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Randomized Clinical Trial of Therapeutic Music Video Intervention for Resilience Outcomes in Adolescents/Young Adults Undergoing Hematopoietic Stem Cell Transplant: A Report from the Children's Oncology Group

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Abstract

Background—To reduce the risk of adjustment problems associated with Hematopoietic Stem Cell Transplant (HSCT) for adolescents/young adults (AYA), we examined efficacy of a therapeutic music video (TMV) intervention delivered during the acute phase of HSCT to: (a) increase protective factors of spiritual perspective, social integration, family environment, courageous coping, and hope-derived meaning; (b) decrease risk factors of illness-related distress and defensive coping; and (c) increase outcomes of self-transcendence and resilience.

Methods—A multi-site, randomized controlled trial (COG-ANUR0631) conducted at 8 Children's Oncology Group sites involving 113 AYA aged 11–24 years undergoing myeloablative HSCT. Participants, randomized to the TMV or low-dose control (audiobooks) group, completed 6 sessions over 3 weeks with a board-certified music therapist. Variables were based on Haase's Resilience in Illness Model. Participants completed measures related to latent variables of illness-related distress, social integration, spiritual perspective, family environment, coping, hope-derived meaning and resilience at baseline (T1), post-intervention (T2), and 100-days post-transplant (T3).

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Results—At T2, the TMV group reported significantly better courageous coping (ES=0.505; *P*=0.030). At T3, the TMV group reported significantly better social integration (ES=0.543; *P*=.028) and family environment (ES=0.663; *P*=0.008), as well as moderate non-significant effect sizes for spiritual perspective (E=0.450; *P*=0.071) and self-transcendence (ES=0.424; *P*=0.088).

Conclusion—The TMV intervention improves positive health outcomes of courageous coping, social integration, and family environment during a high risk cancer treatment. We recommend the TMV be examined in a broader population of AYA with high risk cancers.

INTRODUCTION

High distress experienced by adolescents/young adults (AYA) during hematopoietic stem cell transplant (HSCT) contributes to persistent defensive coping and poor social and family relationships during acute treatment – placing AYA at additional risk for adjustment problems in survivorship.[1–4] Conversely, protective factors may buffer adverse cancer effects and assist AYA to positively adjust during and after treatment.[5,6] Some AYA experience positive growth following treatment, while others do not; the absence of predictive models describing AYA post-HSCT adjustment make it difficult, if not impossible, to identify who is at-risk requiring additional support or intervention.[7–9]

Effective coping strategies and psychosocial support during HSCT are key to improving adjustment and quality of survival;[10–12] however, theoretically-derived interventions specifically designed for AYA are few and tenuous.[13–15] Recognizing that HSCT usually induces high symptom distress that is difficult to manage and in the absence of predictive models to identify AYA at risk, this paper reports efficacy of the Therapeutic Music Video (TMV) intervention (COG ANUR0631), as a preventive intervention for AYA undergoing HSCT.

Our study was guided by the Resilience in Illness Model (RIM, Figure 1).[6,16] This strengths-based, positive health model elucidates pathways by which risk and protective factors influence AYA adjustment to difficult life circumstances. RIM was developed and evaluated through a series of mixed methods studies;[17,18] exploratory and confirmatory evaluations in AYA with cancer indicate a well-fitting measurement model and the full model predicts proximal and distal outcomes (R^2 = 0.62 to 0.72).[17,18] For this study, we hypothesized the TMV would: (a) increase protective factors of spiritual perspective, social integration, family environment (adaptability, cohesion, communication), courageous coping, and hope-derived meaning (primary proximal outcomes), (b) decrease risk factors of illness-related distress (uncertainty in illness, symptom-related distress) and defensive coping (secondary proximal outcomes), and (c) increase outcomes of self-transcendence and resilience (secondary distal outcomes).

