Background

- The Promise Study (NCT02694809) is a presurgical intervention trial in post-menopausal women with DCIS.
- Intervention: Conjugated Estrogens/Bazedoxifene.
- Recruiting DCIS patients for presurgical studies is challenging.
- Perceived motivators and barriers to trial participation have not been formally studied from patient or healthcare provider (HCP) perspective.
- Understanding motivators and barriers to patient participation will enhance recruitment strategies.

Methods

- Six virtual focus groups:
  - At-risk, post-menopausal women (PMW) without DCIS history (3)
  - Women with history of DCIS (1)
  - HCPs who treat 25+ DCIS patients per year (2)
  - Physicians (1), APPs and Nurses (1)
- Participants across United States.
- Third party facilitator generated discussion.
- Predetermined, standardized topics:
  - Knowledge of Prevention
  - Knowledge of DCIS
  - Perceived motivators and barriers to trial participation in general, and specifically for DCIS trials for PMW and HCP
  - Clinical trial recruitment materials
  - Hormone replacement therapy
  - Healthcare delivery and clinical trials during COVID-19
- Qualitative thematic analysis completed in Nvivo12 using focus group transcripts.

Results

- PMW and HCPs identified numerous unique motivators and barriers.
- PMW and HCPs did not emphasize time commitment as a barrier.
- PMW were not motivated by financial incentives.
- Access to superior treatment is a motivator for participation.
- Risk of harm from interventions is a deterrent to participation.
- PMW and HCPs agreed that:
  - Access to better treatment
  - Increased monitoring by medical team
  - Financial incentive

Conclusions

- Post-menopausal women (PMW) lacked knowledge about DCIS.
- Healthcare Providers (HCP) and PMW agreed that:
  - Risk of harm from interventions is a deterrent to participation.
  - Access to superior treatment is a motivator for participation.
- PMW were not motivated by financial incentives.
- PMW and HCPs did not emphasize time commitment as a barrier.
- PMW and HCPs identified numerous unique motivators and barriers which could result in missed recruitment opportunities.
- DCIS educational materials, maximizing patient motivators, and minimizing patient barriers to clinical trial participation may increase recruitment to presurgical DCIS trials.