

Development of a Novel Massage Therapy Outcome Measure for Children and Young Adults Receiving Hematopoietic Cell Transplant

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<https://doi.org/10.3822/ijtmb.v16i3.839>

Background: Children receiving hematopoietic stem cell transplantation (HCT) often experience an unfortunate sequelae of negative effects including pain, deconditioning, and anxiety. Massage therapy (MT) has demonstrated effective non-pharmacological management of fatigue, pain, and anxiety in patients undergoing cancer treatment. Existing studies have been limited by the lack of available MT-specific outcome measures to track responses to interventions.

Purpose: This study aimed to describe the creation of a novel MT-specific outcome measure to be utilized in the pediatric acute-care setting and establish construct validity for this measure to assess clinical effectiveness of MT interventions.

Setting: An oncology ward at a large pediatric tertiary medical center in the United States.

Participants: A total of 58 children and young adults undergoing HCT.

Research Design: Retrospective Cohort Study.

Intervention: A panel of massage therapists created a novel outcome measure, OMPREP, for use in MT sessions and performed a literature review to ensure face validity of the tool. This outcome measure was administered to patients and data were collected retrospectively to assess construct validity.

Results: A total of 1,333 MT sessions were completed (80.7% completion rate) with the novel OMPREP outcome measure utilized on 100% of visits. Mean engagement

($p < .001$), response ($p < .001$), and pain ($p < .001$) scores were all significantly greater at evaluation and discharge compared to the lowest observed scores post-HCT.

Conclusion: The novel MT-specific outcome measure, OMPREP, was feasible and demonstrated construct validity when implemented in a pediatric acute-care setting by massage therapists. This new tool may offer a quantitative measure of MT-interventions and assist in tracking patient outcomes.

KEYWORDS: massage therapy; pediatrics; oncology; hemopoietic cell transplantation; outcome measure; cancer

INTRODUCTION

Hematopoietic cell transplantation (HCT) involves the transfer of bone marrow, blood, or umbilical cord blood stem cells into a patient for the treatment of numerous life-threatening blood, immune, and metabolic disorders.^(1,2) HCT requires pre-chemotherapy and/or radiation to suppress the patient's immune system in preparation for receiving healthy donor stem cells.⁽¹⁾ Subsequent fatigue, pain, nausea, and anxiety⁽³⁻⁵⁾ often impact and limit participation and engagement in everyday activities. As a result, recipients of HCT experience deconditioning and a reduction in overall quality of life during prolonged hospital admissions.⁽¹⁻⁶⁾ This negative sequelae following HCT

continues into survivorship and results in higher rates of anxiety and depression, poorer peer interactions, and reduced physical functioning compared to non-cancer survivors.⁽⁷⁻⁹⁾

Alternative and complementary therapies, such as massage therapy (MT), are becoming increasingly popular in the management of side effects for patients with cancer.^(3,4) Massage therapy has been identified as a beneficial, non-pharmacological intervention to aid in the management of side effects^(1,5,10-20) for patients undergoing HCT.^(11,21) Massage therapy has demonstrated a reduction in fatigue,^(1,22) pain,⁽²³⁾ nausea,⁽⁴⁾ and anxiety,⁽²⁴⁻²⁷⁾ and improvement in mood^(22,25) and quality of life⁽²²⁾ when performed in coordination with traditional medical care.

As MT continues to grow in popularity for patients receiving HCT, it is important for clinicians to track patient outcomes using standardized assessments to determine whether interventions are clinically effective. Unfortunately, there are no standardized outcome measures for the use of massage therapists in the hospital setting to track patient outcomes for children and young adults receiving HCT. Existing literature identifies some general concerns regarding the outcome assessments used in the studies evaluating MT's impact on patient side effects from cancer or cancer treatment. Most studies utilized multiple outcome measures^(1,11,17,18,20) though these assessments do not span the scope of MT practice. The outcome assessments used in these studies were not created by massage therapists, and therefore, were not solely intended for use for evaluating MT outcomes.

A MT-specific outcome assessment was developed at Nationwide Children's Hospital (NCH), Columbus, Ohio, USA for children and young adults receiving HCT and who were enrolled in a quality improvement initiative called Transplant Energize Me Patient Outcomes (TEMPO[®]).⁽⁵⁾ TEMPO[®] is a multidisciplinary program which includes MT, physical therapy, occupational therapy, and therapeutic recreation. To quantify patient outcomes for MT during TEMPO[®], a novel outcome assessment was created, named OMPREP. OMPREP objectively tracks: (1) Orientation (the patient's state or awareness), (2) Muscle state based on tone and texture, (3) Pain, (4) Response to treatment, (5) Engagement, and (6) Pressure during therapy.

