

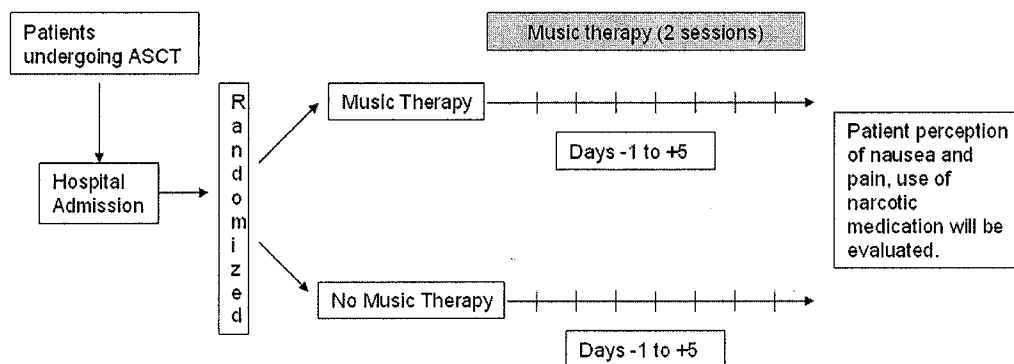
4.1 Randomization

Patients will be randomized 1:1 to music therapy or no music therapy using blocked randomization with random block sizes. Randomization will be stratified by diagnosis (myeloma or lymphoma). The randomization list will be generated before the start of the study and kept in a secured location which will only be accessible to the protocol coordinator.

5.0 STUDY DESIGN

5.1 Overall Design

Patients randomized to receive music therapy will receive 2 sessions of live music therapy, at least 48 hours apart, from a Music Therapist-Board Certified (MT-BC, certified through the Certification Board for Music Therapists) in their room (see Section 7.2). This will occur between days -1 and +5, with the first music therapy session being as close to day +1 as possible and the second session being at least 48 hours later (but no more than 96 hours later). Although patients may be receiving different preparative regimens for transplant, studies have demonstrated that higher symptom burden occurs at time of transplant (day 0) towards time of nadir.^{10, 11} Setting our dates from days -1 to +5 allows for a standard time frame for which patients undergoing ASCT could be evaluated. It also allows for a finite duration for which narcotic medication use could be evaluated.



Those patients randomized to standard therapy (no music therapy) are allowed to listen to music; however they will not receive interactive music therapy from a certified therapist. Following day +7, music therapy will be offered to all patients who are interested in participating.

5.2 Outcome Measures

5.2.1 Pain and Nausea

No narcotic or anti-emetic therapy will be administered for at least 2 hours prior to music therapy sessions or to assessments. For patients randomized to receive music therapy, assessments will be done by a physician assistant on the Bone Marrow Transplant service. Patients will rate nausea and pain at the beginning and end of the first music therapy session on a validated visual analog scale.¹²⁻¹⁴ The scale will be 10cm with the least nausea or pain at point 0 and the greatest nausea or pain at point 10. Patients will mark their level of nausea and the distance will be measured. Patients will be asked to rate their nausea and pain on day +5 and day +7. (Appendix 1 and 2)

For patients who are randomized to the control arm, assessments will be done by a physician assistant on the Bone Marrow Transplant service. Similarly, patients will rate nausea and pain using the visual analog scale. Two assessments will take place on day +1 (30 minutes apart), in order to simulate experience of those receiving music therapy (who