Cancer Research Consortium of West Michigan
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FAST FACTS

URCC 18007 - RANDOMIZED PLACEBO CONTROLLED TRIAL OF BUPROPION FOR CANCER RELATED FATIGUE

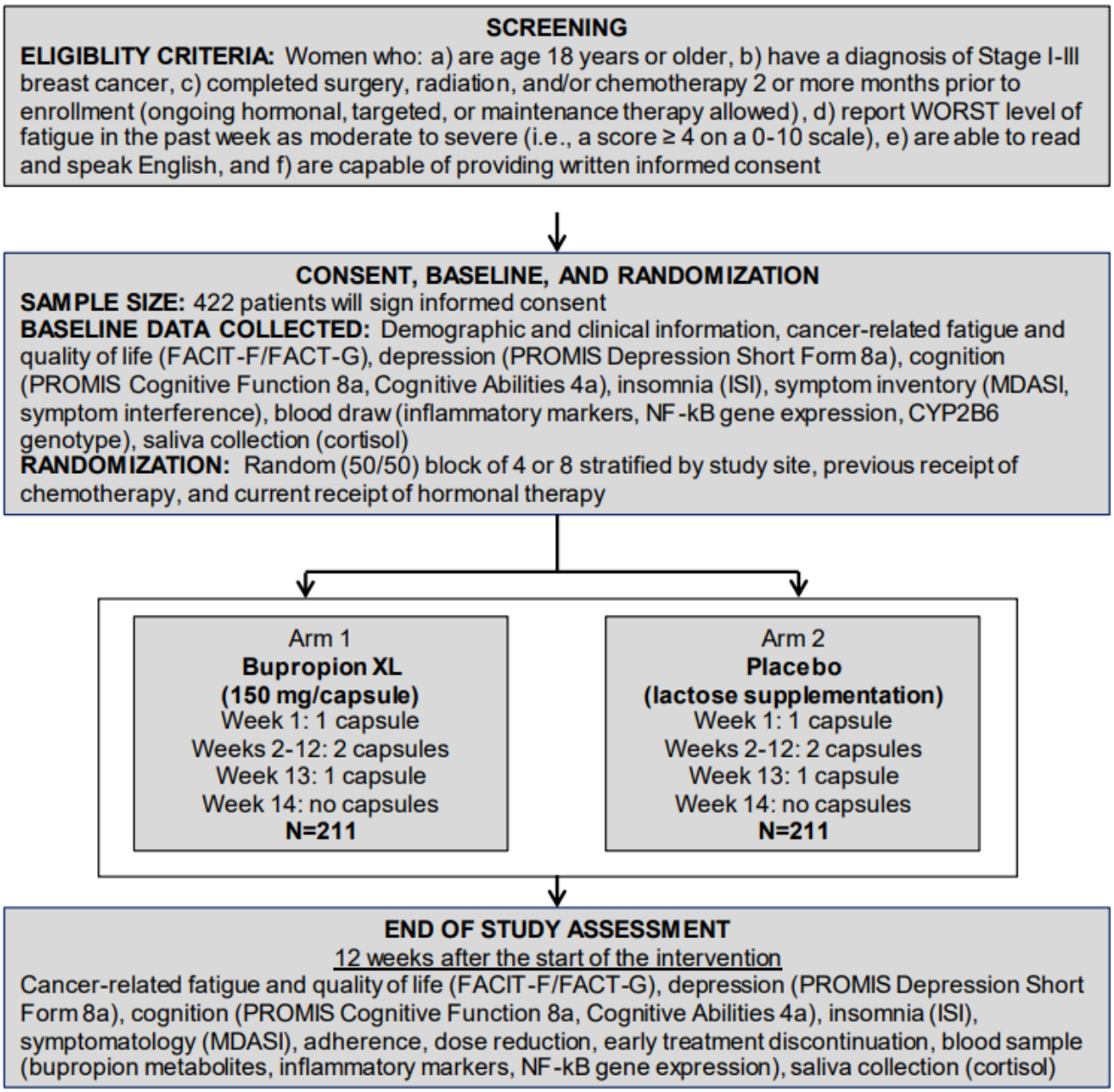
Inclusion Criteria

1. Be at least 18 years of age
2. Be female
3. Have a diagnosis of Stage I-III breast cancer
4. Report WORST level of fatigue in the past week as moderate to severe (i.e., a score ≥ 4 on a 0-10 scale, Screening Measures, question 1)
5. Have completed surgery, radiation, and/or chemotherapy 2 or more months prior to enrollment (participants can be receiving maintenance, targeted or hormonal therapy)
6. Able to read and speak English
7. Currently not pregnanct or breastfeeding. Women of child-bearing potential must agree to use adequate contraception, i.e, abstinence, IUD (intrauterine device), hormonal contraceptive (birth control pills) or barrier method (condoms) prior to study entry and for the duration of study participation
8. Be capable of providing written informed consent

Exclusion Criteria

1. Be currently taking any medications that contain Bupropion(e.g Wellbutrin, Forfivo, Aplenzin, or Zyban)
2. Be taking an MAOI linezolid, or methylene blue within two weeks prior to enrollment
3. Be taking any anti-psychotic medications within a week prior to enrollment.
4. Have a history of renal impairment (i.e., glomerular filtration rate < 45)
5. Have a history of cirrhosis (i.e., Child-Pugh score ≥ 5)
6. Have a history of seizures
7. Have a history of bulimia or anorexia nervosa
8. Report a history of sensitivity to bupropion
9. Report an allergy to lactose
10. Have psychiatric or neurological disorder(s) that would interfere with study participation per physician or physicians designee.

SCHEMA


SCREENING