The aim of this study was to establish construct validity for the quantitative variables of OMPREP. Additionally, we hoped to evaluate the feasibility of administering OMPREP during MT sessions provided throughout the hospital admission for children and young adults undergoing HCT.

METHODS

Participants

We conducted a retrospective cohort study using convenience sampling to assess the construct validity and feasibility of OMPREP. Inclusion criteria for this study were: (1) patients between one day old and 21 years of age who received either reduced intensity or myeloablative conditioning before transplant using any graft source; (2) patients receiving allogeneic HCT from haploidentical, matched related, and matched unrelated donors; and (3) patients admitted between September 1, 2016 through December 31, 2020. Exclusion criteria from data analysis included: (1) patients with any comorbidity that precluded participation in the TEMPO[®] project (e.g., neurologic deficits impeding physical exercise); (2) patients who died during HCT admission; and (3) patients who did not receive any MT intervention during their admission. Patient data, including patient demographics and OMPREP scores, were sourced from electronic medical records. The study procedures described were approved by the Institutional Review Board at NCH (STUDY00012521).

Outcome Measure Development and Face Validity

Without an established outcome assessment within the MT profession for this patient population, a novel, objective outcome assessment tool to evaluate responses for patients receiving HCT was created. Five licensed hospital-based massage therapists specializing in treatment of patients undergoing HCT and who had undergone Oncology Massage training met over a 12-month period, bi-monthly, to determine what items should be included on the OMPREP. To establish face validity of the tool, we completed a thorough review of the literature on MT as a complimentary therapy for children and young adults with cancer or receiving

HCT.^(1,5,10–20,22–24,26–28) We identified 6 key aspects of massage: patient orientation, muscle state, pain, response to treatment, engagement, and the level of pressure applied by the massage therapist. These components were, therefore, included in OMPREP. Scoring and scoring criteria for OMPREP was discussed across multiple meetings until consensus was reached among all massage therapists who oversaw the development of the outcome assessment. OMPREP was designed to be objectively scored by the massage therapist. The finalized outcome assessment, OMPREP, is presented in Table 1. The same five massage therapists who developed OMPREP and were providing treatment to children and young adults undergoing HCT were trained on the delivery and scoring of OMPREP at a single, in-person educational session. To ensure quality assurance, questions and feedback were addressed by the group continually throughout the project. Informal feedback was available via email or in-person discussions with the massage therapists who designed the assessment. The assessment was completed and documented for every MT session for every participant in TEMPO[®].

Massage Therapy Treatment Sessions

As per TEMPO[®] program, patients receiving HCT are prescribed MT for a 30-minute session, a maximum of five times per week, although session frequencies vary based on how the patient presents emotionally, physically, and medically. Sessions addressed issues such as fatigue, pain, nausea, anxiety, and muscle tension. Patients were able to decline therapy if feeling unwell. During each session, the patient could request focus on any part(s) of the body such as head/neck/shoulders/back, upper and/or lower extremities or any combination of the aforementioned. Very light pressure was used to avoid overtaxing muscles and bruising or bleeding due to lowered blood counts (specifically platelets) due to the HCT process.⁽¹⁵⁾ OMPREP was intended to be administered at every MT session.

Statistical Analyses

All data were sourced from the patient's electronic medical record. Data were summarized using standard descriptive

statistics. The mean and standard error were calculated for continuous or ordinal variables. The frequency and percentage were calculated for all nominal variables. To establish construct validity, the mean and 95% confidence intervals for the ordinal variables of OMPREP were summarized longitudinally over three time points—pre-transplant evaluation, patients' lowest post-transplant observation score on the OMPREP, and discharge evaluation. We adapted the same methodology used by Gonzales et al.⁽⁵⁾ for the ordinal variables (Engagement, Response, Pain) of OMPREP. The lowest post-transplant scores on OMPREP occur at different time points for each participant, but occur most often in the week post-transplant. This score was utilized to normalize patient outcome data because length of stay, medical complexity, and function differs between participants. The comparison in scores between time points were completed using linear mixed effects models with a random intercept for each patient and *p* values were adjusted using the Tukey method for multiple comparisons, and those less than 0.05 were considered statistically significant. Feasibility of OMPREP was described using completion rate. Analyses were completed using SAS software, version 9.4 (SAS Institute, Cary, NC).

