

- Symptoms are common among patients receiving treatment for advanced cancers but go undetected or unaddressed up to half the time.
- Routine collection of electronic PROs have shown improvement in several areas of patient health in a large single site study (Basch 2017).
- PRO-TECT is designed to determine if advanced cancer patients at intervention sites have better clinical outcomes (longer survival, fewer ER visits and unplanned hospitalizations, and better quality of life and physical function) than usual care.

**Aim 1:** Determine whether systematic integration of electronic patient-reported symptoms into cancer care delivery improves meaningful patient-centered outcomes.

**Aim 2:** Elicit perspectives about benefit-burden tradeoffs for integrating PROs into clinical workflow from different stakeholders.

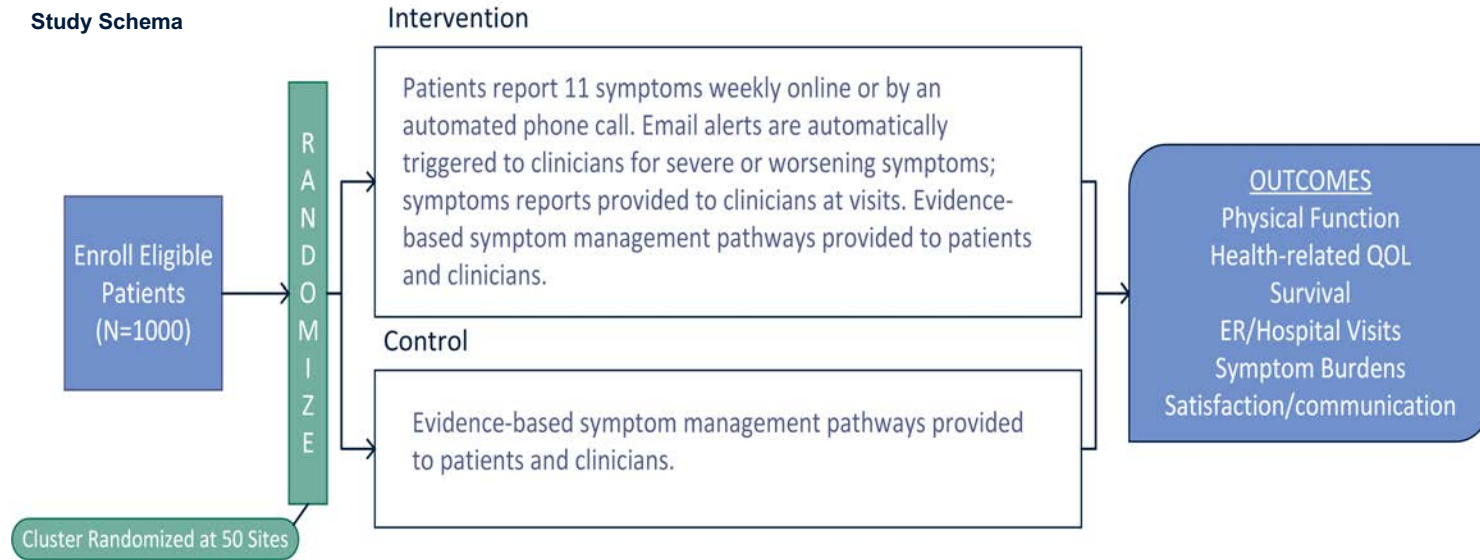
**Aim 3:** Identify barriers, facilitators, and strategies used by practices to integrate PROs into clinical workflow.

**RATIONALE**

**OBJECTIVE**

**National cluster randomized controlled trial to determine the value, acceptability, and feasibility of integrating PROs into routine community cancer**

- rationale/objective
- study schema
- treatment plan/intervention
- key eligibility criteria
- follow up



**STUDY SCHEMA**

Patient Symptom Guide

- rationale/objective
- study schema
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What can I do to manage my pain?

Ways to Manage Pain

Talk to your cancer care team about pain medications and their side effects.