ELIGIBLITY CRITERIA: Women who: a) are age 18 years or older, b) have a diagnosis of Stage I-III breast cancer, c) completed surgery, radiation, and/or chemotherapy 2 or more months prior to enrollment (ongoing hormonal, targeted, or maintenance therapy allowed), d) report WORST level of fatigue in the past week as moderate to severe (i.e., a score ≥ 4 on a 0-10 scale), e) are able to read and speak English, and f) are capable of providing written informed consent
CONSENT, BASELINE, AND RANDOMIZATION
SAMPLE SIZE: 422 patients will sign informed consent
BASELINE DATA COLLECTED: Demographic and clinical information, cancer-related fatigue and quality of life (FACIT-F/FACT-G), depression (PROMIS Depression Short Form 8a), cognition (PROMIS Cognitive Function 8a, Cognitive Abilities 4a), insomnia (ISI), symptom inventory (MDASI, symptom interference), blood draw (inflammatory markers, NF-kB gene expression, CYP2B6 genotype), saliva collection (cortisol)
RANDOMIZATION: Random (50/50) block of 4 or 8 stratified by study site, previous receipt of chemotherapy, and current receipt of hormonal therapy
Arm 1
Bupropion XL
(150 mg/capsule)
Week 1: 1 capsule
Weeks 2-12: 2 capsules
Week 13: 1 capsule
Week 14: no capsules
N=211
Arm 2
Placebo
(lactose supplementation)
Week 1: 1 capsule
Weeks 2-12: 2 capsules
Week 13: 1 capsule
Week 14: no capsules
N=211
END OF STUDY ASSESSMENT
12 weeks after the start of the intervention
Cancer-related fatigue and quality of life (FACIT-F/FACT-G), depression (PROMIS Depression Short Form 8a), cognition (PROMIS Cognitive Function 8a, Cognitive Abilities 4a), insomnia (ISI), symptomatology (MDASI), adherence, dose reduction, early treatment discontinuation, blood sample (bupropion metabolites, inflammatory markers, NF-kB gene expression), saliva collection (cortisol)