RESULTS

A total of 58 patients (9.3±5.9 years old at the time of HCT, male: 50.0%) were included in this study. Patient demographic data can be found in Table 2.

Construct Validity of Ordinal Variables on the OMPREP

Mean engagement scores at evaluation and discharge were significantly higher than at the lowest engagement score post-HCT (evaluation: 4.02±0.17, lowest score post-HCT: 1.14±0.23, discharge: 3.90±0.23; adjusted *p* ≤ .001). Mean response scores at evaluation and discharge were significantly higher than at the lowest response score post-HCT (evaluation: 4.79±0.10, lowest score post-HCT: 4.16±0.12, discharge: 4.94±0.04; adjusted *p* ≤ .001). Mean pain scores at evaluation and discharge were significantly higher than at the lowest pain score post-HCT (evaluation: 4.71±0.56, lowest score post-HCT: 3.67±1.12, discharge:

TABLE 1. OMPREP Outcome Assessment

<i>Data Type</i>	<i>Subscale</i>	<i>Score</i>	<i>Score Criteria</i>
Ordinal	Engagement	5	Eager for session, excited, engages with therapist, interactive
		4	Agreeable to session, ready for session, engages with therapist
		3	Withdrawn, allows massage but does not engage with therapist
		2	Hesitant to session, needs encouragement, occasionally pulls away
		1	Guarded, tense, pulls away, requires distraction to engage
		0	Refuses, medically unstable, unavailable for session
Ordinal	Response	5	Relief
		4	Decreased Pain
		3	No change
		2	Irritated/Agitated
		1	Increased Pain
		0	Refuses, medically unstable, not in room
Ordinal	Pain	5	No cries or complaints
		4	Aching/dull, moaning, crying, guarding areas
		3	Throbbing, crying
		2	Deep, curled up, crying, inability to move
		1	Doesn't allow touch to skin
		0	Refuses, medically unstable, not in room
<i>Data type</i>	<i>Subscale</i>	<i>Category</i>	<i>Category Criteria</i>
Nominal	Pressure	Lime	No restriction, firm, controlled pressure
		Tangerine	Slightly firm muscle contact, nurturing, slow
		Plum	Contact with superficial muscle, slow, nurturing
		Ripe Peach	Skin contact, resting hands with no weight, slow, nurturing
		Bubble	Very light resting hands, weight of a feather, slow, nurturing
		No Pressure	Refuses, overall health status, not available for session
Nominal	Muscle tension/ texture	Normal/Baseline	Age-appropriate muscle tone/tension
		Hypo/Hypertonia	Hypotonia-reduced muscle strength, low tone Hypertonia-abnormal increase in muscle tension
		Spasm/Spastic	Contracted muscles, compulsive movements, twitching
		Rigidity	Muscle tension, stiffness, inability for muscles to relax normally
Nominal	Orientation	Atrophy/Withering	Wasting away, muscle weakness, decreased mass
		Baseline	Normal orientation for patient
		Tired/Fatigued	By verbal report or appearance
		Lethargy	Barely responding to therapist, not easily aroused
		Disoriented	Appears confused, not making sense, RN needs notified
		Did not arouse	RN or family clears for massage, Patient remains asleep throughout session

TABLE 2. Demographics and Transplant Characteristics

Characteristic	N (%)
Patients	58
HCT Age	
< 42 months	11 (19)
42mo - 12yrs	28 (48)
>12 years	19 (33)
Male Sex	29 (50)
Race	
White	39 (67)
Black	9 (16)
Other/Unknown	10 (17)
Diagnosis	
ALL	8 (14)
AML	14 (24)
MDS	4 (7)
Sickle Cell	7 (12)
Aplastic Anemia	8 (14)
Other	17 (29)
Regimen	
Myeloablative	30 (52)
Donor Type	
Related	14 (24)
Haploidentical	5 (9)
Unrelated	29 (50)
Unknown	10 (17)

ALL = acute lymphocytic leukemia.
MDS = myelodysplastic syndromes.

4.78±0.42; adjusted $p \leq .001$) indicating that pain was lessened at evaluation and discharge compared to the post-HCT nadir. Table 3 presents the ordinal scales and mean scores at each time point. Figure 1 presents the mean scores for engagement, response, and pain at evaluation, lowest score observed post-HCT, and at discharge.

