Cancer Research Consortium of West Michigan
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FAST FACTS

WF- 30917CD - A STEPPED-CARE TELEHEALTH APPROACH TO TREAT DISTRESS IN CANCER SURVIVORS

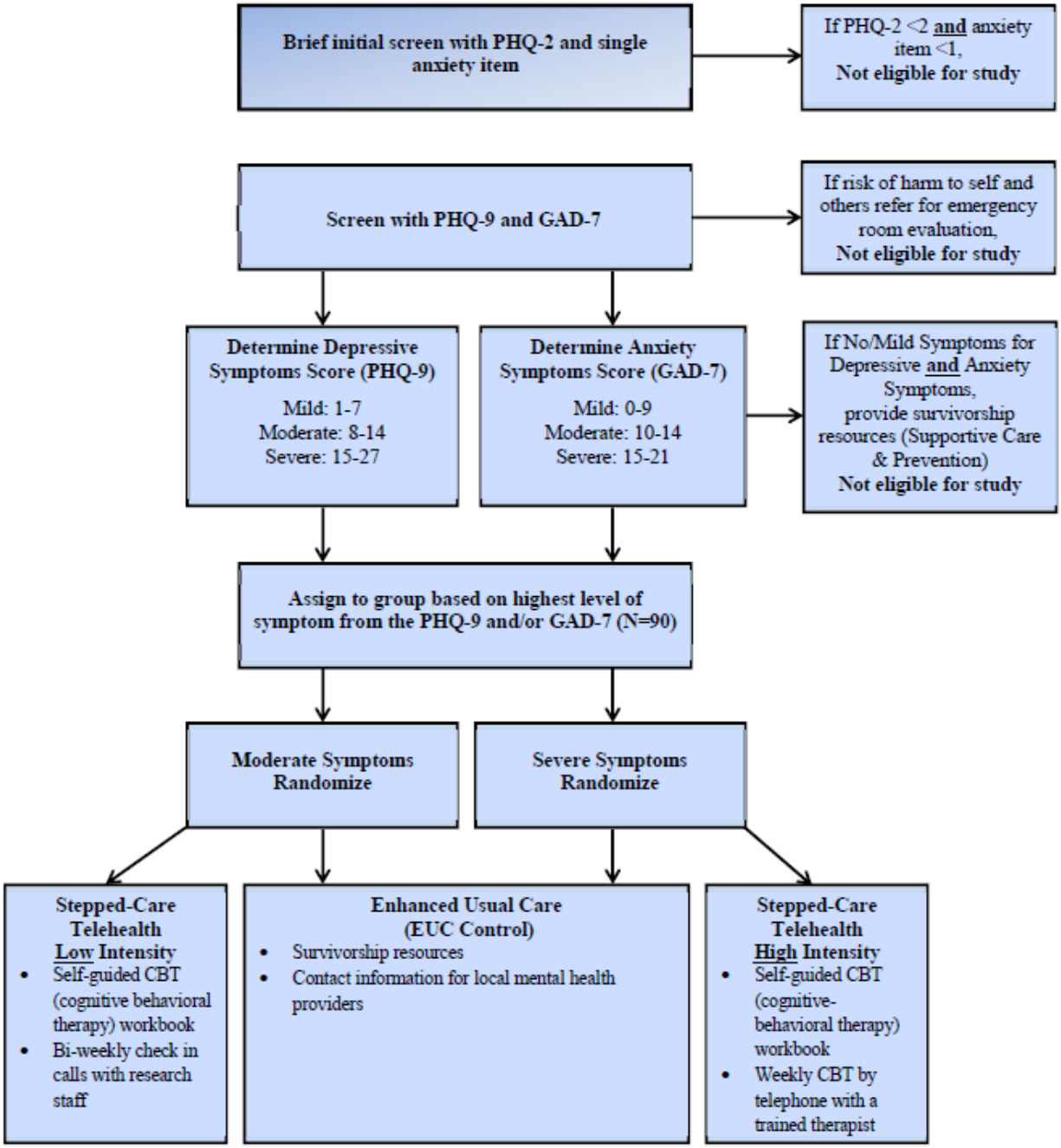
Inclusion Criteria

1. Age ≥18 years
2. Score ≥10 on the GAD-7 and/or a score ≥8 on the PHQ-9, indicating clinically significant anxiety or depressive symptoms, respectively.
3. Past history of treated (newly diagnosed or recurrent)28,29 breast, colorectal, prostate, gynecologic (only uterine and cervical) cancers (Stage I, II, or III) or any stage lymphoma (Hodgkin's or non-Hodgkin's).
4. 6-60 months post-treatment (surgery, chemotherapy, radiation therapy, and/or maintenance therapies) for cancer. Time frame applies to most recent completion of treatment if participant had a cancer recurrence. It is acceptable to be on hormonal therapies.3
5. Participant resides in California, Georgia, Illinois, Kansas, Michigan, Minnesota, Missouri, New Mexico, North Carolina, North Dakota, South Carolina, Virginia, Tennessee, or Wisconsin.
6. Study-trained therapist in the state where the participant resides.
7. Must be able to speak and understand English.
8. Must have access to a telephone. If a patient does not have access to a phone or has difficulty paying for minutes for a mobile phone, the research team should contact the Wake Forest investigators or site coordinators to arrange for assistance.

Exclusion Criteria

1. Current psychotherapy [regular appointment(s) with a psychologist, counselor, or therapist within the last 30 days prior to randomization]
2. Self-reported active alcohol or substance abuse within the last 30 days
3. Past history of prostate cancer or non-Hodgkin's lymphoma with only active surveillance (i.e., no surgery, chemotherapy, or radiation therapy)
4. Progressive cancer (must be considered no evidence of disease or stable)
