinhoven, Van Hemert, & Bolk, 2000), that contains 10 items that measure reassurance-seeking from physicians.
4. Quality of life will be measured with the SF-8 instrument (Ware, Kosinski, Dewey, & Gandek, 2001). The SF-8 is a health-related QoL measure that provides an assessment of general physical (PCS) and mental (MCS) health with a 4-week recall period..

Additional variables to control:
1. As group cohesion may influence the impact of our CE group intervention, we will measure this construct at the end of the 6-week intervention for both the intervention and the control group. Cohesion will be measured with the Group Cohesion Scale-Revised (GCS-R) (Treadwell, Laverture, Kumar, & Veeraraghavan, 2001). The GCS-R is a 25 item questionnaire measuring group cohesion in terms of interaction and communication among group members. An example of an item is 'group members usually feel free to share information'.
2. Group alliance: we will use the California Psychotherapy Alliance Scale (CALPAS) (Gaston, 1991). The CALPAS is a 24-item scale that has four theoretically derived alliance dimensions: (1) the 'therapeutic alliance'; (2) the 'working alliance'; (3) the therapists contribution to the alliance; (4) the agreement on goals and tasks of therapy.
3. Therapeutic working group alliance measurement will be taken immediately following the last

session for both the intervention and the control group.
4. Satisfaction with therapy: will be measured using Satisfaction with Therapy and Therapist Scale Revised (STTS-R). The STTS-R is a 12-item scale measuring the patients level of satisfaction with both the group therapy and the therapist in the CBT group (Oei & Green, 2008).
5. Credibility of intervention will be measured using: Credibility Expectancy Questionnaire (CEQ) Version II, a scale for measuring treatment expectancy (six items) and rationale credibility (two items) (Devilly & Borkovec, 2000).

### Overall study start date
01/10/2014

### Completion date
01/10/2017

## Eligibility

### Key inclusion criteria
1. First diagnosis of BC or GC with stages I-III
2. Disease-free at the start of the group
3. 18 years or older
4. Completion of treatment, with the exception of adjuvant chemotherapy or hormonal replacement therapy
5. A score of 13 or greater on the severity subscale of the FCRI (range 0-36), suggesting clinical levels of FCR (7)
6. A score of at least 24 on the cancer-specific distress measure, indicating clinical levels of distress (Impact of Events Scale; range 0-75) (52, 53).
If a participant develops a recurrence in the course of the study, she will remain in the group but her follow-up data will be excluded from final analysis. Finally, all participants meeting inclusion criteria will take part in a baseline pre-group interview with the group leaders that will detail the general expectations of group work.

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Female

### Target number of participants
144

### Key exclusion criteria
1. Non-English speakers
2. Previous cancer recurrence
3. Enrolled in another group psychotherapy at the time of the start of the study or during the

course of the six sessions
4. Unresolved mental health disorder judged to be clinically contra-indicated and/or likely to affect the group work, based on disclosure by the potential participant or clinically identified by the group leader. These individuals will be offered individual mental health services.

### Date of first enrolment
01/10/2014

### Date of final enrolment
01/10/2017

## Locations

### Countries of recruitment
Canada

### Study participating centre
**McGill University**
Montreal
Canada
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## Sponsor information

### Organisation
Canadian Cancer Society (Canada)

### Sponsor details
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### Sponsor type
Charity

### ROR
https://ror.org/017343w90

## Funder(s)

### Funder type
Charity

### Funder Name
Canadian Cancer Society (Canada) - Quality of life grant # 702985

### Alternative Name(s)
Canadian Cancer Society – Ontario, Société canadienne du cancer, CCS, SCC

### Funding Body Type
Private sector organisation

### Funding Body Subtype
Trusts, charities, foundations (both public and private)

### Location
Canada

## Results and Publications

### Publication and dissemination plan
Not provided at time of registration

### Intention to publish date

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary
Not provided at time of registration

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | feasibility study results | 01/09/2014 | | Yes | No |
| Protocol article | protocol | 25/04/2016 | | Yes | No |