Description of Nominal Variables on the OMPREP

The highest proportion of children had their pressure level described as “ripe peach” (49.6%), followed by “plum” (48.3%), “bubble” (1.5%), and “tangerine” (0.7%). The highest proportion of children had

their muscle tension or texture described as hyper- or hypotonia (54.1%), followed by normal/baseline (39.6%), spasm/spastic (4.7%), and rigidity (1.7%). The highest proportion of children had their orientation described being at baseline (48.5%), followed by being tired/fatigued (41.4%), lethargy (6.8%), did not arouse (2.4%), and disoriented (0.9%). See Table 1 for reference on categories.

Feasibility of OMPREP

A total of 1,333 MT sessions were completed out of 1,652 attempts (80.7% completion rate). Of the sessions that were completed, OMPREP was scored on 100% of the patients. Common reasons for a patient to miss a MT session would be patient not medically stable (as reported by the nurse), parent or patient declined, or patient was out of the room. 100% of missed sessions were recorded in the electronic medical record. The median number of MT session refusals per patient was 1, with a range from 0-27 refusals. The median length of stay within the hospital was 35 days, with a range from 16-113 days. Median number of MT attempted sessions was 22 per participant (ranging from 1-65 attempts), or 4.4 sessions per week.

DISCUSSION

As alternative and complementary therapies such as MT become increasingly utilized in the hospital setting to aid in the management of side effects for patients with cancer,^(3,5) it will be imperative that there are outcome assessments to evaluate efficacy of treatment and guide clinical decision-making for clinicians. The development of outcome assessments for massage therapists will assist clinicians in choosing appropriate interventions and modifying their treatments to meet the needs of the individual they are treating. It will also assist in the establishment of evidence-based practices for best patient outcomes for MT. Our study is the first to develop a MT outcome assessment to evaluate outcomes for children and young adults receiving HCT in a hospital-based setting. The development and initial validity testing of OMPREP is an important first step to routine implementation of outcome assessments to evaluate outcomes for all patients receiving MT in the hospital setting.

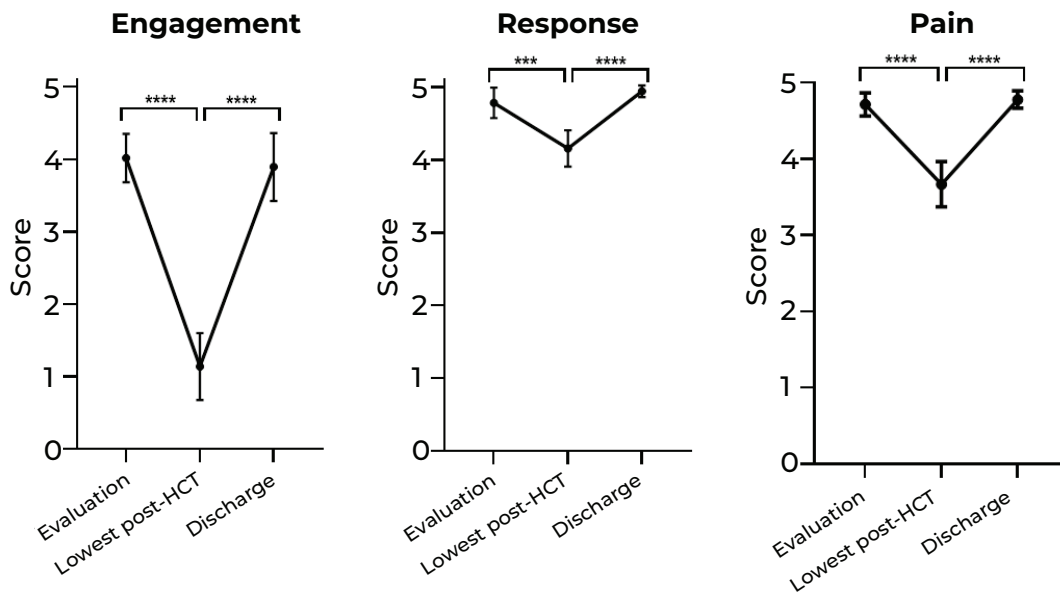
TABLE 3. OMPREP: Engagement, Response, and Pain Scores^a

