

**MDACC 2004-0024: Chemotherapy and Mindfulness Relaxation: A Randomized Trial
At M.D. Anderson Cancer Center and M.D. Anderson Community Clinical Oncology Program**

FAST FACTS

ELIGIBILITY CRITERIA

1. Patients must be ≥ 18 years of age.
2. Patients must be anticipated to undergo at least four cycles of chemotherapy treatment for non-hematopoietic cancer.
3. Patients must NOT have had any previous treatment with chemotherapy.
4. Patients must NOT have any evidence of distant metastatic disease.
5. Patients must be able to read/speak in English.
6. Patients must NOT have any known psychotic diagnosis.
7. Patients must have an expected survival of at least six months.
8. Patients must have the ability to understand and the willingness to sign a written informed consent document.
9. This study is open to both male and female cancer patients of all racial/ethnic groups.
10. Patients will be excluded from study if they:
 - have a known psychotic diagnosis;
 - will undergo an undefined number of chemotherapy regimens;
 - will undergo concrete planned immune therapy (*e.g.* GCSF [filgrastim], GMCSF [pegfilgrastim, sagramostim], IL2, Interferon, etc.) during or within 3 months of completing chemotherapy.

Note: Patients should not be excluded from trial on the possibility that they may need to be started on filgrastim (GCSF), pegfilgrastim (GMCSF), etc., some point during the trial. If it is determined by the treating physician that filgrastim, pegfilgrastim, etc., is clinically necessary the patient may be given drug and remain on study. Patients who have planned immune therapy will not be eligible for trial.

PRE-STUDY PARAMETERS

1. Seventeen questionnaires must be filled out at baseline (Please See Section 8.2.1)

TREATMENT PLAN

PILOT PHASE:

Prior to implementing the full randomized trial, a pilot study will be conducted at two CCOP sites. GRCOP has been selected as one of the sites. All aspects of the pilot phase will be identical to the proposed larger randomized trial except: All patients (25) will be assigned to the Mindful Relaxation Group. All the assessment instruments and time points will be the same as in the larger randomized trial. However, the pilot trial will technically end at the midpoint of chemotherapy in terms of determining whether it is appropriate to start the larger randomized trial. See Section 4.1.

RANDOMIZED TRIAL

Patients will be randomized to one of the following groups:

- GROUP 1:** Mindful Relaxation Group [MR] – MR consists of one recorded MR exercise to be conducted repetitively throughout the course of chemotherapy.
- GROUP 2:** Relaxing music group [RM] where participants will listen to music for the same amount of time as the MR participants – RM group will receive a CD that they will utilize in a manner identical to the MR CD but which does not cover any specific instructions on relaxation or meditation.
- GROUP 3:** Standard care control group where participants will receive standard medical education on Chemotherapy [SC]