Robb's Contextual Support Model of Music Therapy (CSM-MT) guided selection of TMV intervention components. Grounded in motivational and developmental coping theory, the CSM-MT describes how music interventions create predictability, autonomy support, and relationship support to promote positive health outcomes.[19] The CSM-MT has informed development of several music therapy interventions to improve coping and manage distress.[19–21] Unlike distraction-based, passive music listening interventions, the TMV uses music to provide (a) predictability through clearly defined goals and structured, preferred music, (b) autonomy support through AYA-directed choices about music, lyric writing, video content, and involvement of others, and (c) relationship building through a non-threatening, creative activity to help AYA explore, identify, and express what is important to them (Table 1).[15,22–25] As a music therapy intervention, TMV components are delivered within a therapeutic relationship by a credentialed professional.[26]

TMV intervention components directly address RIM protective factors by encouraging AYA to actively engage with their environment (courageous coping); reflect on their experiences and identify what is important (spiritual perspective, social integration, family environment); identify future hopes/desires (hope-derived meaning); involve family, peers, and/or healthcare providers in their project as desired (social integration, family environment); and communicate ideas to others (social integration, family environment).

METHODS

Participants

After scientific and institutional review board approvals, transplant staff introduced the study to potentially eligible AYA. Study personnel then provided interested AYA with detailed information before obtaining informed consent/assent. Participants were recruited from 8 Children's Oncology Group (COG) institutions, including 3 with affiliated adult transplant programs. Eligibility criteria included: AYA aged 11 to 24 years; undergoing a myeloablative HSCT for cancer; and ability to read and speak English. Exclusion criteria included: cancer diagnosis not common to AYA; physician determination of cognitive impairments precluding ability to complete measures; and being married and/or having children.

Procedures

Participants completed baseline measures (T1) via a secure web-based server within 30 days of HSCT unit admission and were immediately randomized to the TMV or low-dose, control group using 24 strata (8 sites individually stratified by 3 age groups: 11–14, 15–18, 19–24). Then, both groups received six sessions, 2 per week during the acute HSCT phase. Follow-up evaluations occurred after session 6 (T2) and 100-days post-transplant (T3). Data collectors, masked to group assignment, monitored data collection to answer questions and ensure a quiet environment. Treatment and evaluation fidelity strategies included: standardized training; manualized, audio-recorded protocols for quality assurance (QA) monitoring; computerized QA checklists; and bi-monthly intervention and evaluation team conference calls.[27,28]

Study Conditions

Both study conditions, delivered by a consistent board-certified music therapist, provided the same opportunities for attention. External QA monitoring was done to assure therapists consistently followed protocol for assigned study conditions.

TMV content was designed to accommodate acute phase HSCT demands (Table 1). Most cognitive and active intervention components occurred in sessions 1–3, during the first two weeks of transplant when AYA usually experience less symptom distress. Sessions 4–6 had fewer active components, and provided activity-level flexibility. Sessions 1–3 included singing, brainstorming, lyric writing, discussion, and song recording. Sessions 4 and 5 used AYA-developed song lyrics as a foundation for selecting visual video content (e.g., artwork, photographs) through storyboarding and discussion. In session 6, participants viewed their completed video and had the option of a "Video Premier" with family, friends, and/or hospital staff.

Control group AYA chose from 15 audiobooks selected by a librarian with expertise in AYA literature. The books were age-appropriate, fiction and non-fiction, and balanced in gender and ethnic diversity. During sessions, AYA had the opportunity to listen to and/or discuss the book content; between sessions, AYA could listen to and exchange books as desired.

Measures

RIM variables, calculated based on a latent variable ANCOVA model performed with structural equation modeling (SEM), were used to evaluate outcomes. Measures supporting RIM were selected and evaluated using mixed methods approaches.[6,16,18] Table 2 summarizes each measure's structural and psychometric properties. Cronbach's alpha coefficients from T1 data ranged from .75 to .91 (.60–.94 for subscales). More comprehensive measure descriptions are available in exploratory and confirmatory RIM evaluation reports.[6,16]

Statistical Analysis

Sample size calculation was based on an anticipated 25% mortality rate for HSCT across all transplant types within the first 100 days.[29] Therefore, target recruitment was 175 AYA to accrue 130 AYA at T3, providing 65 AYA in each group and power of .80 for a two-sided *t* test, with alpha 0.05, for detecting differences between group means of 0.50 standard deviation. Because the number of eligible AYA and the recruitment rate were lower than expected during the grant period, we were unable to reach our target sample.

