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Feasibility of Expressive Writing for Body Image Distress and Anxiety Among Adolescent and Young Adult Cancer Survivors

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Protocol Title: Determining the Feasibility of Expressive Writing for Body Image Distress and Anxiety Among Adolescent and Young Adult Cancer Survivors

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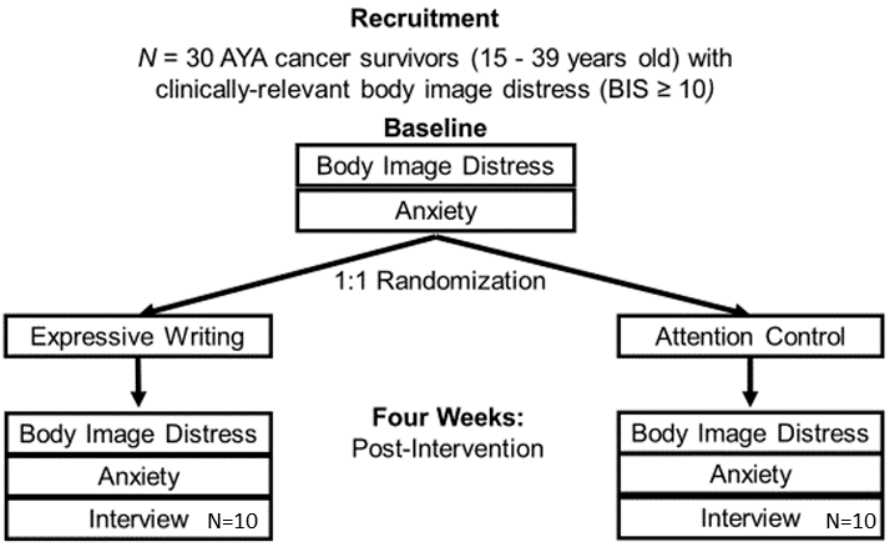
STUDY SCHEMA



ABBREVIATIONS

- AYA: Adolescent and young adult
- BI: Body image
- EW: Expressive writing
- ED: Eating disorder
- BDD: Body dysmorphic disorder
- CBT: Cognitive behavioral therapy
- BIS: Body image scale

STUDY SUMMARY

Each year, about 89,500 adolescents and young adults (AYAs; 15-39 years old) are diagnosed with cancer and up to 60% experience body image (BI) distress [1]. BI is largely developed in adolescence and young adulthood and has implications for self-identity and quality of life [2]. Cancer itself and its associated treatments precipitate changes to appearance as well as body sensation and function, all of which can alter BI and lead to increased anxiety [3]. Cancer-related BI distress is not systematically managed due to multiple factors, including lack of time and lack of provider expertise [7,8]. An in-home BI-focused expressive writing (EW) program offers a promising outlet for addressing BI distress and anxiety in a way that eliminates constraints of clinical time and specialist availability.

BI distress in other populations, namely patients with eating disorders (ED) and body dysmorphic disorder (BDD), is managed as part of those overarching diagnoses with pharmacological interventions (e.g. SSRIs) or intensive psychotherapy [4, 5]. There are no recommended interventions to help AYA cancer survivors cope with BI distress that does not meet criteria for ED or BDD. To address this knowledge gap, the objective of this this pilot randomized-controlled trial is to determine the feasibility of a four-week BI-focused EW intervention to decrease BI distress and anxiety among AYA cancer survivors with the hypothesis that this intervention will reduce BI distress and anxiety. Prior evidence demonstrates that in-home EW interventions can improve quality of life and cognitive processing among adult patients with cancer [9,10,17]. Adaptations of EW, such as digital storytelling, have been utilized in pediatric oncology with evidence of feasibility and trends toward improved emotional and school functioning [11].

Utilizing an explanatory-sequential mixed-methods design, we will randomize 30 AYA cancer survivors with BI distress (based on a screening body image scale [BIS] score ≥10) to a four-week, in-home BI-focused EW intervention or a control writing program. The intervention writing program will follow writing procedures as per Pennebaker and Beal [12] with modifications to include probes relating to emotions regarding body image and the cancer experience. Control participants will write objectively about neutral topics and both groups will be prompted to write for 20 minutes per session. Participants will complete outcome measure assessments for anxiety and BI distress (GAD-7 and BIS) at baseline and at the conclusion of the four-week intervention. Research staff will contact participants after the week 2 and week 4 sessions to review adherence. Participants will then take part in post-intervention interviews to assess acceptability and satisfaction and changes in BI distress and anxiety between groups will be analyzed using linear mixed effects regression.

1.0 Objectives/Specific Aims

Body image (BI) distress and associated anxiety are significant psychosocial concerns for many adolescent and young adult (AYA) cancer survivors. However, these concerns are not routinely or systematically addressed due to multiple factors, including lack of time and lack of provider expertise. This study aims to evaluate the feasibility and acceptability of an in-home BI-focused expressive writing (EW) program for post-treatment AYA cancer survivors with BI distress.

Primary Aim: Determine the feasibility of implementing a four-week, in-home BI-focused EW intervention for post-treatment AYA cancer survivors with BI distress.

- RQ1.1: What is the feasibility of an expressive writing intervention regarding demand (recruitment), implementation (adherence), and practicality (self-guided, at-home intervention)?
    - Endpoints: All participants are recruited over a 12-month period, 50% of participants complete 3 out of 4 (75%) of the at-home writing interventions and 75% of participants complete the baseline and four-week patient-reported measures.

Exploratory Aim: Explore AYA cancer survivors' perspectives of acceptability and satisfaction with the EW and control writing programs using semi-structured interviews.

- RQ2.1: What are the facilitators and barriers to an at-home writing intervention among AYA cancer survivors with body image distress and anxiety?
- RQ2.2: What components of the expressive writing intervention were the most helpful for body image distress and anxiety?
    - Endpoints: Completion of the Acceptability of Intervention Measure, a psychometrically validated implementation scale that specifically measures treatment or service acceptability. Descriptive statistics for this measure (mean and standard deviation) will be reported. Qualitative interviews will also be conducted with participants to review barriers and facilitators.

