Mind-Body Resiliency Intervention for Fear of Cancer Recurrence

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For the Pilot RCT, the primary outcomes are feasibility and acceptability. Our statistical design accounts for use of mixed methods (qualitative and quantitative) to obtain a comprehensive understanding of the feasibility and acceptability of the intervention content and procedures. While we do not expect differences in findings due to sex, we will consider the influence of sex in the interpretation of results.

Qualitative exit interviews will undergo transcription and content analyses. Thematic content analysis of transcribed audio will be conducted. Themes and codes will be theoretically-driven by Uncertainty in Illness Theory and the 3RP theoretical model, coded by two coders, iteratively revised until reaching thematic saturation, and discrepancies reconciled by a third coder until acceptable reliability is achieved. Analyses and interpretations will take into account (1) condition assignment (intervention vs. treatment as usual) and (2) the group structure of the intervention condition.

- Anticipated themes will assess multiple indicators of feasibility and acceptability, including program expectations, recommendations, and perceived changes (positive, negative, severity of fear of recurrence, and healthcare engagement). Participants randomized to the intervention condition will also be asked about each mind-body skill taught (e.g., perceived benefits, challenges, barriers, any modifications made).

Quantitative analyses will be conducted with SPSS software to assess feasibility and acceptability. Quantitative data (e.g., % enrollment, number of intervention sessions attended, and Likert-type ratings of satisfaction) will be tested for normality (i.e., skew<3.0 and/or kurtosis<8.0) and summarized using appropriate descriptive statistics (means, medians, frequencies).

- Feasibility will be indicated if ≥70% of participants are retained at each follow-up assessment. Secondary metrics of feasibility include attendance (a priori benchmark ≥75% attend 6/8 of the treatment sessions), the ratio of eligible participants who enrolled, and interventionist fidelity.
- Acceptability will be assessed by computing frequencies of post-session surveys. A threshold of 80% ratings of “high satisfaction” will indicate acceptability.

Exploratory longitudinal analyses will examine within-subject patterns in FOR, resiliency, and healthcare engagement self-report measures across all three assessments (baseline, post-interventions, 12-weeks post-interventions). Consistent with guidelines for clinical trials, missing data patterns will be assessed at each timepoint and if appropriate will undergo proper handling (e.g., multiple imputation).

- With guidance from biostatistics consultant Dr. Lee, Dr. Hall will conduct adjusted and unadjusted general and generalized linear mixed effects models with repeated measures on FOR (Model 1), resiliency (Model 2), and healthcare engagement (Model 3).
- Adjusted analyses will include any potential covariates correlated with FOR and/or healthcare engagement at alpha=.10.
- For modeling FOR, we will use FCRI scores (continuous, which will be modeled by the general linear mixed effects model, and dichotomized at clinical cut-off, which will be modeled by the generalized linear mixed effects model [i.e., mixed effects logistic modeling]).
- For modeling healthcare engagement, we will use MEPS scores; any discrepancies between MEPS and EMR data will be discussed with Dr. O’Cleirigh and reconciled. General linear mixed effects modeling and generalized linear mixed effects model (i.e., mixed effects logistic modeling) will be used for continuous and categorical variables, respectively.
- Potential intermediary variables will be explored.
- Findings will be interpreted with caution and an understanding that the primary outcomes of the pilot RCT are feasibility and acceptability.