MPLUS software, version 6.12, was used for analysis. We tested efficacy using a structural equation modeling approach, estimating latent-variable ANCOVA models to account for measurement error and to reduce the number of comparisons.[30] Specifically, the randomized groups were compared on latent variables at T2 adjusted for latent variables at T1, and on latent variables at T3 adjusted for latent variables at T1, using scale scores as observed indicators of the latent variables as specified in the RIM measurement model. To provide meaningful interpretations, the effect size for the intervention effect on the T2 and T3 latent variables was computed by converting the *t* value of the intervention coefficients supplied by MPLUS output to a Cohen standardized difference between means.[31]

We tested interaction terms between the intervention effect and baseline (e.g., demographic, treatment-related, and disease-related) covariates. All interaction terms were non-significant and therefore not included in the final models. We tested whether the two randomized arms differed on any baseline characteristics; if significant at a liberal alpha of 0.20 (to ensure conservative adjustment), the covariate was included as a predictor to control for its potentially confounding impact on intervention effect estimations.

We did not adjust alpha for multiple comparisons of outcomes because the use of latent ANCOVA models already reduced the number of comparisons to a select set of latent variables. Furthermore, the latent-variable dependent variables in the ANCOVA tap into unique conceptual areas that represent important pre-planned outcomes from our published RIM model.[6,16] An intent-to-treat analysis was performed in which all available questionnaire data at T2 and T3 were used and participants were analyzed according to their assigned group regardless of their degree of adherence to the protocols for the intervention and low-dose control groups.

RESULTS

Figure 2 summarizes study accrual, intervention delivery, and data collection. The groups were statistically similar on demographic and treatment variables (Table 3) with one exception; the TMV group reported significantly more religious activity participation than the control group (58.6% vs. 37.0%, P=0.02). Therefore, this binary religious activity variable was adjusted in the latent ANCOVA models (Table 4). These models were used to compare the two groups on T2 or T3 latent outcome variables, while adjusting for T1 latent outcome variable and the observed religious activity variable.

We assessed the attrition rate and found attrition at T2 and T3 were not significantly different for the two groups. Nor were T3 completers significantly different from T3 non-completers on baseline demographic variables.

To guide the reader through results, we describe in detail the T2 ANCOVA comparison for the illness-related distress factor (Table 4, Row 1). Illness-related distress was measured in the latent ANCOVA models with two indicators at T1 and at T2. As shown in Table 2, illness-related distress indicators were the symptom distress and uncertainty in illness scale scores. At T2, 36 TMV and 40 control participants had data for the illness-related distress factor, and the MPLUS t value for the latent ANCOVA was equal to −0.686. This t value was equivalent to a Cohen effect size measure of −0.160 standard deviations. A negative sign for the t value and ES implies that the T2 adjusted mean for illness-related distress was lower for the TMV group than the control group; however, the difference was not significant (P=0.493).

At T2, the adjusted mean for the courageous coping factor was significantly greater for the TMV group compared to the control group, after adjusting for T1 latent courageous coping and religious activity. The effect size for this significant difference (ES=0.505; P=0.030) was of moderate magnitude according to the Cohen criteria in which .20 is low, .50 is moderate, and greater than .80 is large.[32] At T3, the TMV group reported significantly better social integration (P=0.028) and family environment (P=0.008) than the control group. The effect sizes were moderate for both of these differences (0.543 and 0.663, respectively).

DISCUSSION

The TMV significantly improved courageous coping immediately post-intervention and significantly improved social integration and family environment at 100-days post-transplant, with additional moderate but non-significant effect sizes for spiritual perspective and self-transcendence. These findings support RIM sensitivity to detect group differences, and TMV efficacy to promote positive growth of AYA in the areas of courageous coping, social integration, and family environment during a high risk, high intensity cancer treatment.