Exploratory Aim: Explore the preliminary efficacy of an at-home, four-week BI-focused EW intervention on reducing BI distress and anxiety in post-treatment AYA cancer survivors.

- RQ3.1: Compared to an attention control group, do the at-home expressive writing group participants report reductions in body image distress and anxiety (BID and GAD-7)?
    - Endpoint: We will determine the preliminary impact of the four-week at-home, body image-focused expressive writing intervention relative to the control on improving body image distress (BIS) and anxiety (GAD-7) utilizing data collected at baseline and four weeks. These outcomes are continuously scaled and appropriately analyzed by Gaussian- based statistical models. We will evaluate change-from-baseline in body image distress and anxiety by including fixed-effects coefficients for time, treatment (expressive writing intervention relative to the control), and the important interaction effects

that will determine whether changes from baseline are greater in the expressive writing group, relative to controls. We will incorporate random Y-intercepts in the model to accommodate the nesting of repeated observations within subject.

2.0 Background and Significance

Importance of the Problem to be Addressed

Body image has been recognized as a major psychosocial concern for cancer patients and encompasses views on physical appearance as well as thoughts and feelings related to how ones' body functions [1]. Cancer itself and its associated treatments often precipitate changes to appearance, sensation, and function, all of which can alter body image and overall psychological stress. This is noted in AYAs undergoing treatment, immediately post-treatment and in the long-term survivorship setting and is noted to be a major concern in up to 60% of patients.

Body image is largely developed in adolescence and young adulthood with implications for self-identity and social relationships [2]. Receiving a cancer diagnosis and undergoing subsequent treatment during this critical developmental time can disrupt the formation of a healthy body image. To date, correlations have been noted between body image disturbances in AYAs and psychosocial adjustment, including anxiety, depression, and social quality of life [3]. These challenges can persist well into the survivorship period with long-lasting mental health implications.

At present, there is sufficient qualitative investigation that describes the prevalence and impact of body image distress in the AYA oncology population. In addition, oncology providers are attuned to these concerns but recognize that these concerns are not systemically addressed due to a lack of time allotted in clinical encounters and an overall lack of expertise or comfort level in discussing body image concerns [7,8]. Body image distress in other patient populations, namely patients with eating disorders (ED) and body dysmorphic disorder (BDD), is managed as part of those overarching diagnoses with pharmacological interventions (e.g., SSRIs) or intensive psychotherapy, such as cognitive behavioral therapy (CBT) [4, 5]. At present, there are no recommended interventions to help AYA cancer survivors cope with body distress that does not meet the criteria for ED or BDD [6,7]. In addition, many patients are not interested in additional medications for symptom management as anti-depressant or anxiolytic medications present the potential for adverse events and are often associated with financial costs.

Rigor of the Prior Research Supporting the Aims

The expressive writing paradigm was designed to promote the processing of a traumatic event by prompting participants to write briefly about thoughts and feelings related to that experience. This was developed by Pennebaker and Beal in 1986 [12] who describe a study in which participants wrote either personally about traumatic life events or trivial topics on 4 consecutive days with no time limits. Their findings indicated that writing about traumatic events could provide benefit in terms of organizing thoughts related to that event. Subsequent work in cancer populations has led to adaptations of this model with time limits to writing, in-

home delivery, and extended timing of sessions over a period of weeks [9, 29]. For survivors of AYA cancer, their diagnosis and subsequent treatments can be considered traumatic events with body image distress and anxiety as persistent manifestations of this experience after treatment is completed [20, 21]. As such, expressive writing represents a yet-unexplored potential intervention to address body image distress and anxiety in the AYA cancer survivor population.

In-home expressive writing interventions have been shown to reduce sleep disturbances and cognitive processing in other adult cancer patient populations [9, 10, 17]. For example, breast cancer survivors with lymphedema have reported significant quality of life concerns. In one study, 107 women with stage II lymphedema completed four, 20-minute writing sessions regarding thoughts and feelings specific to their lymphedema and resultant data revealed a subset of patients for whom expressive writing may have improved quality of life [9]. Another study randomized 277 patients with renal cell carcinoma to either expressive writing or neutral topic writing for four 20-minutes in-home sessions over a period of 10 days [10]. Participants in the expressive writing group reported fewer cancer-related symptoms and improved cognitive processing compared to control participants.

For pediatric cancer patients, digital storytelling can be considered an adaptation of expressive writing. In a study exploring this, 16 pediatric oncology patients composed an unstructured "digital story" using images, speech, and music to represent their cancer experience [11]. In follow-up interviews, participants cited multiple potential benefits to this process, including healing from previous psychosocial trauma, educating others, and serving as a diversion from more clinical aspects of cancer care.

Significance of the Expected Research Contribution

The proposed study will address an existing knowledge gap by investigating the use of expressive writing to address body image distress and its associated anxiety in AYA cancer survivors outside of the oncology clinic. Expressive writing as a paradigm aims to have its participants process a traumatic event by writing about thoughts and feelings regarding their experience with a goal of converting disorganized emotions into organized thoughts [12].

For survivors of AYA cancer, their diagnosis and subsequent treatment can be considered traumatic events with body image distress and anxiety as persistent manifestations of this experience [20, 21]. An in-home expressive writing intervention that prompts participants to explore their thoughts and feelings related to their history of cancer and body image distress offers a promising outlet for addressing these concerns in a cost-effective way that eliminates the barriers of additional clinical time and specialty provider availability.

Innovation

Previous expressive writing interventions or adaptations of expressive writing have targeted adults or pediatric patients and have largely focused on patients receiving treatment. For survivors of AYA cancer, their diagnosis and subsequent treatment can be considered a traumatic event with body image distress and anxiety as persistent manifestations of this experience after treatment is completed [20, 21]. Other tested interventions for psychosocial distress in AYA cancer survivors focus on pharmacological management or psychotherapy such

as CBT. These interventions have primarily been studied in populations with clinically diagnosed depression or anxiety rather than anxiety associated with body image.

