Title: Effects of Digital Stories Intervention on Psychosocial Well-being for Cancer Patients and Caregivers undergoing Hematopoietic Stem Cell Transplantation (HCT) PI: Kim

ASU: Larkey, Langer, Todd
Mayo: Khera; Consultant: Weihs

Award number: R15CA213035 to Arizona State University by National Cancer Institute of the National Institutes of Health
NCT number: NCT03654599
Date: 9/21/2023

Analysis Plan

Preliminary Analyses. We first used univariate and bivariate statistics to determine the distributional characteristics of our outcome measures, explore patterns of missingness, and identify potentially relevant background confounders and covariates. Where appropriate, we also computed reliability estimates (e.g., Cronbach's α, McDonald's ω_T) for composite measures.

Specific Aim 1: To test whether DS are more efficacious for improving psychosocial well-being in cancer patient-caregiver dyads after HCT than an information-only control (IC) condition.

Figure 2

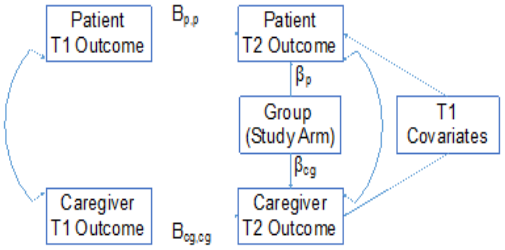
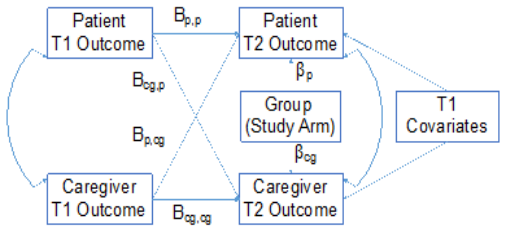


Figure 3



Aim 1 Analyses. To address hypotheses under **Aim 1,** we used a **scientifically rigorous** dyadic structural equation path model (SEM) approach in which the patient-caregiver dyad is the unit of analysis. We estimated dyad member–specific intervention effects (βp and βcg) on each outcome simultaneously in a single SEM, by relating arm (DS vs. IC) to each member's T2 (or T3) score on the outcome, adjusting for that member's T1 score on the same outcome measure (Figure 2). Intra-dyad correlation of responses is explicitly accounted for (see curved "paths" in Figure 2). Relevant baseline covariates (e.g., treatment type) identified in preliminary analyses were adjusted for by relating them to T2 outcomes. To explore intervention effects net of potential partner effects (e.g., T1 patient outcome scores predicting change in caregiver scores and vice versa: βp,cg and βcg, [see Figure 3]), we extended our dyadic SEMs with an Actor-Partner Interdependence Model (APIM) approach. Partner effects can themselves be of interest, as they may capture potentially important relations underlying dyadic communication and emotional support processes. For outcomes that are unique to one dyad member or the other, a conventional ANCOVA-type approach was taken, where T2 (and T3) outcome scores are regressed on Group, adjusting for T1 scores on the corresponding outcome and relevant background covariates. Under **Aim 1 (EQ1-Qualitative)**, the constructivist approach to grounded theory methodology was employed, guided by EQ1 and a model of narrative effects on socio-emotional well-being. Students under the supervision of Dr. Kim transcribed in-depth interview recordings and conduct the analysis using the audio-recordings,

transcripts, memos, and interview notes. Coding and categorization were undertaken using NVivo, which facilitates the development of a cross-group thematic framework while allowing the continual checking of the contextual validity of individual comments or excerpts of discussion. When categorization is complete, axial coding was performed to elicit overarching themes and promote the exploration of relationships between emergent themes with three experienced researchers until agreement on the assigned codes is reached.

Specific Aim 2: To examine potential mediating and moderating factors proposed in a model to explain the influences of DS on psychosocial well-being in HCT patients and caregivers.

Aim 2 Analyses. To address **EQ2** under **Aim 2**, we extended the models used under Aim 1, by including and testing for the interactions between Group (DS vs. IC) and potential moderators (*age, gender; use of other support services)* to determine if the intervention effects differ across levels of these factors after adjusting for relevant background covariates identified in preliminary analyses. Interaction effects significant at $p < .10$ will be probed so that the form of the interaction (i.e., differences in magnitude and/or sign of the intervention effect across levels of each potential moderator) can be characterized. To address **EQ3** under **Aim 2**, we evaluated indirect effects of the intervention (Group) on outcomes (e.g., emotional and social well-being) through putative mediators (e.g., identification, transportation, and emotional processing and expression), selected based on the proposed Narrative Effects model [see Figure 1] in dyadic SEMs (general form: Group → Mediator [T2] → Outcome [T2 or T3]), adjusting for relevant background covariates identified in preliminary analyses. We used methods and software applications described and developed by Valeri and VanderWeele, which expand on the work of Preacher and Hayes. From these analyses we obtained estimates and tests (based on bootstrap standard errors) of the indirect effects of the intervention on primary and secondary outcomes via hypothesized mediators (e.g., identification, engagement, emotional support). We also used methods and tools described and developed by Preacher and Kelley[82] to characterize the magnitudes of the indirect effects examined.

Missing Data and Non-compliance. We employed an ITT analysis strategy and mitigate potential effects of attrition on estimates of treatment effects and statistical power by using full information maximum likelihood estimation and/or multiply imputed datasets, depending on patterns of missingness observed and the analytic model used. To explore potential impacts of intervention non-compliance (e.g., not viewing all DS) on estimates of intervention effects, we used complier-average causal effect (CACE) and propensity score (PS) methods, which model and adjust for non-compliance, and then compare ITT, CACE, and PS-based estimates.

Data Management. All data forms were designed using uniform principles that have been employed in many of our studies and that are intended to minimize coding. We performed 100% visual comparison of primary outcome items from the database against the paper forms. After data entry, operational reports were generated that (1) document the completeness with which forms are being collected and (2) for every item on every form, report the number and percentage of missing values.