The effect size for courageous coping was moderate, indicating that TMV participants increased their use of positive coping strategies to a greater extent than control participants. Concurrently, we found no change in the use of defensive coping strategies. This finding is important since individuals are more likely to use defensive coping strategies during life-threatening or high distress situations like HSCT.[7] Although initially adaptive, prolonged use of defensive coping strategies is associated with more risk-taking behaviors, and less positive adjustment; movement toward positive forms of coping is desirable.[33] The TMV helped AYA use positive coping strategies during treatment, which is associated with better long-term adjustment in cancer survivors.[8,17]

Although engaging in meaningful activities can sometimes alleviate symptom distress, we found no significant effects for illness-related distress immediately or 100-days post-transplant. Given high levels of HCST-related symptom distress and uncertainty, patients may benefit from interventions that offer physiologically-based relaxation and/or uncertainty management strategies to reduce these risk factors. Significant effects were found 100-days post-transplant for social integration and family environment and moderate but non-significant effect sizes were found for spiritual perspective and self-transcendence. The TMV was designed to help AYA identify and reflect on what is important to them through lyric writing and selection of visual images. Qualitative analysis of AYA lyrics and video images revealed that AYA were identifying peers (i.e., social integration), family members

(i.e., family environment), and faith/spirituality (i.e., spiritual perspective) as important sources of support.[34] At T2, AYA had just viewed their video and may not have had adequate time to share, reflect on, and fully integrate the meaningfulness of their video, which may explain why positive change for these measures did not occur until T3.[35,36]

At T3 we saw notable, but non-significant improvement in the secondary distal outcome self-transcendence. Time for self-reflection is essential for AYA to derive meaning from and integrate their cancer experience in order to transcend or move beyond their cancer treatment.[35–37] One-hundred days may not be adequate time to fully reflect on and integrate what AYA explored through their videos. Unknown is whether, having "survived" the transplant, additional time for self-reflection would result in additional gains.

Timelines for intervention delivery/completion offer additional evidence supporting TMV clinical feasibility for AYA during HSCT. Despite high level HSCT-related symptom distress, 75% of TMV participants were able to complete the intervention within 30 days, which was +/− 9 days within the proposed three week delivery timeframe. The remaining 25% were successful, but required more time to complete the intervention; reasons for delayed sessions included symptom distress, intensive care unit admissions, and/or tandem transplants requiring multiple admissions. Our ability to flexibly manage intervention delivery in response to AYA symptom distress, without jeopardizing treatment integrity, was monitored through rigorous quality assurance strategies.[27] Post-intervention interviews revealed AYA and parent appreciation for scheduling flexibility that honored AYA needs.[23]

There are four study limitations. First, risk for bias in condition delivery increased because music therapists delivered both conditions to control for individual therapist qualities and mask data collectors to AYA group assignment. This risk was mitigated through stringent treatment fidelity procedures across conditions.[27] Second, the study was underpowered. Instead of the planned 80% power, we had 57% power to detect a medium effect size (0.50) at T2 using samples of 36 and 40 for intervention and control groups, respectively, and 52% at T3 using samples of 31 and 36. Therefore, potential for type II error was greater than initially planned. Third, missing data due to attrition at T2 or T3 may have contributed to biased intervention effect estimates. Fourth, no formal cost analysis was done; however, services from board-certified music therapists are increasingly considered standard care in pediatric hospitals.[38,39]

In summary, few interventions target the unique psychosocial needs of AYA with cancer. The RIM was a useful guide for TMV evaluation, and TMV was beneficial for improving positive coping, social integration, and family environment for AYA undergoing HSCT. Future studies examining distal outcomes beyond 100-days post-HSCT would help determine whether additional time would improve observed gains in self-transcendence. As part of a larger trial, we are evaluating the TMV in a broader population of AYA with high risk cancers to inform intervention translation and uptake.