To our knowledge, no studies have tested the impact of a remote, expressive writing intervention for body image distress and anxiety among AYA cancer survivors. The application of expressive writing to address these concerns shifts current clinical practice paradigms by recognizing these concerns as separate and unique psychosocial issues in this population that can be addressed in a way that empowers participants to explore their own thoughts and feelings. Specifically, an in-home expressive writing intervention allows AYA cancer survivors the opportunity to reflect and write about body image distress and anxiety in a non-threatening environment devoid of the burden of increased worry or guilt that some AYA cancer patients describe when sharing emotional responses to their cancer experience [22-24]. This intervention is accessible to all socioeconomic and geographic groups and can be adapted based on language preference.

3.0 Preliminary Data

The proposed research is a pilot study. To our knowledge, this is the first investigation that explores the feasibility and potential impact of an expressive writing intervention on body image distress and anxiety in AYA cancer survivors. Little is known about the use of expressive writing specifically in the AYA population with body image concerns and anxiety.

4.0 Investigative Team

Principal investigator (PI) Wytiaz is a medical oncology fellow and an early-stage investigator. Faculty advisor Knoerl is a nurse scientist with experience as an investigator in AYA oncology and non-pharmacologic supportive care interventions. Biostatistician John Rice will oversee all planned statistical analyses. Sub-investigators Chugh, Walling and Karimi will assist with study advertisement and participant recruitment. Sub-investigators Chugh and Walling are co-directors of the Michigan Medicine adolescent and young adult program with both clinical and research experience in the field of AYA oncology.

5.0 Methods

5.1 Design

This study is a randomized-control feasibility trial that will utilize an explanatory-sequential mixed-methods design, to randomize 30 AYA cancer survivors (1:1 randomization) with BI distress (based on a baseline body image scale [BIS] score ≥10) to a four-week, in-home, BI-focused EW intervention or a control writing program. Randomization will be stratified based on age/developmental stage (15-25 years, 26-39 years) [31].

5.2 Subject Recruitment

Participants will be recruited at the C.S. Mott Children's Hospital Pediatric Hematology Oncology Clinic and the Rogel Cancer Center Clinics. Recruitment will take place over a period of 6 months with a plan to initiate intervention at three time points following enrollment of 10 participants at each time point. We will use an active clinic-based recruitment strategy as follows: 1) Study team staff will meet patients in the clinic rooms to

advertise and recruit for study; 2) Study investigators will share the study with oncology colleagues to allow patient referral; 3) Recruit patients enrolled in the AYA oncology program; and 4) Recruit patients through institutional social media campaigns.

5.3 Informed Consent Process

Patient consent to participate will be obtained at the beginning of the study over the phone or in-person. The study team will be available to answer any questions about the study before the patient agrees to participate. All participants will sign the consent (e.g., electronically via SignNow) and receive a copy of the consent. We will also be recruiting individuals 15 – 17 years old. Individuals under the age of 18 will not have attained the legal age for consent to treatments or procedures involved in the research. In these instances, parental permission for the child to participate and child assent will be obtained. Further, as this is a minimal risk study, parental permission for the child will be obtained from at least one parent or court appointed guardian, even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child. Parental permission for a child to participate will be documented in writing on the consent form (e.g., SignNow). Assent will be required for all children participants. All children will be required to sign (e.g., SignNow) the assent box on the informed consent. We will have two study members on the phone when interacting with children during the consent process in accordance with the Rule of Threes (Appendix A). We will document the outcome and date of the consent/assent discussion in our enrollment and screening logs.

5.4 Subject Selection

5.4.1 Inclusion Criteria

a. Age 15-39 years
b. History of one or more cancer diagnoses within the past 5 years and with all treatment (surgery, chemotherapy, radiation) completed ≥ 3 months before enrollment)
c. BIS ≥10 at time of screening
d. Ability to provide consent or assent and parental consent if applicable.

5.4.2 Exclusion Criteria

a. Plan to receive surgery, radiation, chemotherapy (including biologic agents, immunotherapy, and other targeted agents) for cancer treatment during the study period (from baseline assessment through post-four-week assessments and interview). Participants may continue with surveillance (such as imaging or biopsies) during the study period.
b. Initiation of new treatments for body image distress or anxiety (e.g., pharmacologic, psychotherapy) ≤8 weeks prior to study enrollment. Although, participants may continue psychosocial

or pharmacological treatments for anxiety or body image distress if the treatment were initiated at least eight weeks prior to study enrollment, the dose has not changed, and they report clinically relevant body image distress.

c. History of limb-altering surgery or amputation (surgical exclusions are based on the premise that significant appearance-altering surgeries may impact body image distress differently than other cancer therapies)
d. Currently receiving end-of-life care

5.5 Expressive Writing Intervention

Theory: The expressive writing paradigm developed by Pennebaker and Beal in 1986 [12] was designed to elicit processing of a traumatic event by prompting participants to write briefly about thoughts and feelings related to that experience. Specifically, participants wrote either personally about traumatic life events or trivial topics on 4 consecutive days with no time limits. Findings indicated that writing about traumatic events could provide benefit in terms of organizing thoughts related to that event. Subsequent work in cancer populations has led to adaptations of this model with time limits to writing (frequently 20 minutes), in-home delivery, and extension of sessions over a period of weeks [9, 29].

Session Delivery: Participants will be contacted via email weekly with the writing assignment and instructions to complete a 20-minute in-home writing session. Email prompts will also encourage patients to set a timer for 20 minutes prior to writing initiation.

Content: The intervention writing program will include four prompts that probe participants' thoughts and feelings regarding body image and the cancer experience (see Table 1). Prompts are adapted from resources for BDD and ED [18, 27].

