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Music and expressive arts therapy for women with a history of gynaecological cancer

Submission date	Recruitment status	[ ] Prospectively registered
23/03/2012	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
03/04/2012	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
01/12/2015	Cancer	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Each year about 2,900 women are diagnosed with gynaecological cancer in Sweden and about 1,000 women die of the diseases. Gynaecological cancer and its treatments are affected by social and cultural values regarding illness, death, sexuality and femininity. Women being treated for these diseases may suffer from many different side-effects, such as varying degrees of altered bowel and bladder function, abdominal pain, bodily changes and problems with sexual function, health and wellbeing. There is a great need for psychosocial support and specialised treatment for women afflicted with gynaecological cancer. These women are subjected to a great deal of social stress. Many women experience fear of recurrence, and need strategies to handle that stress. They must, in addition to the threat of death by the disease, also deal with the loss of female body parts, which often have strong symbolic meanings. For most women of childbearing age their reproductive capacity is lost due to surgery, and the woman goes quickly into menopause. This involves weight gain, hot flashes and an experience of growing old before time. The experiences can be traumatic and affect the woman’s self-concept and identity. She often feels estranged from her body and does not quite know who she is as a woman, and in relationship to others. Self-esteem is also often affected and it is not unusual to experience shame and guilt. Therapy can lead to improved self-esteem and the experience of once again feel like an integrated person. This means greater self-acceptance and having the personal strength to stand up for oneself. Self-image, negative body sensations and sexual difficulties are central issues after completion of treatment, but these are often questions left to "silence". The aim of this study is to evaluate a form of music therapy for women with a history of gynaecological cancer who have completed medical treatment. The music therapy method to be evaluated is based on listening to selected pieces of music, working with art, and talking about the experiences in regards to coping with the illness. In this study we will examine how concerns about recurrence, body experiences, sexual function and existential health are influenced by the music therapy session. We will focus on problems that arise from having been treated for gynaecological cancer.

Who can participate?
Women aged between 18 and 75 who have completed treatment for gynaecological cancer, without recurrence.

What does the study involve?
Participants are randomly allocated to one of two groups. One group attends 12 sessions of individual music therapy. After the individual therapy is completed, the other group are offered six sessions of group therapy with music therapy and expressive arts. Three questionnaires are filled out by the participants before and after treatment, and after three months. The questions cover the following areas: quality of life, fear of recurrence, body image and body experiences, and sexual and existential health.

What are the possible benefits and risks of participating?
Not provided at time of registration.

Where is the study run from?
Aalborg University, Denmark, the Department of Clinical Cancer Epidemiology, KCE, Department of Oncology-Pathology at Karolinska Institute, the Oncology Clinic at Karolinska University Hospital, and Expressive Arts Stockholm AB, Sweden.

When is the study starting and how long is it expected to run for?
April 2012 to December 2013

Who is funding the study?
Aalborg University (Denmark), Ekhaga Foundation, O-B Jeppson Music Therapy Foundation, and Ax:son Johnson Foundation (Sweden).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A randomised controlled trial for women with a history of gynaecological cancer assessing the feasibility, experiences and potential effectiveness of receptive music therapy (KMR) and expressive arts therapy

Study objectives
Fear of relapse decreases, the body image is better integrated and the existential and sexual health and well-being increases as an effect of short-term music therapy (KMR) for women with a history of gynaecological cancer.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Committee, Karolinska Institutet, Stockholm, Sweden, 19/01/2012, ref: 2012/5:1

Study design
Randomised controlled 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
Fear of recurrence in gynaecological cancer patients

Interventions

A short-term intervention called KMR will be implemented. KMR (Short Music Journeys) is a receptive form of music therapy that includes the uses of expressive arts techniques (EXA) (especially drawing and writing). This approach will be conducted both in individual therapy and in group therapy.

The KMR method has been developed by Margareta Wärja in collaboration with Swedish psychotherapists from the tradition of The Bonny Method of Guided Imagery and Music (GIM) and the tradition of expressive arts. The theory and approach of KMR is based on humanistic philosophy, existential psychology, psychodynamic theory, attachment theories, phenomenology, and theories of the arts as providers of experiences that create meaning and improve quality of life. Pre-recorded short pieces of music will be used in a psychotherapeutic framework to address issues of existential and sexual health, body image, and fear of recurrence. Visual art techniques will be used to process and work with images and experiences evoked by the music.