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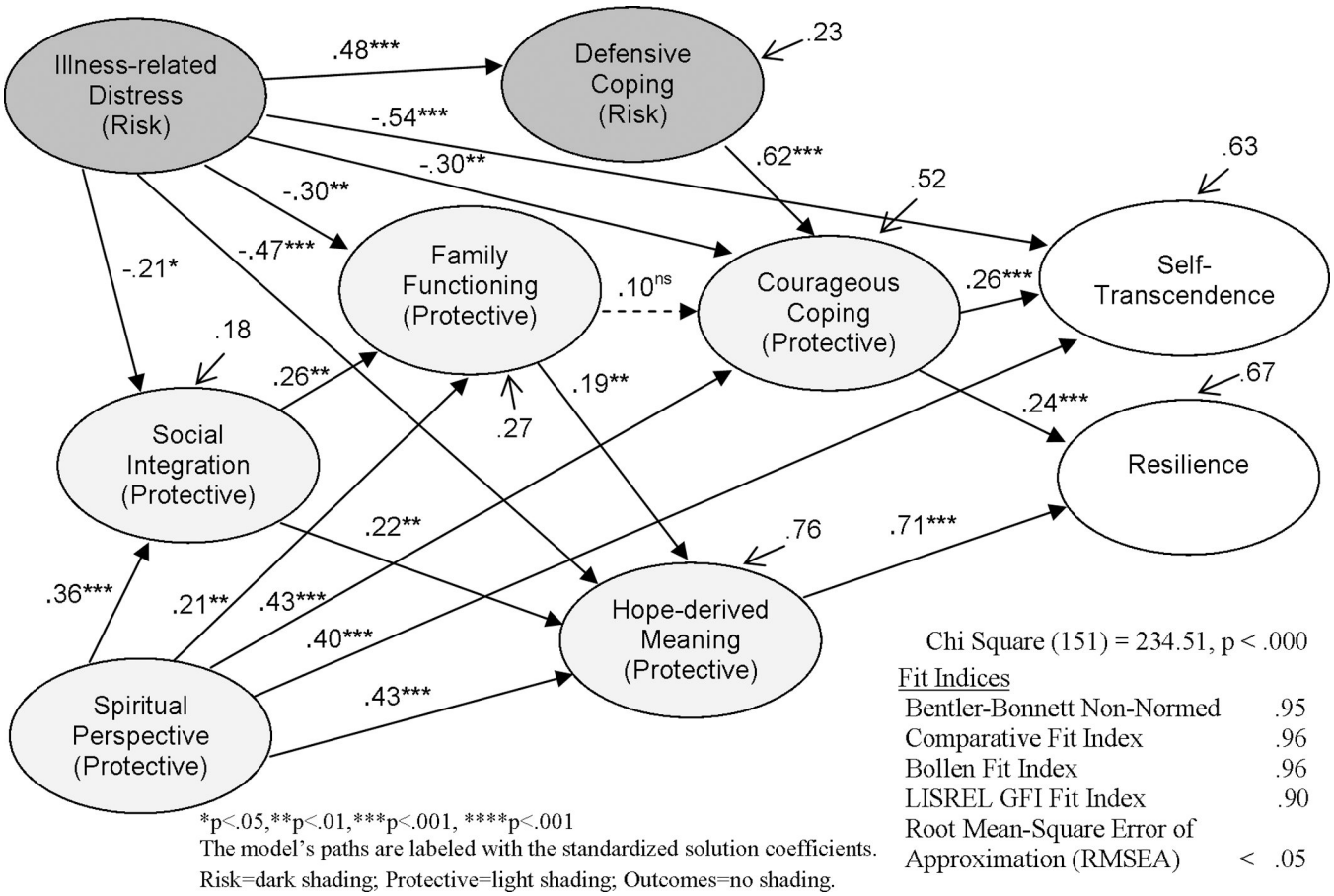

Figure 1.

Exploratory RIM guiding the study.