Table 1: Writing Prompts, Intervention and Control

Trial Arm	Intervention Group	Control Group
Week 1	How did your body support you through cancer care? In what ways do you feel like it let you down?	Describe in detail the activities you completed in the 24 hours prior to this task.
Week 2	Can you imagine a time in the future when you feel comfortable in and with your body? How would that feel and does it depend on your cancer status?	Describe in detail your current surroundings.
Week 3	Describe a time when you changed your behaviors based on thoughts about your body (avoided social events, etc.). What feelings did you have after this?	Review the plot of the last book you read/movie or television show you watched.

Week 4	How would you speak to a friend with negative thoughts about their body? Is this different than your internal dialogue either during cancer treatment of after?	Detail the events of your most recent vacation or trip away from home, from departure to arrival home.

Ensuring Treatment Fidelity: We will address components of treatment fidelity in our intervention delivery to reduce unsystematic variation that could impact internal or external validity [30]. We are administering a theoretically grounded expressive writing intervention via a standardized protocol and a specified dose (number, frequency, set of intervention activities). To ensure participant receipt of treatment and enactment of treatment skills, study staff will call participants prior to intervention start (week 1), after week 2 writing prompt and at the end of the intervention (week 4) to document information about participants' between session use of the expressive writing program (e.g., frequency, duration, barriers). This will be completed within ±3 days of the assigned time point.

5.6 Low-Dose Attention Control

We will employ an attention control group to control for non-specific effects of prompted writing. Control participants will write objectively about neutral topics as demonstrated in table 1 [12]. Control group participants will also be contacted via an electronic reminder (email) weekly with the writing assignment and instructions to complete a 20-minute in-home writing session. Email prompts will also encourage patients to set a timer for 20 minutes prior to writing initiation. Measures to ensure fidelity will mirror those of the intervention group.

5.7 Time and Events Table

Data Collection Tool	Minutes	Baseline[a]	Week 1[b,c]	Week 2[b,c]	Week 3[b]	Week 4[b,c,d,e]
Screening	10	X				
Informed Consent	10	X				
GAD-7		X				X
BIS		X				X
Writing Prompts (EW or control)	20		X	X	X	X
Acceptability of Intervention Measure	5					X
Semi-Structured Interviews	45					X
Demographics	5	X				
Concurrent Medication Form	5	X				X
Study Team Contact for Adherence	5-10		X	X		X

[a]Baseline outcome assessments must be completed within ±7 days of time point.
[b]Writing prompts must completed within +7 days of assignment.
[c]Study staff contact must be completed within ± 3 days of time point.
[d]Week 4 outcome assessments must be completed within ±7 days of time point.
[e]Semi-structured interviews must be completed within +7 days of time point.

6.0 Measures

Outcome Measures

Adherence

Adherence to the writing interventions (expressive writing group and control writing group) will be measured using self-report and attendance tracking. All participants will self-report the completion of each writing prompt and the number of minutes spent writing (20 minutes recommended) for each session using weekly logs at home. Adherence will be reported as a number and percentage of total writing prompts completed out of a total of 120. Adherence will also be reported in a stratified manner with numbers and percentages of writing prompts completed by the intervention and control groups, respectively (60 each).

Acceptability

Acceptability will be measured by the Acceptability of Intervention Measure, which is a psychometrically validated implementation scale that specifically measures treatment or service acceptability [13]. This is a 4-item measure of perceived intervention acceptability. Items are measured on a 5-point Likert scale and score is reported as a calculated mean with higher scores indicating greater acceptability (no cut-off scores for interpretation are yet available).

Semi-Structured Interview Guide

Upon conclusion of the four-week writing intervention by all participants, the research staff will schedule a post-assessment qualitative interview with randomly selected 20 participants (10 expressive writing group and 10 control group participants) to review their perceived acceptability of the writing program. This sample size is chosen to account for participants who may decline interview or be lost to follow-up. These interviews will focus on participants' experience with body image distress throughout the intervention period, barriers to implementation and suggestions for improvement. Other questions will include reasons for study participation and expectations for the intervention. Interviews will be conducted by Zoom or telephone based on participant preference. Interviews will be recorded using an audio recorder. Interviews will be facilitated by the PI or study staff member with participants identified by their patient ID only to preserve confidentiality. These recordings will not be shared and will be transcribed. The PI will code these N=20 transcripts using an inductive coding schema. Final codes will be compiled into a master document and the PI will then review these codes and group codes into themes. The number of codes associated with each theme will be reported.

Body image concerns

We will explore if BIS and GAD-7 scores change upon conclusion of the intervention. BIS is a 10-item scale comprised of affective, behavioral, and cognitive items. Each item is scored on a 0-3 scale with total scores ranging from 0-30. This has been validated for use in clinical trials involving cancer patients with total score s ≥10 consistent with body image distress [14-16].

Anxiety

GAD-7 is a 7-item scale for self-reporting generalized anxiety symptoms with each item also scored on a 0-3 scale based on the frequency of occurrence of the items described. Score totals of ≥5, ≥10, and ≥15 represent mild, moderate, and severe anxiety, respectively [17].

Other Measures

Demographics Questionnaire: Participants will report age, sex, race/ethnicity, marital status, highest level of education completed, prior clinical trial experience, and employment status.

Medical Record Chart Abstraction Form: Study staff will abstract cancer type, stage, and treatment history.

Concurrent Medication Form: Study staff will interview participants about their use of medications and behavioral treatments (such as psychotherapy) for body image distress and anxiety that have been present for at least eight weeks prior to enrollment. They will perform this interview at baseline and at four-week follow-up visit.

7.0 Procedures

Screening and Consent. Study staff will identify potentially eligible participants for screening, including administering the Body Image Scale (BIS). This questionnaire has been validated for assessing body image in patients with cancer, suitable for use in clinical trials, with cutoff score of ≥10 shown to be clinically significant [14-16].

Randomization. Following the baseline measures and confirmation of eligibility, AYA cancer survivors will be randomized to either the in-home, body image-focused expressive writing intervention group or the control writing group following a stratified block- randomization schedule with block sizes randomly determined of sizes 6 – 10. Block randomization assures roughly equal n per group throughout the recruitment phase of the study so that if the study is halted prior to completion for any reason, study data will still be roughly balanced for statistical analysis. Randomization will be stratified based on age/developmental stage (15-25 years, 26-39 years) [30].