Measure	Scale	Evaluation (pre-HCT)	Lowest Score (post-HCT)	Discharge from Hospital
Engagement	5 Eager 4 Agreeable 3 Withdrawn 2 Hesitant 1 Guarded 0 Refuses	4.02±0.17	1.14±0.23 ^b	3.90±0.23 ^c
Response	5 Relief 4 Decreased Pain 3 No change 2 Irritated/Agitated 1 Increased Pain 0 Refuses	4.79±0.10	4.16±0.12 ^b	4.94±0.04 ^c
Pain	5 No cries or complaints 4 Aching/dull, moaning, crying 3 Throbbing, crying 2 Deep, curled up, crying 1 Doesn't allow touch to skin 0 Refuses	4.71±0.56	3.67±1.12 ^b	4.78±0.42 ^c

^aData in Table 3 were analyzed using linear mixed models with Tukey-adjusted *p* values; significance level of .05 was used.

^bIndicates significant differences from evaluation.

^cIndicates significant differences from post-transplant low point.



[Level of significance] * = <.05. ** = <.01, *** = <.001, **** = <.0001; HCT = hermatopoietic cell transplantation.

FIGURE 1. Mean OMPREP scores at evaluation, lowest post-HCT, and discharge

Content validity was established through describing face validity procedures and evaluating construct validity of the novel outcome assessment, OMPREP. Face validity was established using the information gained from a comprehensive

literature review and clinical expertise. The summation of this knowledge was used to design an outcome assessment that would be clinically relevant to patients receiving HCT. It was important to the developers of OMPREP to ensure

that all key aspects of MT were included in the outcome assessment, suggesting that it may be relevant to other populations. Construct validity of the measure was established for the ordinal variables on the OMPREP, which included engagement, response, and pain. The results from our study demonstrate that these variables respond in a similar, predictable “U-shaped” or “inverted U-shaped” pattern as described by Gonzales et al.⁽⁵⁾ for functional mobility. This is important because we would expect Engagement, Response, and Pain to change in relation to changes in functional mobility. These findings suggest that the ordinal variables of the OMPREP are responsive to change over time for patients admitted to the hospital for HCT.

When examining nominal constructs of OMPREP, we found that the most common pressure utilized during MT intervention was described as “ripe-peach” or “plum”. This level of pressure is consistent with making contact no deeper than the superficial muscle and would be appropriate for patients undergoing HCT, as they are at risk for bruising and bleeding.⁽²⁸⁾ In addition, most children and young adults had abnormal muscle tension or texture (60.3%) noted by the massage therapist, underpinning the potential need for MT intervention. Finally, most patients had some impairment in their orientation level (51.5%) which is consistent with other literature findings that fatigue is a commonly noted side effect of HCT treatment.^(18,22,23,25,27,28)

Finally, we found that the OMPREP was feasible to implement in the hospital-based, clinical setting. Every MT session had a documented OMPREP assessment. The only sessions in which the OMPREP assessment was not recorded were the sessions in which MT was missed. We also found that that over 80% of prescribed MT treatments were completed for participants with a median of 4.4 sessions/week.

Limitations and Future Directions

There are several limitations to this study. First, all data were collected via a retrospective chart review, from a single institution, and it included a small sample of participants undergoing a similar procedure which may prevent generalizability of the results. Second, we were only able

to evaluate construct validity of OMPREP. For future studies, criterion-related validity and reliability of OMPREP should be established. In addition, it may be beneficial to establish validity of this outcome assessment for other patient populations. Specific areas of treatment patients requested massage therapy was beyond this study but could be identified in the future. Despite these limitations, the real-world application of the outcome assessment may be beneficial to track MT-related outcomes for children and young adults undergoing HCT.

CONCLUSION

The results from our study suggest that OMPREP, a novel outcome assessment for massage therapists treating children and young adults undergoing HCT, demonstrates construct validity and is feasible to implement in a hospital-based clinical practice. It will be important to continue to refine and establish validity and reliability of OMPREP as an outcome assessment for it to be utilized in other clinical settings and populations, including for patients with burns and those requiring post-operative care. The addition of this outcome measure will allow for future empirical studies to assess the efficacy of MT interventions for children and young adults undergoing HCT.

ACKNOWLEDGMENTS

The authors would like to thank the children who participated in this study and their families. We would also like to thank the Clinical Therapies Department at Nationwide Children’s Hospital for their support and resources.

CONFLICT OF INTEREST NOTIFICATION

The authors declare there are no conflicts of interest. No external funding was obtained for this study.

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