Mind-Body Resiliency Intervention for Fear of Cancer Recurrence

NCT04876599

Prepared 8/18/2023

Synopsis of Protocol

Preparation (approximately 4-6 months)

- Submission of protocol to Dana-Farber/Harvard Cancer Center IRB (MGH and BIDMC cancer centers are part of the DF/HCC)
- Finalization of all materials, including electronic surveys (REDCap) and exit interview guide
- Training of the interventionist on the adapted intervention (see Study Team Structure)
- Registration on clinicaltrials.gov

Recruitment (approximately 4 months)

- Participant recruitment (see Recruitment and Retention Plans)

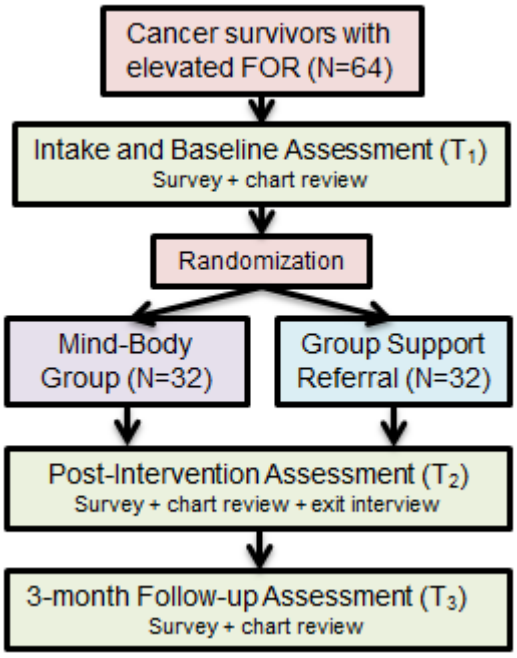
Intervention, exit interviews, and three survey assessments (26 months): The total length of participation for each enrolled subject will be approximately 5 months. Mind-body groups are anticipated to last 8 weeks (2 months), which is the duration of the original Relaxation Response Resiliency Program (3RP); however, this will be informed by the earlier intervention refinement phase from the Aim 1 study. A timeline for the pilot RCT (N=64) is presented below.

- A baseline assessment (T1) consisting of a survey with proposed self-report measures. We will also conduct a chart review to measure indices of healthcare engagement (see Outcome Measures, Section 4.3)

- Randomization to either 8-week arm (full descriptions in Narrative Study Description, 4.2.a)
    - (1) adapted group mind-body intervention, or
    - (2) treatment as usual (referral for cancer support group through SurvivorJourneys)

- Post-intervention assessment (T2) consisting of the survey, our chart review of healthcare engagement, and an exit interview
    - Exit interviews will take place within 1 week post-intervention (see Research Strategy, Measures, Aim 2 Primary Outcomes)

- 3-month follow-up assessment (T3) consisting of the survey and our chart review of healthcare engagement



Analysis and reporting of primary outcomes (feasibility and acceptability) and exploratory outcomes (12 months)

- Cleaning of survey data
- Transcription of exit interviews
- Quantitative analyses (see Section 4.4., Statistical Design and Power)
- Qualitative analyses (see Section 4.4., Statistical Design and Power)
- Report of findings on clinicaltrials.gov
- Manuscript and grant preparation (see Research Strategy, Table 3: Planned Deliverables)