



Guided Imagery & Music in Cancer

CLINICALTRIALS.GOV IDENTIFIER
NCT03936075

RECRUITMENT STATUS
ACTIVE, NOT RECRUITING

FIRST POSTED
MAY 3, 2019

LAST UPDATE POSTED
JULY 8, 2020

STUDY DESCRIPTION

Brief Summary

This is an RCT pilot study to explore the potential effects of the Guided Imagery & Music method for women with breast or gynecologic cancer, during active treatment. The study explores the potential impact in quality of life parameters such as mood, fatigue, and hope.

Condition or Disease: Cancer Ovaries
Cancer Uterus Cervix
Cancer, Breast
Cancer, Metastatic

Intervention/treatment: Behavioral: the Guided Imagery and Music method
Behavioral: standard care and verbal counselling

Phase: N/A

DETAILED DESCRIPTION

Guided Imagery and Music is a music-assisted psychotherapy method which has been used as a complementary, supportive psychosocial therapy in cancer care. However, its effects have never been explored during the period of active chemotherapy or radiotherapy treatment in various cancer populations, and especially gynecologic and breast cancer. This pilot study is an effort to explore the feasibility of the method to increase quality of life in this population by possibly reducing side-effects of treatment such as fatigue, improving mood, and building resilience as expressed through levels of hope.

STUDY DESIGN

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|-------------------------------|---|---|---------------|
| Study Type: | Interventional | Actual Study Start Date: | July 2018 |
| Estimated Enrollment : | 20 participants | Estimated Primary Completion Date: | June 2020 |
| Intervention Model : | Parallel Assignment | Actual Study Completion Date: | December 2020 |
| Masking: | Double (Participant, Care Provider) | Date: | |
| Primary Purpose: | Supportive Care | | |
| Official Title: | Guided Imagery & Music in Active Treatment for Gynecologic or Breast Cancer: An RCT Pilot | | |

ARMS AND INTERVENTIONS

| Arm | Intervention/treatment |
|---|--|
| Experimental: intervention treatment with the provision of 6 individual sessions of the Guided Imagery and Music method as a psychological supportive intervention, and psychometric questionnaires collection | Behavioral: the Guided Imagery and Music method the method involves listening to the music while describing the experience to the therapist, any visual imagery that is evoked by the music, emotions, body sensations, thoughts or memories. after the music listening session, there is discussion upon making meaning of the experience and finding resources as potential coping skills |
| Placebo Comparator: control standard care treatment with psychometric questionnaires collection and two individual counselling sessions, at baseline (week 1) and at the end (week 6) | Behavioral: standard care and verbal counselling the participants receive their usual cancer treatment and two individual counselling sessions |

OUTCOME MEASURES

Primary Outcome Measures: 1. Profiles of Mood States (POMS) Brief version (adapted) [Time Frame: Baseline and up to 12 weeks (post-intervention)]
Brief version adapted in Greek. A 30-item scale designed to assess six different moods namely tension, anger, vigor, fatigue, depression, confusion. It requires to indicate mood state over the last week, with a single word, each item ranging from 0(not at all) to 4 (extremely). The questionnaire is a sum of its 6 sub scales (each addressing the aforementioned moods), with a total score from 0 to 120. Lower scores indicate better mood states.

Secondary Outcome Measures: 1. Herth Hope Index [Time Frame: Baseline and up to 12 weeks (post-intervention)]
A 12-item Likert-format instrument assessing current levels of hope from 1(strongly disagree) to 4 (strongly agree). It consists of three sub scales, examining interconnectedness, temporality and spirituality, and positiveness or expectancy. A higher score of the sum or the 3 sub scales indicates a higher hope level with scores ranging from 12 to 48.

2. Cancer-related Fatigue Scale (CFS) [Time Frame: Baseline and up to 12 weeks (post-intervention)]
An instrument consisting of 15 items that assess physical, affective, and cognitive dimensions of fatigue at present moment, with Likert scales ranging from 1 to 5. the physical sub scale consists of 7 items, the affective sub scale consists of 4 items, and the cognitive sub scale consists of 3 items and the total of all 3 sub scales indicate that greater scores correspond to greater fatigue levels.

3. Visual Analogue Scale for Hope (VAS-H) [Time Frame: obtained 6 times throughout the completion of intervention (up to 12 weeks)]
 VAS is a single, frequent measurement to address the current levels of hope. Its s based on a 100cm horizontal line from 1cm (hopeless) to 100cm (hopeful)
4. Visual Analogue Scale for Fatigue (VAS-F) [Time Frame: Obtained 6 times throughout the completion of intervention (up to 12 weeks)]
 VAS is a single, frequent measurement to address the current levels of fatigue.
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ELIGIBILITY CRITERIA

Ages Eligible for Study: 18 to 75 Years (Adult, Older Adult)

Sexes Eligible for Study: Female

Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Speaking Greek
- receiving chemotherapy or radiotherapy treatment for breast or gynecologic cancer
- first occurrence or metastatic
- have an interest in engaging in creative psychotherapies through music

Exclusion Criteria:

- women with active psychosis or PTSD symptomatology
 - women receiving other psychological support
 - women too ill to participate according to doctors' instructions
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CONTACTS AND LOCATIONS

Contacts

Locations

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| Greece, Attiki | Aretaieion University Hospital | Athens |
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Sponsors and Collaborators

Aalborg University

Aretaieion University Hospital

SONORA Organisation for Music Therapy and Research

Investigator

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|------------------|---------------------|--------------------|
| Study Director : | Niels Hannibal, PhD | Aalborg University |
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MORE INFORMATION

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| Responsible Party : | Aalborg University |
| ClinicalTrials.gov Identifier : | NCT03936075 |
| Other Study ID Numbers : | 62/19-06-18 |
| First Posted : | May 3, 2019 |
| Last Update Posted : | July 8, 2020 |
| Last Verified : | July 2020 |
| Studies a U.S. FDA-regulated Drug Product: | No |
| Studies a U.S. FDA-regulated Device Product: | No |
| Keywords provided by Aalborg University: | <i>Guided Imagery & Music (GIM) gynecologic cancer breast cancer receptive music therapy chemotherapy radiotherapy</i> |
| Additional relevant MeSH terms : | <i>Breast Neoplasms</i> |