Expressive Writing or Control Writing Intervention. Study staff at the University of Michigan will send participants an email weekly with writing prompt and instructions.

Outcome Schedule. Participants will complete the measures electronically via REDCap at baseline and four weeks. Study staff will interview participants about their anxiety or body-image distress medication use at baseline and four weeks using the Concurrent Medication Form. Following the study period, we will conduct individual, semi-structured interviews with AYA participants (10 intervention group participants and 10 control group participants).

8.0 Data Management

All study materials will be numbered with participant ID numbers and not participants' actual names. Prospectively collected electronic survey data, writing intervention responses and forms will be administered using REDCap and all electronically collected data and forms will be stored on REDCap or Dropbox. Data used for screening and recruitment will be stored in a password protected excel spreadsheet within Dropbox. REDCap is HIPAA compliant. Participants will be contacted no more than four times by email or telephone as a reminder to complete the surveys.

There is no scheduled date for the data to be destroyed as research is an ongoing process and the collected data may be used for several analyses following the completion of the primary study. Links to identifiable data will be destroyed once all data are disseminated. Screening data collected from participants who are ineligible or decline participation will be destroyed once the study is completed (e.g., manuscripts/abstracts published).

9.0 Data Analysis

All statistical analyses will be conducted using SAS, R or Stata statistical software. Statistical assumptions will be tested in concert with all techniques, and appropriate data transformations or model adjustments will be employed if needed to meet these assumptions. If the proposed statistical plans cannot be conducted after applying reasonable data transformations or model adjustments, we will revert to alternative non-parametric or Bayesian techniques. Statistical reports will emphasize means, medians, effect size estimates, and their 95% confidence intervals for interpretation. Hypothesis testing will employ 2-tail alpha to reject the null hypothesis at 0.05, and analyses will consider p-values <0.10 coinciding with noteworthy clinically meaningful effects [32].

Missing Data. We will employ maximum likelihood-based modeling, which is robust when there are mild to moderate levels of missing data, so that subjects with one or more missing observation(s) continue to contribute to model estimates where data are available and are not eliminated listwise. If the missing data exceeds 20% of the planned data and is determined to be missing at random or missing completely at random, we will employ multiple imputation methods to preserve the value of available data and minimize bias.

Sample Size Considerations. We are conducting the pilot study to determine feasibility, not to demonstrate the efficacy of the in-home, body image-focused expressive writing intervention relative to the control condition. For n = 30, at the anticipated 75% completion rate (3 out of 4 writing interventions) the estimated confidence interval based the adjusted Wald method calculation is (0.5880, 0.8848) with a margin of error of 0.1484.

Aim 1 Analyses. The in-home, body image-focused expressive writing intervention will be feasible if 1) all participants are recruited over a 12-month period (Demand) [31], 2) 50% of participants complete 3 out of 4 (75%) of the at-home writing interventions (Implementation and Practicality), and 3) 75% of participants complete the baseline and four-week patient-reported measures (Implementation). Descriptive statistics will be used to calculate the feasibility metrics.

Aim 2 Exploratory Analyses. Participants will complete the Acceptability of Intervention Measure, a psychometrically validated implementation scale that specifically measures treatment or service acceptability. This is a 4-item measure of perceived intervention acceptability. Items are measured on a 5-point Likert scale and score is reported as a calculated mean with higher scores indicating greater acceptability (no cut-off scores for interpretation are yet available). We will report descriptive statistics for this measure (mean and standard deviation) to quantitatively characterize perceive acceptability of the expressive writing intervention. Qualitative interviews will be transcribed by a professional HIPAA compliant transcription agency. We will analyze interview data using inductive content analysis [34]. Dr. Wytiaz and the study team will read transcripts to derive codes, discuss labels to group codes into categories, and identify major themes and corresponding exemplar quotes. The interviewer will write reflexive memos after each interview and review memos with corresponding audio recordings to discern linkages, gaps, and questions. Two coders will review the transcript and negotiate a code if they disagree on initial codes.

Exploratory Analyses. We will determine the preliminary impact of the four-week at-home, body image-focused expressive writing intervention relative to the control on improving body image distress (BIS) and anxiety (GAD-7) utilizing data collected at baseline and four weeks. These outcomes are continuously scaled and appropriately analyzed by Gaussian- based statistical models. We will evaluate change-from-baseline in body image distress and anxiety by including fixed-effects coefficients for time, treatment (expressive writing intervention relative to the control), and the important interaction effects that will determine whether changes from baseline are greater in the expressive writing group, relative to controls. We will incorporate random Y-intercepts in the model to accommodate the nesting of repeated observations within subject.

10.0 Protection of Human Subjects

10.1 Potential Risks

This study presents no more than minimal risks to study participants. However, the risks associated with participating in this study include anxiety/distress related to answering the questions in the surveys or interviews or participating in the expressive writing intervention (low probability), or 2) the time required to complete the study requirements (low probability). Further, as with any research study, loss of privacy/confidentiality is a concern, but is unlikely given the precautions we are taking to protect subjects' confidentiality/privacy.

10.2 Protection Against Risk

To decrease the risk of anxiety/distress due to answering survey or interview questions or participating in the expressive writing intervention, we will refer any participants experiencing anxiety or distress to their usual care provider.

We will take several steps to decrease the risk of loss of privacy and confidentiality. The PI will train the study team in all study procedures (e.g., recruitment, data collection, maintaining participant confidentiality/privacy). Study team members will be required to report any participant confidentiality or privacy concerns to the PI. Study staff will screen the minimal

information required to identify eligible participants. All written study materials will be numbered with participant ID numbers and not participants' actual names. All collected patient-reported outcomes will be directly entered into REDCap (Research Electronic Data Capture). Electronic study files will be stored on DropBox. The consent form includes the informed consent statement required by the University of Michigan IRBs for studies involving human subjects. This statement identifies the subject as the owner of the information received.