Also, talk to your cancer team about non-medication ways to reduce your pain. These include:

- Acupuncture (small flexible needles inserted at specific points on the body to treat pain)
- Biofeedback (a method used to teach you ways to feel and control the way your body responds to situations)
- Hot and cold compresses
- Hypnosis or meditation
- Massage or reflexology (a special type of massage where pressure is applied to reflex zones on your feet, hands or outer ears to affect your entire body)
- Relaxation or guided imagery (focusing on images that bring feelings of relaxation)
- Physical therapy
- Light exercise, Yoga, Tai Chi, Qigong, or Reiki therapy
- Distractions – like watching TV, music, or hobbies

Call your cancer care team if:

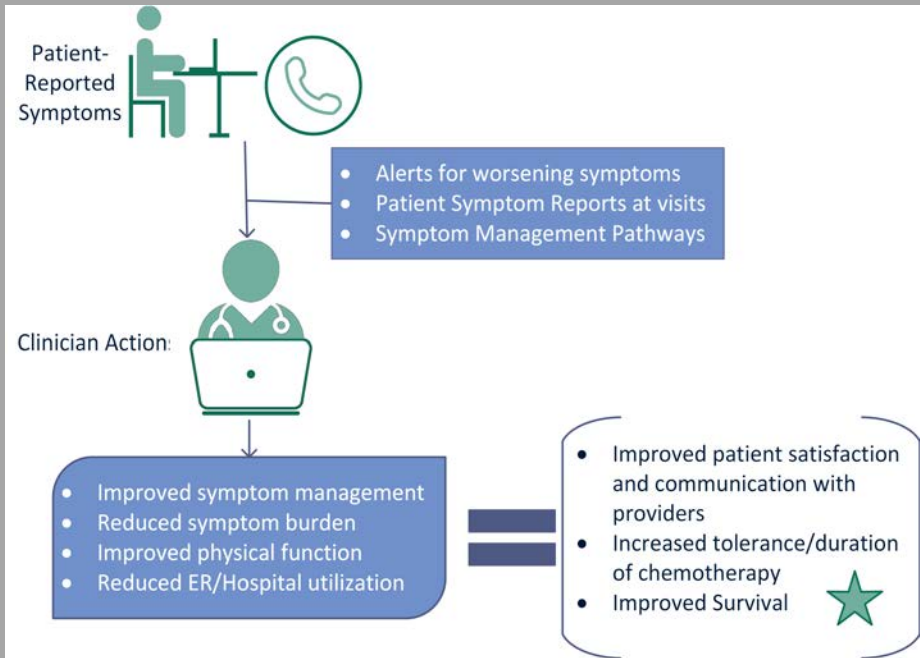
- You feel new pain
- Your pain isn't getting better or going away
- Pain comes on quickly
- Pain makes it hard to eat, sleep, work, or be active
- The pain medicine is not working as fast or for as long as it used to
- You develop constipation while taking pain medications
- You develop nausea, vomiting, rash or confusion while taking pain medications

If you are on pain medication, take it in the right amount and at the correct time for best results.

If you take the pain medicine too late, it may not work as well. **Don't stop** taking pain medicine unless you discuss this with your cancer care team first.

**Opioid (narcotic) pain medications** are strong medications used to treat moderate to severe pain. These medications require a written prescription.

People who take opioids, as prescribed, for cancer pain rarely become addicted.



TREATMENT PLAN / INTERVENTION



## Inclusion

- Age  $\geq$  21 years
- Adv./metastatic cancer of any type
- Receiving outpatient systemic cancer treatment for non-curative/palliative intent, including chemotherapy, targeted therapy, or immunotherapy
- Enrolled at any point during a course or cycle of treatment
- Understand English, Spanish or Mandarin Chinese

## Exclusion

- Cognitive deficits
- Currently in a therapeutic clinical trial
- Treated with curative intent
- Receiving hormonal therapy only
- Indolent lymphomas
- Leukemias

## Early Results

- 23 sites across 12 states randomized.
- 882 patients enrolled of planned 1,200.
- 95% compliance for completing weekly PROs.
- ~40% of PROs trigger alerts to clinicians for severe or worsening symptoms.
- Pain (49%) and physical function (45%) were the most common.
- Over half of patients chose to weekly self-report via email (58%) and 42% chose automated calls to phone.

## KEY ELIGIBILITY CRITERIA/EARLY RESULTS



**PRO-TECT Study (AFT-39)**  
**Electronic Patient Reporting of Symptoms During Cancer Treatment**

Ethan Basch, MD, UNC Lineberger Comprehensive Cancer Center

rationale/  
objective

study  
schema

treatment plan/  
intervention

key eligibility  
criteria

follow up

This trial (AFT-39) is funded by an award from the Patient-Centered Outcomes Research Institute (PCORI)

To learn more or to open this trial at your site, e-mail:  
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**FUNDING SUPPORT**

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