At-Risk Patient and Healthcare Provider Perspectives on Clinical Trial Participation for Ductal Carcinoma in Situ

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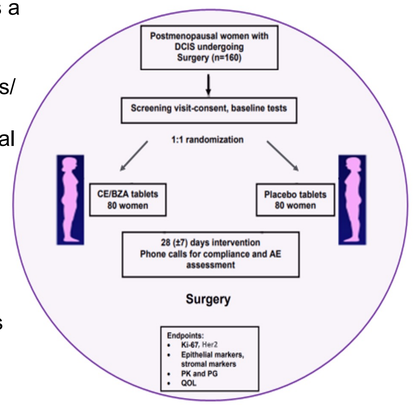
Background

- 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 DCIS clinical trial patient 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

PMW 3 Focus Groups → HCPs 2 Focus Groups → DCIS patients 1 Focus Group

Results

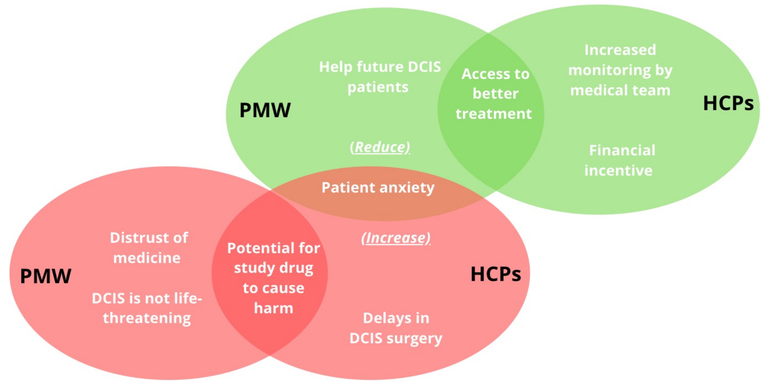


Figure 1: Similarities and differences among PMW and HCP perceptions of motivators (in green) and barriers (in red) to DCIS clinical trials

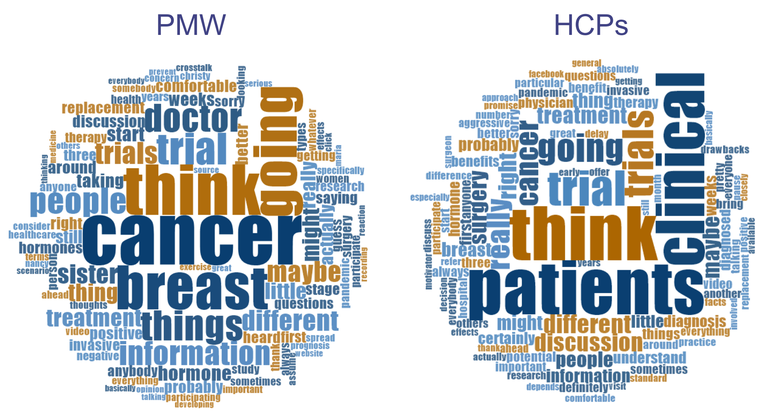


Figure 2: Word Cloud of most frequently used 100 words by PMW (left) and HCPs (right)

Results

Table 1: PMW and HCP Selected quotes from focus groups by featured topic

Topic	Perceived	Group	Quote
Anxiety	Barrier	HCP	"…there's a lot of patients that hear the word 'clinical trial,'…the next thing they think is, 'I have something. I'm dying, there's no treatment, and now I'm in a clinical trial,…'There's something they're not telling me.' So, it might be the psychological effect…"
	Motivator	Patient	"Even though it has a good prognosis, I think just hearing the word cancer puts fear in you. So, anything that you think can help you would try."
Access to Newer or Better Treatment	Motivator	HCP	"I think also that it's very possible that the current clinical trial therapy could be more effective than the standard of care. So, she basically is getting a therapy ahead of everybody else"
		Patient	"Maybe it might be a cure or maybe she might get better under a clinical trial."
Potential to Cause Harm	Barrier	HCP	"…You're dealing with a novel agent and certainly, the benefits versus the risks are not that well studied yet, i.e., that's why the drug's being trialed." "…There's additional tests required or additional biopsy required because the clinical trial requires that. So, that leads that there's some potential complications from all the additional tests."
		Patient	"…the fact that she wants to do a clinical trial when what you have described is that it's non-invasive, it's stage zero, the doctors know how to treat it. Why would she even make herself…a guinea pig when what she's taking might harm her or give her side effects or longterm consequences that she's stuck with when the regular treatment has been proven to work very well and be very effective."

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

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