A mixed methods design with a complex intervention will be applied. Imbedded in the design is a randomised control trial with an individual intervention and a wait-list control group later receiving a group intervention. A qualitative phase of in-depth interviews, literature reviews and a pilot-study has preceded the RCT. Another qualitative phase of interviews and measures will follow after the RCT. Twenty patients will be included in the group receiving individual treatment and forty in the control group. After inclusion, screening, signing of informed consent and base-line measures have been completed; the patient will be randomised to either individual treatment or the wait-list group.

Individual KMR/EXA Therapy (Group A):
The procedure starts with one interview session, followed by twelve weekly therapy sessions each 60 minutes. Four psychotherapists trained in the KMR framework are assigned to the study. They will work from a semi-structured protocol outlining general steps and time posts in the therapy process.

Group Therapy KMR/EXA (Group B):
The procedure starts with one interview session, followed by six weekly group therapy sessions each 120 minutes. Each group consists of five to six members. Two-three therapists trained in the KMR framework are assigned to the study. They will work from a semi-structured protocol outlining general steps and time posts in the group therapy process.

Measurements will be taken pre-, post- and follow-up (after 3 months)

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Reduced fear of recurrence
2. Improved sexual health
3. Improved integration of body-image
4. Improved existential health and well-being

The evaluation of these symptoms will be assessed through detailed self-evaluation questionnaires, specifically constructed and validated for this population, and two standardised questionnaires [EORTC QLQ-C30, MontgomeryÅsberg Depression Rating Scale (MADRS)]

Measured at:

Group A, Intervention group (individual treatment):
T0 Screening (0 months)
T1 Baseline (0 months)
T2 End of treatment (C:a 5 months)
T3 Follow-up (C:a 8 months after baseline)

Group B, wait-list group (later group-intervention):
T0 Screening (0 months)
T1 Baseline (0 months)
T2 End of wait-list, before group-intervention (C:a 5 months)
T3 End of treatment (C:a 8 months after baseline)
T4 Follow-up (C:a 11 months after baseline)

Secondary outcome measures

1. Experience and change of quality of life
2. Experiences of cancer treatment
3. Experiences of and change in self-care
4. Experience of information and care from health care personnel
5. Experiences of and changes in body- and self-image, self-esteem and confidence
6. Experiences of and changes in feelings of guilt and shame
7. Experiences of and changes in social interactions and networking
8. Experiences of and changes in practices of cultural events, music and art, and hobbies
9. Experiences of and changes in practices of journal writing and expressive writing
10. Experience of and change in coping strategies
11. Previous experiences of sexual abuse
12. Previous experiences of traumatic life events
13. Experiences of participation in a music therapy study (specific questions in the questionnaire and in qualitative interviews with samples of participants and therapists)
14. Acceptability and feasibility of our methodology (specific questions in the questionnaires and in qualitative interviews with samples of participants)
15. Drop-out analysis:
15.1. Exclusions
15.2. Recruitment rates
15.3. Loss to follow-up
15.4. Drop-outs (group therapy after wait-list)
15.5. Missing data

Measured at:

Group A, Intervention group (individual treatment):
T0 Screening (0 months)
T1 Baseline (0 months)
T2 End of treatment (C:a 5 months)
T3 Follow-up (C:a 8 months after baseline)

Group B, wait-list group (later group-intervention):
T0 Screening (0 months)
T1 Baseline (0 months)
T2 End of wait-list, before group-intervention (C:a 5 months)
T3 End of treatment (C:a 8 months after baseline)
T4 Follow-up (C:a 11 months after baseline)

Overall study start date
02/04/2012

Completion date
31/12/2013

Eligibility

Key inclusion criteria
1. Women with a history of gynaecological cancer
2. At follow-up at the Department of Gynaecological Oncology, Karolinska University Hospital, Stockholm, Sweden, 3-24 months after primary treatment
3. 18-75 years
4. Fluent in written and spoken Swedish language

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
75 Years

Sex
Female

Target number of participants
60

Key exclusion criteria
1. Relapse
2. High risk of relapse during the study period
3. A history of mental disorder or substance abuse
4. > 75 years

Date of first enrolment
02/04/2012

Date of final enrolment
31/12/2013

Locations

Countries of recruitment
Sweden

Study participating centre
Karolinska Institutet
Stockholm
Sweden
171 76

Sponsor information

Organisation
Aalborg University (Denmark)

Sponsor details
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Sponsor type
University/education

Website
http://www.mt-phd.aau.dk

ROR
https://ror.org/04m5j1k67

Funder(s)

Funder type
University/education

Funder Name

Aalborg University, Faculty of the Humanities (Denmark)

Funder Name
Ekhaga Foundation (Sweden) Ref. 2011-66

Funder Name
O-B Jeppson Music Therapy Foundation (Sweden)

Funder Name
Ax:son Johnson Foundation (Sweden)

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