5. Self-reported psychotic symptoms in the last 30 days prior to randomization (See item in Appendix 4: "Have you seen things that aren't really there or have you heard voices when no one else was around within the last 30 days?")
6. Active suicidal ideation with plan and intent
7. Any change in psychotropic medications within the last 30 days (See Appendix 25)
8. Hearing loss that would preclude participating in telephone sessions (determined by brief hearing assessment administered by research staff at each NCORP component). Individuals who can compensate for hearing loss through the use of a hearing device or TDD phone, and through the use of such devices are able to communicate with the study therapist by telephone, will be included. If the therapist cannot communicate with the participant by telephone, the participant will be excluded.
9. Failure/inability/unwillingness to provide names and contact information for two family members or friends to serve as emergency contacts during the course of the study

SCHEMA


Brief initial screen with PHQ-2 and single anxiety item
If PHQ-2 <2 and anxiety item <1, Not eligible for study
Screen with PHQ-9 and GAD-7
If risk of harm to self and others refer for emergency room evaluation, Not eligible for study
Determine Depressive Symptoms Score (PHQ-9)
Mild: 1-7
Moderate: 8-14
Severe: 15-27
Determine Anxiety Symptoms Score (GAD-7)
Mild: 0-9
Moderate: 10-14
Severe: 15-21
If No/Mild Symptoms for Depressive and Anxiety Symptoms, provide survivorship resources (Supportive Care & Prevention) Not eligible for study
Assign to group based on highest level of symptom from the PHQ-9 and/or GAD-7 (N=90)
Moderate Symptoms Randomize
Severe Symptoms Randomize
Stepped-Care Telehealth Low Intensity
• Self-guided CBT (cognitive behavioral therapy) workbook
• Bi-weekly check in calls with research staff
Enhanced Usual Care (EUC Control)
• Survivorship resources
• Contact information for local mental health providers
Stepped-Care Telehealth High Intensity
• Self-guided CBT (cognitive-behavioral therapy) workbook
• Weekly CBT by telephone with a trained therapist