We will also follow the guidelines set forth by the University of Michigan when conducting research with minors (Appendix A). The guidelines are as follows:

1. All study team members must complete an online training course outlining responsible conduct, university expectations and best practices for interactions involving minors. Study team members must renew the certification annually.

2. Study team members who interact with minors must complete a university background check every two years. Background checks are also required for individuals supervising study team members who interact with minors.

3. Study team members must adhere to the Code of Conduct, which includes the Rule of Threes. Under the Rule of Threes, study team members are not permitted to have interactions with minors that cannot be witnessed by an adult third party. When the research necessitates that the study team member interacts with the minor alone an additional adult must witness the interaction, the interaction must occur in an open public setting, or the interaction is video or audio-taped and the recording is stored in a secure location accessible to other study team members. To meet this guideline, we will ensure that the patient's parent/guardian is present during the consent phone call and that two study staff members are present during all interviews.

10.3 Potential benefits of the Proposed Research

The participants may or may not receive direct benefits from participating in this study. This study expects minimal risk for participants.

10.4 Compensation for Participants

Participants will receive a $50 gift card if they participate in one of the treatment conditions and complete the required surveys.

11.0 Data and Safety Monitoring

This study will be monitored in accordance with the NCI approved University of Michigan Rogel Cancer Center Data and Safety Monitoring Plan.

The study team will meet every six months or more frequently depending on the activity of the protocol. The discussion will include matters related to the safety of study participants (SAE/UaP reporting), validity and integrity of the data, enrollment rate relative to expectations, characteristics of participants, retention of participants, adherence to the protocol (potential or real protocol deviations) and data completeness. At these regular meetings, the protocol

specific Data and Safety Monitoring Report form will be completed and signed by the Principal Investigator or by one of the co-investigators.

Data and Safety Monitoring Reports will be submitted to the University of Michigan Rogel Cancer Center Data and Safety Monitoring Committee (DSMC) every six months for independent review.

12.0 Adverse Event Reporting

Adverse events related to this study are not expected. However, any adverse events resulting from research procedures will be reported to IRBMED per institutional guidelines.

13.0 References

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14.0 Appendices

Appendix A: Children on Campus (Standard Practice Guide Policy 601.34)

Appendix B: Demographics Questionnaire

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Appendix A: Children on Campus (Standard Practice Guide Policy 601.34)

SPG U-M Standard Practice Guide

UNIVERSITY OF MICHIGAN

Standard Practice Guide Policies

Children on Campus

601.34

Applies to: Faculty, Staff and Students

I. PURPOSE AND SCOPE OF POLICY

It is the policy of the University of Michigan to promote the health, wellness, safety, and security of children who are entrusted to the university's care and custody and/or participate in programs/events/studies. This policy applies to all children-related U-M programs/events

/studies, whether they are actually held on campus, virtually, or at an off-site location, and programs/events/studies held by others in university facilities.

The university has specific policies addressing children as employees, patients, research subjects, research laboratory visitors, and volunteers. The Children on Campus policy supports and complements these existing policies and guidelines. It also describes the resources that are available to all departments and units to help protect children engaged in University of Michigan programs/event/studies. Most of these resources can be accessed on the Children on Campus website (http://childrenoncampus.umich.edu/)..

Review examples of inappropriate conduct with children.

Review exceptions to this policy (http://childrenoncampus.umich.edu/about/policy/).

II. PROGRAM REGISTRATION

A. REGISTRATION

All University of Michigan units and departments are responsible for registering authorized programs/events (http://childrenoncampus.umich.edu/program-event- registration/) covered under this policy All programs/events should be registered with sufficient time to meet the requirements of

this policy, but no later than 60 days before the program/event start date. Programs/events must be registered annually.

B. PLANNING

For a list of topics that program/event administrators are required to consider in the planning and evaluation of registered programs/events refer to the Program Planning Checklist (http://childrenoncampus.umich.edu/wp-content/uploads/2018/04/Planning- Checklist-042618.pdf).

C. CRIMINAL BACKGROUND SCREENING

Screening through the National Sex Offender Registry and national criminal background screenings must be completed and evaluated before any program/event faculty, staff or authorized adult may begin working with children. The criminal background and National Sex Offender screening will be conducted by University Human Resources for all U-M programs/events. If a criminal record is discovered, the application must be referred to Risk Management Services for evaluation.

All authorized adults or program/event faculty and staff who have supervisory responsibilities or have direct interactions with children in programs/events covered by this policy are required to submit to a screening. After that, screenings are required every two years.

D. PARTICIPANT REQUIREMENTS

Parents and legal guardians of children must submit required forms consistent with the planned activities of the program before being allowed to participate. For a list of required forms refer to Program/Event required forms (http://childrenoncampus.umich.edu/resources/forms/).

Completed forms may contain sensitive personal information and must be transmitted and kept secure in a manner consistent with guidelines provided by the Information Assurance Safely Use of Sensitive Data guidance. (https://www.safecomputing.umich.edu/protect-the-u/safely-use-sensitive-data?nav)

E. TRAINING

All authorized adults or program/event faculty and staff working with children are required to be trained on policies and issues related to children's health, safety, and security. Required training must be completed annually and may differ based on the role of the authorized adult. For a list of training courses and requirements refer to Required Training (http://childrenoncampus.umich.edu/training/).

Documentation of training completion must be maintained by the program/event administrator for three years.

III. USE OF UNIVERSITY FACILITIES

Program administrators of non-University-Sponsored programs/events using university facilities are required to certify that they are fully compliant with all requirements set forth within this policy, including completion of national criminal background and National Sex Offender Registry screening, for all authorized adults before being allowed to use university facilities.

University facility managers leasing or allowing the use of university facilities for non- University-Sponsored programs/events primarily serving children are required to obtain written confirmation that

programs are fully compliant with all requirements set forth within this policy before being allowed to use or lease university facilities.

Facility managers are responsible for registering programs consistent with this policy.

