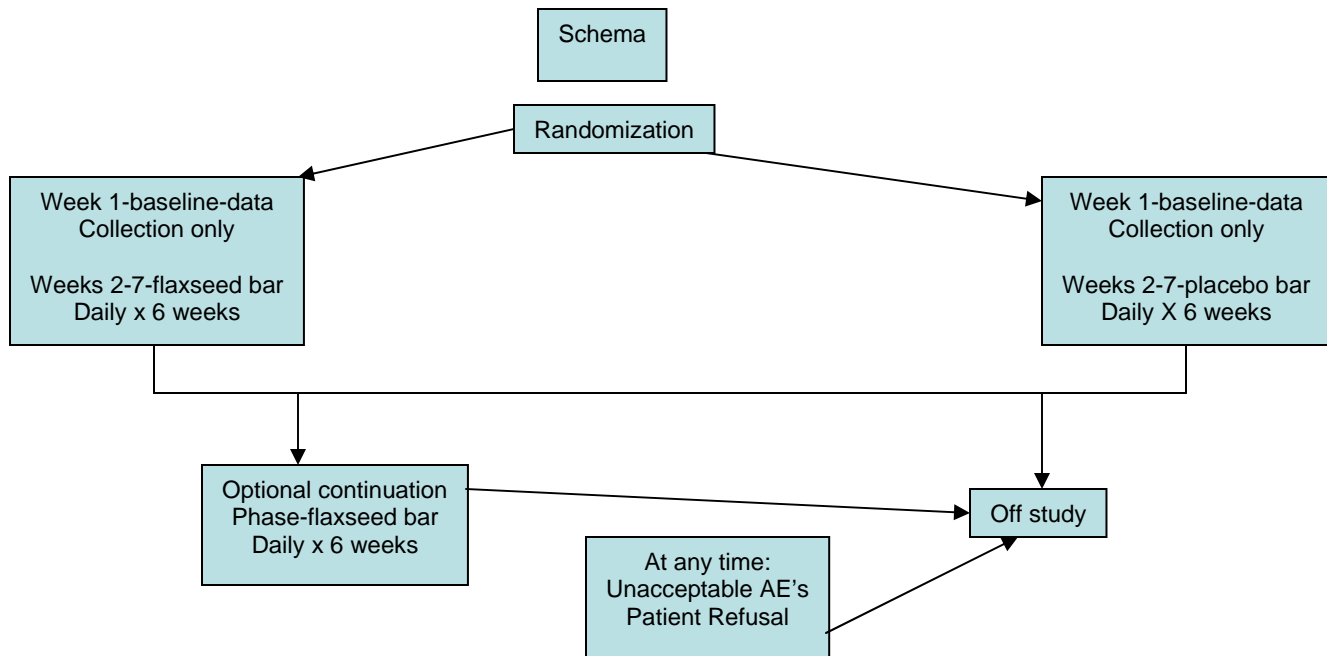


N08C7-Phase III, Randomized, Placebo-controlled, Double-Blind Trial of Flaxseed for the Treatment of Hot Flashes



This is a Phase III randomized, placebo-controlled, double-blind trials looking at flaxseed bars, versus placebo bars for the treatment of hot flashes.

Major Inclusion Criteria

- Postmenopausal women ≥ 18 yrs. of age, with a history of breast or other cancer (currently NED) or who do not wish to take estrogen because of a perceived increase risk of breast cancer.
- Botherome hot flashes (≥ 28 hot flashes per week).
- Presence of hot flashes ≥ 1 month prior to study entry.
- Life expectancy >6 months.
- ECOG PS of 0 or 1.
- Able to complete questionnaires alone or with assistance and able to provide informed consent.

Major Exclusion Criteria

- Any of the following ≤ 4 weeks prior to registration: Androgens, estrogens, progesterones¹.
- History of allergic or adverse reaction to flaxseed.
- Current (≤ 7 days prior to registration) or planned use of other agents for the treatment of hot flashes¹.
- Women of child bearing potential or premenopausal women.
- Use of other herbal supplements for any reason, including soy¹.
- Diagnosis of IBS, Crohn's, colitis or any other GI condition that prevents the consumption of seeds or nuts¹.
- Anti-coagulants or anti-platelets (81mg of ASA is allowed)¹.
- Anti-hypertensives.
- Diabetics, requiring treatment (oral or injectable).
- Any anti-cancer therapy except adjuvant trastuzumab or endocrine therapies¹.

1. See protocol for more specific details.

*** For use by NCCTG study personnel ONLY. Not for patient use***