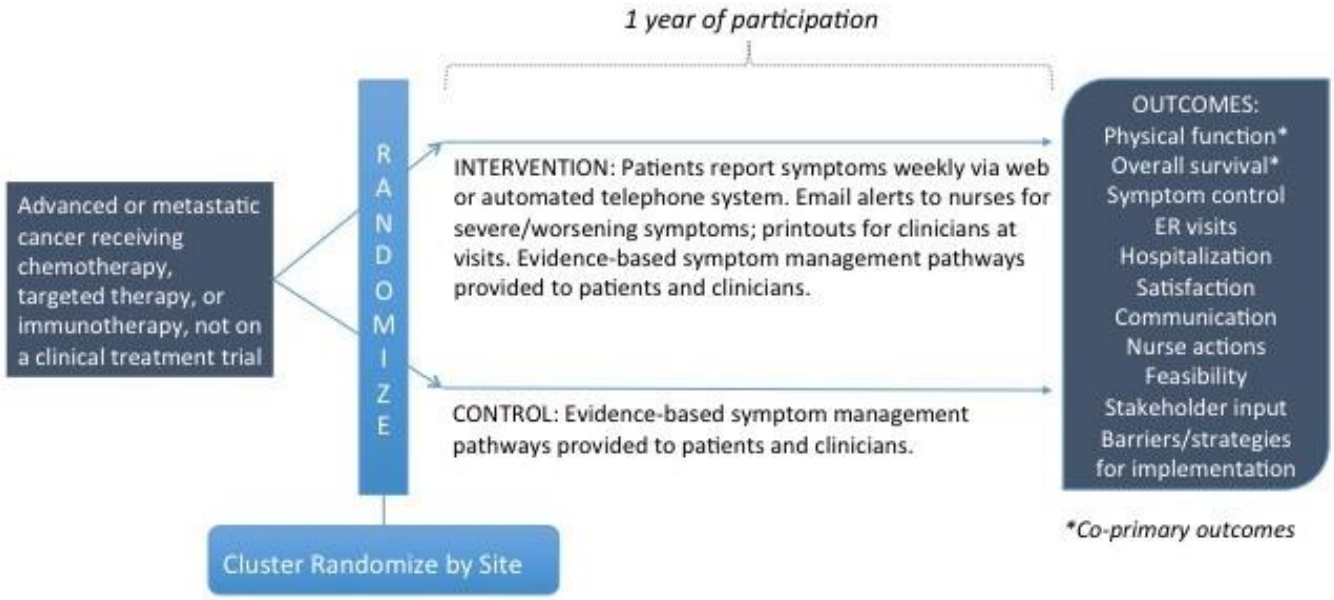
PRO-TECT SCHEMA



1.3. Primary Objective

The primary objective of this study is to determine whether systematic monitoring of symptoms via patient-reported outcomes (PROs) during routine cancer care delivery improves meaningful clinical outcomes, including quality of life, symptom control, survival, emergency room visits, duration of chemotherapy administration, and patient satisfaction with care.

1.4. Secondary Objectives

Secondary outcomes of this study are to:

- Elicit perspectives from patients, CRAs, and clinicians about effort, benefits, and burden of patient self-reporting of symptoms with alerts and reports to clinicians.
- Identify barriers, facilitators, and strategies used by practices to integrate PROs into clinical workflow through interviews, questionnaires, and selected site visits.
- Obtain perspectives of stakeholders about PROs through debriefings at study completion.

2. Patient Selection and Population

2.1. Inclusion and Exclusion Eligibility Criteria

Inclusion Criteria:

1. Adults (21+) with advanced/metastatic cancer of any type (EXCEPT leukemia or indolent [slow growing] lymphoma)
2. Receiving outpatient systemic cancer treatment for non-curative/palliative intent, including chemotherapy, targeted therapy, or immunotherapy.
3. Enrolled at <u>any point</u> in their treatment trajectory, meaning during any line of treatment, and at any point during a course or cycle of treatment.
4. Can understand English, Spanish, and/or Mandarin Chinese.

Exclusion Criteria:

1. Cognitive deficits that would preclude understanding of consent form and/or questionnaires.
2. Current participation in a therapeutic clinical trial (because these often involve PRO questionnaires and intensive monitoring).
3. Patients being treated with <u>*curative*</u> intent (e.g., adjuvant chemotherapy for breast, lung, or ovarian cancer; primary curative therapy for testis cancer or lymphoma).
4. Receiving hormonal therapy only (e.g., tamoxifen or aromatase inhibitors in breast cancer; androgen deprivation therapy in prostate cancer; or octreotide in neuroendocrine cancers)
5. Indolent lymphomas (due to their prolonged time courses that may be minimally symptomatic).
6. Leukemias (time courses inconsistent with other tumor types in chronic and acute leukemias).
7. Does not understand English, Spanish, or Mandarin Chinese.