IV. REPORTING OBLIGATIONS

A. GENERAL

All members of the university community must act immediately when criminal activity involving children is taking place, is alleged or suspected.

For emergency assistance or to report a crime in progress, dial 9-1-1- to connect with university or local police.

For a non-emergency situation, notify the Division of Public Safety and Security or call the local police department. Follow instructions provided by police with respect to all communication, questioning and notification of parents, program administrators or others.

Suspicions about possible wrongdoing can be reported anonymously through the university's compliance website (https://compliance.umich.edu/)or by calling the Compliance Hotline at 866-990-0111. The Hotline is available 24 hours a day and is staffed by multilingual interview specialists.

B. REPORTS OF KNOWN OR SUSPECTED ABUSE OR NEGLECT OF CHILDREN

Anyone participating in a University-Sponsored program/event or a non-University- Sponsored program/event operating in university facilities who knows, suspects or receives information indicating that a child has been abused, neglected, or who has other concerns about the safety of children MUST immediately inform the Division of Public Safety and Security or the local police department. In addition, the program/event administrator should be notified when it is safe and appropriate to do so.

Anyone who knows or suspects abuse or neglect of children should also notify the Michigan Department of Health & Human Services by calling 855-444-3911. This toll- free phone number is available 24 hours a day.

C. MANDATED REPORTERS AND THEIR LEGAL OBLIGATIONS

Michigan's Child Protection Law, MCL § 722.621, et seq., designates individuals in certain occupations and professions as mandated reporters. Mandated reporters must immediately report known or suspected mental or physical abuse or neglect of a child made known to them in their professional or official capacity directly to the Department of Health and Human Services by calling 855-444-3911 (24/7 toll-free number). A written report must be submitted to the Department of Health and Human Services within 72 hours of the initial verbal report. Even those who are not mandated reporters may report known or reasonably suspected child abuse to the Department of Health and Human Services.

A complete list of mandated reporters can be found in the Michigan Department of Health and Human Services Mandated Reporters' Resource Guide (https://www.michigan.gov/documents/dhs/Pub-112_179456_7.pdf).

University faculty, staff, or students who are working with children in their professional or official capacity and who have questions about whether they may be considered mandated reporters under

Michigan law should contact their supervisor, program administrator, dean or vice president. The Office of the Vice President and General Counsel is also available to provide advice.

Notes

These policies require a level two password for access.

1. UMHHC Policy 02-05-013: Suspected Child Abuse and Neglect

2. UMHHC Policy 03-07-018: Minors: Consent to Confidential Health Services

3. UMHHC Policy 03-07-019: Access to and Disclosure of a Minor Patient's Protected Health Information (PHI)

SPG Number:

601.34

Date Issued:

January 13, 2014

Last Updated:

September 9, 2021

Next Review Date:

September 9, 2026

Applies To:

Faculty, Staff and Students

Owner:

Office of the Executive Vice President and Chief Financial Officer

Primary Contact:

Risk Management Services

Related Policies:

Discrimination and Harassment (/policy/201.89-1) Employment of Minors (/policy/201.20)

Policy for Research with Human Participants (/policy/303.05) Violence in the University Community (/policy/601.18)

Related Links:

Children on Campus website (http://childrenoncampus.umich.edu/)

Michigan Department of Health and Human Services Children's Protective Services (https://www.michigan.gov

/mdhhs/0,5885,7-339-73971_7119_50648---,00.html)

Michigan Department of Health and Human Services Mandated Reporters' Resource G…
(https://www.michigan.gov/documents/dhs/Pub-112_179456_7.pdf)

Information Assurance Safely Use Sensitive Data (https://www.safecomputing.umich.edu/protect-the-u/safely- use-sensitive-data?nav=)

EHS Requirements for Minors in Research Operations (http://ehs.umich.edu/wp-content/uploads/2016/02

/Minors_in_Research_Facilities.pdf)

Regental Bylaw 14.06 (http://www.regents.umich.edu/bylaws/bylaws14.html#6)

Michigan Medicine Policy 02-05-013, Suspected Child Abuse and Neglect
(http://www.med.umich.edu/i/policies

/umh/02-05-013.html)

Michigan Medicine Policy 03-07-018, Children: Consent to Confidential Health Se…
(http://www.med.umich.edu

/i/policies/umh/03-07-018.html)

Michigan Medicine Policy 03-07-019, Access to and Disclosure of a Minor Patient…
(http://www.med.umich.edu

/i/policies/umh/03-07-019.html)

Hard copies of this document are considered uncontrolled. If you have a printed version, please refer to the University SPG website (spg.umich.edu) for the official, most recent version.

Appendix B: Demographics Questionnaire

1. **What is your age in years**?

_____

2. **What sex were you assigned at birth?:**
    1. Male
    2. Female
    3. Prefer not to answer

3. Which term do you use to describe your current gender identity?
    1. Female
    2. Male
    3. Transgender female
    4. Transgender male
    5. Gender non-conforming
    6. Other_____
    7. Prefer not to answer

4. **Race (Select all for those with which you identify):**
    1. American Indian or Alaska Native
    2. Asian
    3. Black or African-American
    4. Native Hawaiian or Other Pacific Islander
    5. White
    6. Unknown or do not wish to report
    7. Other_____

5. **Ethnicity (Select the choice with which you most closely identify):**
    1. Hispanic or Latino
    2. Not Hispanic or Latino
    3. Unknown or do not wish to report

6. **Education (Select highest education you have received):**
    1. Some high school

2. Completed high school
3. Some college or technical training
4. University undergraduate degree
5. University post graduate degree

7. Marital status

1. Single
2. Married
3. Separated
4. Divorced
5. Widowed

8. Employment status

1. Working full-time
2. Working part-time
3. Working at home
4. Working, but on medical leave
5. Student
6. Retired
7. Not working

9. Have you participated in any other clinical trials?

1. Yes
2. No

If you did not receive oncology care at the University of Michigan, please respond to the following questions:

1. Cancer Type (Select all that apply)

a. Leukemia
b. Lymphoma
c. Sarcoma or Bone Cancer
d. Melanoma
e. Breast
f. Other_____

2. How long has it been since you last received cancer treatment? Please provide the approximate number of months or the date of your last treatment (such as chemotherapy, immunotherapy, radiation, or surgery).

