

# A Clinical Trial to Investigate the Effect of Pollen Extracts on Menopausal Symptoms in Healthy Women.

NCT06889753

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Status	RECRUITING
Phase	Phase 2
Sponsor	Graminex LLC
Enrollment	120 participants

## Key Eligibility Criteria

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### Inclusion (8)

- Females between 45-60 years of age, inclusive
  - BMI 18.5 kg/m<sup>2</sup> - 34.9 kg/m<sup>2</sup> inclusive
  - Self-reported menopausal women who have not had a menstrual period for >12 months prior to screening and are experiencing at least moderate menopausal symptoms as assessed by the total MRS score of e9 at screening
  - Presence of menopausal symptoms for at least six months prior to screening including, vasomotor symptoms (hot flushes, sweating) AND at least two of the following symptoms: sleep disturbance, joint pain, mood changes, fatigue and lack of energy, vaginal dryness, urinary changes, and changes in sexual function
  - Agrees to maintain current lifestyle as much as possible throughout the study, including diet, exercise, medications, dietary supplements, and sleep
- ... and 3 more (see full listing online)

### Exclusion (25)

- Females who have had unilateral oophorectomy or hysterectomy or uterine ablation
  - Allergy (including bee products or pollen, sensitivity, or intolerance to investigational products or placebo ingredients)
  - Ongoing diagnosis with anxiety disorder, sleep disorder, or major depression as assessed by the QI
  - Ongoing unstable diagnosis of musculoskeletal disorders as assessed by the QI
  - Current untreated urogenital diagnosis as assessed by the QI
- ... and 20 more (see full listing online)

## Locations (1 total)

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KGK Science Inc., London, Ontario, Canada