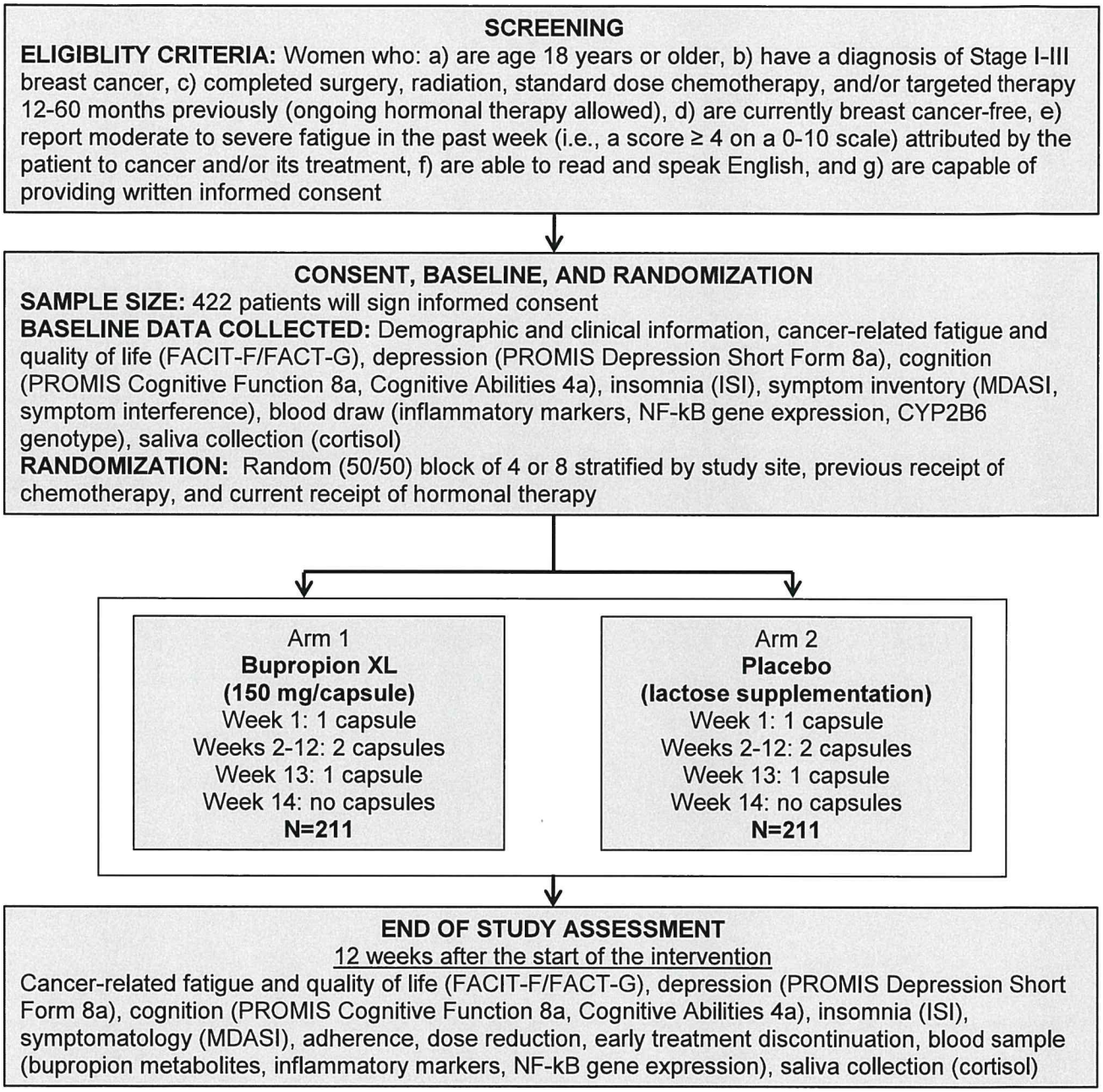
SCHEMA


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, standard dose chemotherapy, and/or targeted therapy 12-60 months previously (ongoing hormonal therapy allowed), d) are currently breast cancer-free, e) report moderate to severe fatigue in the past week (i.e., a score ≥ 4 on a 0-10 scale) attributed by the patient to cancer and/or its treatment, f) are able to read and speak English, and g) 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)