_____

3. Please list any medications or behavioral treatments for anxiety or depression that you are currently taking/receiving.

_____

Appendix C: Concurrent Medication Form

We are interested in learning about your use of medications or other treatments for anxiety or depression symptoms.

Baseline

Please list the following information for any medications or behavioral treatments you are currently using for anxiety or depression.

- Name: Please list the name of the medication/treatment
- Dose: What is the dose or strength of the medication (for example: milligrams)
    - If behavioral treatment, please leave blank
- Frequency: How often are you taking this medication/treatment (for example: I take the prescribed dose one per day)
    - If behavioral treatment, please list the number of sessions per week or month
- Route: How do you take this medication/treatment (for example: by mouth, IV, inhale, apply to skin)
    - If behavioral treatment, please leave blank
- Indication: What is the medication prescribed for (e.g., anxiety or depression or other?)
- Taking as prescribed? Are you taking the medication/treatment as recommended? (yes or no)
- Start Date? Please state when you started the medication/treatment

Anxiety and Depression Medications/Treatments at Baseline						
Name	**Dose**	**Frequency**	**Route**	**Taking as prescribed**	**Start Date**	**End Date**

Appendix D: Generalized Anxiety Disorder, 7 Items (GAD-7)

GAD-7 Anxiety

Over the last two weeks, how often have you been bothered by the following problems?	Not at all	Several days	More than half the days	Nearly every day
1. Feeling nervous, anxious, or on edge	0	1	2	3
2. Not being able to stop or control worrying	0	1	2	3
3. Worrying too much about different things	0	1	2	3
4. Trouble relaxing	0	1	2	3
5. Being so restless that it is hard to sit still	0	1	2	3
6. Becoming easily annoyed or irritable	0	1	2	3
7. Feeling afraid, as if something awful might happen	0	1	2	3

Column totals _____ + _____ + _____ + _____ =

Total score _____

If you checked any problems, how difficult have they made it for you to do your work, take care of things at home, or get along with other people?

Not difficult at all	Somewhat difficult	Very difficult	Extremely difficult
☐	☐	☐	☐

Source: Primary Care Evaluation of Mental Disorders Patient Health Questionnaire (PRIME-MD-PHQ). The PHQ was developed by Drs. Robert L. Spitzer, Janet B.W. Williams, Kurt Kroenke, and colleagues. For research information, contact Dr. Spitzer at ris8@columbia.edu. PRIME-MD® is a trademark of Pfizer Inc. Copyright© 1999 Pfizer Inc. All rights reserved. Reproduced with permission

Scoring GAD-7 Anxiety Severity

This is calculated by assigning scores of 0, 1, 2, and 3 to the response categories, respectively, of "not at all," "several days," "more than half the days," and "nearly every day."
GAD-7 total score for the seven items ranges from 0 to 21.

0–4: minimal anxiety

5–9: mild anxiety

10–14: moderate anxiety

15–21: severe anxiety

Appendix E: Body Image Scale (BIS)

BODY IMAGE SCALE

In this questionnaire you will be asked how you feel about your appearance, and about any changes that may have resulted from your disease or treatment. Please read each item carefully, and place a firm tick on the line alongside the reply which comes closest to the way you have been feeling about yourself, during the past week.

Name: _____ Date: _____

	Not at all	A little	Quite a bit	Very much
Have you been feeling self-conscious about your appearance?	.....	.....	.....	.....
Have you felt less physically attractive as a result of your disease or treatment?	.....	.....	.....	.....
Have you been dissatisfied with your appearance when dressed?	.....	.....	.....	.....
Have you been feeling less feminine/masculine as a result of your disease or treatment?	.....	.....	.....	.....
Did you find it difficult to look at yourself naked?	.....	.....	.....	.....
Have you been feeling less sexually attractive as a result of your disease or treatment?	.....	.....	.....	.....
Did you avoid people because of the way you felt about your appearance?	.....	.....	.....	.....
Have you been feeling the treatment has left your body less whole?	.....	.....	.....	.....
Have you felt dissatisfied with your body?	.....	.....	.....	.....
Have you been dissatisfied with the appearance of your scar?	.....	.....	.....	.....
	Not Applicable			

Dr P. Hopwood, CRC Psychological Medicine Group, Stanley House, Christie Hospital NHS Trust, Wilmslow Road, Withington, Manchester M20 4BX Tel.: 0161 446 3683 Fax: 0161 446 8103.

Appendix F: Acceptability of Intervention Measure (AIM)

Acceptability of Intervention Measure (AIM)

	Completely disagree	Disagree	Neither agree nor disagree	Agree	Completely agree
1. (INSERT INTERVENTION) meets my approval.	①	②	③	④	⑤
2. (INSERT INTERVENTION) is appealing to me.	①	②	③	④	⑤
3. I like (INSERT INTERVENTION).	①	②	③	④	⑤
4. I welcome (INSERT INTERVENTION).	①	②	③	④	⑤

Appendix G: Writing Prompts

Trial Arm	**Intervention Group**	**Control Group**
Week 1	How did your body support you through cancer care? In what ways do you feel like it let you down?	Describe in detail the activities you completed in the 24 hours prior to this task.
Week 2	Can you imagine a time in the future when you feel comfortable in and with your body? How would that feel and does it depend on your cancer status?	Describe in detail you current surroundings.
Week 3	Describe a time when you changed your behaviors based on thoughts about your body (avoided social events, etc.). What feelings did you have after this?	Review the plot of the last book you read/movie or television show you watched.
Week 4	How would you speak to a friend with negative thoughts about their body? Is this different than your internal dialogue either during cancer treatment of after?	Detail the events of your most recent vacation or trip away from home, from departure to arrival home.