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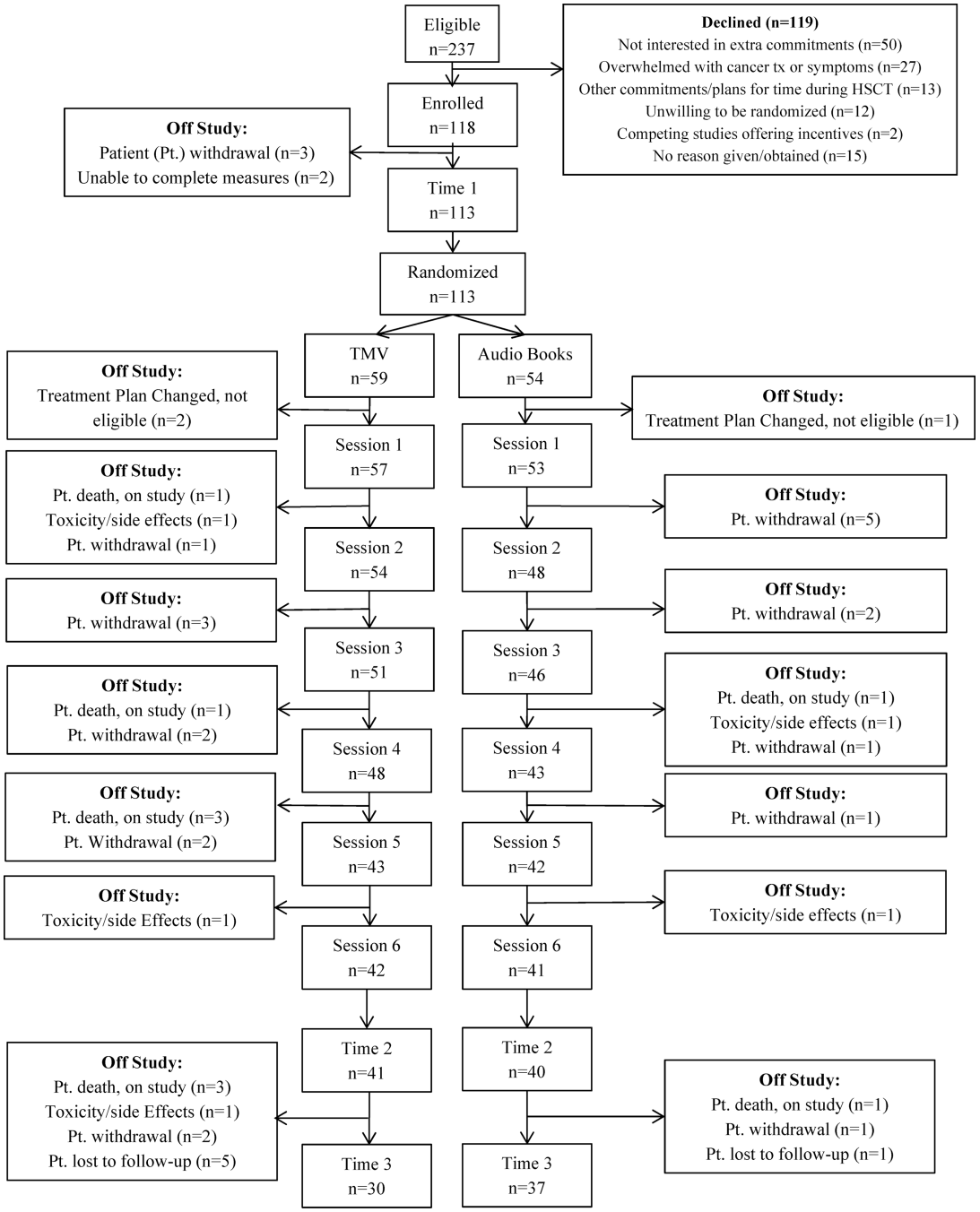

Figure 2.

CONSORT diagram for trial accrual, intervention delivery, and data collection.

Note: The death rate did not differ significantly between the two arms (two-sided Fisher exact test, p = .21).

Table 1

TMV Intervention: Summary of Contextual Support and Intervention Content

Elements of Contextual Support from CSM-MT	Summary of Intervention Content by Session[a]		
	Week	Session	TMV Intervention Content
Structure • Familiar, predictable music • Song Scripts • Storyboards • Leveled Involvement **Autonomy Support** • AYA-Directed • Choices (music, lyrics, visual images, vocalists, involving others) • Quality product **Relationship Support** • Music to communicate unspoken thoughts, feelings, dreams for future • AYA-Centered • Therapist support • Family, peer, healthcare provider involvement	1	1	- Learn how to use a songwriting script - Select music for project (i.e., offered 10 songs from 5 music genres)[b] - Brainstorm ideas for lyric/video content (i.e., what is important to AYA)
	1	2	- Write lyrics to a familiar song using a songwriting script - Discuss lyrics and what is important to AYA - Sing/practice song with CD accompaniment track - Select who will sing on the song recording
	2	3	- Sing/rehearse completed song - Discuss AYA thoughts about/reflections on video project - Digitally record vocal soundtrack for video - Listen to AYA vocals mixed with accompaniment track[b]
	2	4	- Begin storyboard process (i.e., select visual images to go with song lyrics) - Listen to completed song/discuss visual images – memories/importance - Digital camera available during hospitalization
	3	5	- Gather visual images and/or take pictures - Complete storyboard - Listen to completed song/discuss visual images - memories/importance
	3	6	- Private viewing of music DVD - Optional “Video Premiere” (i.e., AYA invites other to view)

AYA = adolescents/young adults; CD= compact disc; DVD = digital video disk; TMV = therapeutic music video.

[a] Sessions facilitated by board-certified music therapists.

[b] CD accompaniment purchased for each music video project. Music selections available upon request.

Table 2

Psychometric Properties of Measures at Baseline (N=113)

Latent Variable/ Manifest Variable	Measures	Number of items	Possible range	Mean (SD)	High score indicates greater (or more) …	Cronbach's alpha
Illness-Related Distress						
Symptom distress	McCorkle Symptom Distress Scale[40]	11	1–5	1.8 (0.6)	symptom distress	0.82
Uncertainty in illness	Mishel Uncertainty in Illness Scale[41]	28	1–5	2.3 (0.5)	illness uncertainty	0.89
Coping-Defensive						
Emotive/evasive coping	Jalowiec Coping Scale-Revised[42] *Emotive & Evasive Subscales*	18	0–3	1.2 (0.5)	emotive/evasive coping	0.79
Spiritual Perspective						
Spirituality-frequency	Reed Spiritual Perspective Scale[37]	4	1–6	4.0 (1.5)	spiritual practices	0.87
Spirituality-beliefs	Reed Spiritual Perspective Scale[37]	6	1–6	4.5 (1.3)	spiritual beliefs	0.94
Social Integration						
Perceived social support from health care providers	Perceived Social Support – Health Care Providers[6]	20	1–5	3.7 (0.6)	perceived support-provider	0.90
Perceived social support from friends	Perceived Social Support – Friends[43]	20	1–5	4.1 (0.6)	perceived support-friends	0.90
Perceived social support from family	Perceived Social Support – Family[43]	20	1–5	4.0 (0.7)	perceived support-family	0.91
Family Environment						
Family cohesion	Family Adaptability/Cohesion Scale II[44]	16	1–5	3.7 (0.6)	cohesion	0.89
Family adaptability	Family Adaptability/Cohesion Scale II[44]	14	1–5	3.4 (0.6)	adaptability	0.83
Family communication-problem	Parent-Adolescent Communication Scale[44]	10	1–5	3.2 (0.7)	communication	0.82
Family communication-open	Parent-Adolescent Communication Scale[44]	10	1–5	4.0 (0.7)	communication	0.90
Family strengths	Family Strengths Scale[44]	12	1–5	3.7 (0.6)	family strength	0.83
Coping- Courageous						
Confrontive coping	Jalowiec Coping Scale-Revised[42] *Confrontive Subscale*	10	0–3	1.4 (0.6)	confrontive coping	0.80
Optimistic coping	*Optimistic Subscale*	9	0–3	2.1 (0.6)	optimistic coping	0.75
Supportant coping	*Supportant Subscale*	5	0–3	1.7 (0.6)	supportant coping	0.60
Hope-Derived Meaning						
Expectancy/interconnectedness	Herth Hope Index[45]	4	1–5	4.3 (0.6)	hope	0.65

Latent Variable/ Manifest Variable	Measures	Number of items	Possible range	Mean (SD)	High score indicates greater (or more) …	Cronbach's alpha
	Expectancy/Interconnectedness Subscales					
Positive readiness	*Positive Readiness Subscale*	4	1–5	4.3 (0.6)	hope	0.62
Outcomes						
Self-Transcendence	Reed Self-Transcendence Scale[37]	15	1–4	3.3 (0.4)	self-transcendence	0.75
Resilience in illness	Haase Resilience in Illness Scale[6]	15	1–6	5.1 (0.6)	resilience	0.81

Table 3

Baseline Characteristics by Study Group

	TMV		Control		Overall		
Demographics	**n**	**Mean/%**	**n**	**Mean/%**	**n**	**Mean/%**	***P* value[a]**
Age (mean (SD); range)	59	17.1 (3.6); 11–24	54	17.5 (3.9); 11–24	113	17.3 (3.8); 11–24	0.54
Gender (%)	59		54		112		0.98
Female		42.4		42.6		42.5	
Male		57.6		57.4		57.5	
Hispanic (%)	59		54		113		0.30
No		79.7		87.0		83.2	
Yes		20.3		13.0		16.8	
Race (%)	59		54		113		0.93
African-American		11.9		9.3		10.6	
White		55.9		61.1		58.4	
More than one race		22.0		18.5		20.4	
Other[b]		5.1		7.4		6.2	
Unknown or not reported		5.1		3.7		4.4	
Currently attend school (%)	57		54		111		0.55
No		29.8		35.2		32.4	
Yes		70.2		64.8		67.6	
Level of school completed (%)	57		54		111		0.71
Grade school		35.1		27.8		31.5	
High school		42.1		46.3		44.1	
College		22.8		25.9		24.3	
Household income (%)	59		54		113		0.27
<$25,000		13.5		24.1		18.6	
$25,000–$75,000		39.0		44.4		41.6	

	TMV		Control		Overall		
Demographics	**n**	**Mean/%**	**n**	**Mean/%**	**n**	**Mean/%**	***P* value[a]**
>$75,000		34.0		20.4		27.4	
Unknown or not reported		13.5		11.1		12.4	
Religious activity participation (%)	58		54		112		0.02
Inactive or infrequent		41.4		63.0		51.8	
Occasional or regular		58.6		37.0		48.2	
Employment status (%)	58		54		112		0.78
Full-time		8.6		5.6		7.1	
Part-time		13.8		11.1		12.5	
Not employed		77.6		83.3		80.4	
Primary diagnosis (%)	59		53		112		0.99
Leukemia		45.8		47.2		46.4	
Lymphoma		25.4		24.5		25.0	
Solid tumor		28.8		28.3		28.6	
Transplant type (%)	59		53		112		0.30
Autologous		35.6		45.3		40.2	
Allogeneic/Syngeneic		64.4		54.7		59.8	

[a] Study group comparisons were made using chi-square (all categorical) and *t* tests (age).

[b] Includes American Indian, Alaskan Native, Asian, Native Hawaiian, Pacific Islander and other race.

Table 4

Effect size measures for latent variable outcomes obtained from structural equation models.

	T2					T3				
Factor	**n_1**	**n_2**	***t***	**Cohen effect size**	***P* value**	**n_1**	**n_2**	***t***	**Cohen effect size**	***P* value**
Illness-Related Distress	36	40	−0.686	−0.160	0.493	31	36	−0.487	−0.121	0.626
Coping-Defensive	36	40	0.855	0.199	0.393	31	36	−0.328	−0.082	0.743
Spiritual Perspective	40	40	1.283	0.291	0.199	30	37	1.805	0.450	0.071
Social Integration	39	40	1.015	0.231	0.310	31	37	2.197	0.543	0.028
Family Environment	40	40	1.374	0.311	0.169	30	37	2.659	0.663	0.008
Hope-Derived Meaning	40	40	−1.154	−0.261	0.248	30	37	0.734	0.183	0.463
Coping-Courageous	36	40	2.167	0.505	0.030	31	36	1.096	0.273	0.273
Self-Transcendence	36	40	0.737	0.172	0.461	31	36	1.706	0.424	0.088
Resilience	40	40	0.936	0.212	0.349	30	37	1.05	0.262	0.294

Notes:

n_1 is sample size for TMV group; n_2 is sample size for control group.

t indicates *t* value for treatment effect obtained from mplus output and defined as ratio of unstandardized estimate/standard error.

Cohen effect size defined as: t*(SQRT(((n1+n2)/(n1*n2))*((n1+n2)/(n1+n2-2)))).[26]

A positive (negative) sign for the t value and ES implies that the T2 or T3 adjusted mean for the latent Factor was higher (lower) for the TMV group than the control group.