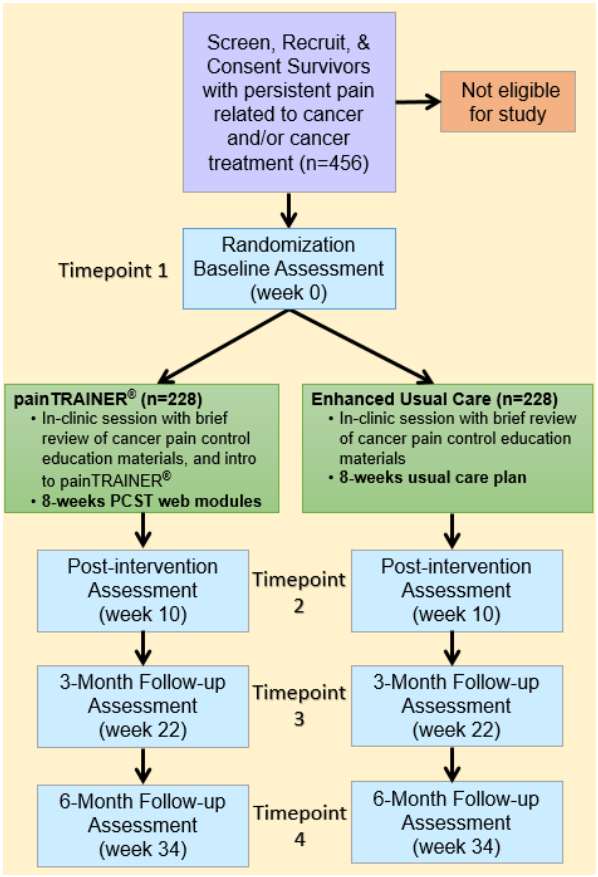
SCHEMA

Internet-delivered Management of Pain Among Cancer Treatment Survivors (IMPACTS)

Primary Endpoints: Pain severity and pain interference (pre- to post-intervention change)

Secondary Endpoints: Pain severity/interference (3- and 6-month follow-up), opioid/analgesic medication use, health-related quality of life, and pain management self-efficacy



Arms:

Enhanced Usual Care - Participants in the Enhanced Usual Care arm continue to receive their usual care provided by their own physician. They attend a single clinic visit where they will receive printed educational materials addressing cancer pain and control, which will be briefly reviewed in clinic.

painTRAINER® - Participants in the painTRAINER® arm will continue to receive their usual care provided by their own physician (as in the Enhanced Usual Care arm) and will receive access to the Internet-based painTRAINER® pain coping skills training program. Participants will attend a single clinic visit where they will receive printed educational materials addressing cancer pain and control, which will be briefly reviewed in clinic, and log-in instructions to access painTRAINER®. Participants will then complete the 8 painTRAINER® modules on their own (~one per week) led by the program's "virtual" coach.

Study Sample: n = 456 participants (228 per arm)

Study Duration: 34 weeks

Brief Eligibility Criteria

- Must have a history of a cancer diagnosis and treatment.
- ≥3 months, but not more than 24 months have elapsed since the completion of definitive cancer therapy (i.e., time since the last day of chemotherapy administration) with either no evidence of residual disease or with stable disease at the time of screening.
- Must have completed all planned anticancer therapy with the exception of maintenance therapy when appropriate.
- Must have pain indicated by a score of ≥ 4 on *PROMIS Pain Intensity (1a) scale*, using the Pain Eligibility Interview within the ***Screening Interview***.
- Must have a score of "Most Days" or higher on the *Graded Chronic Pain Scale Revised (Abbreviated)* using the Pain Eligibility Interview within the ***Screening Interview***.
- Must be on a stable analgesic regimen over a period of at least 14 days prior to enrollment.
- Must have pain of new onset or significantly exacerbated since the time of cancer diagnosis or initiation of cancer treatment.

4. PARTICIPANT SELECTION

4.1 Patient Inclusion Criteria

4.1.1 Must have a history of a cancer diagnosis and treatment. Must have a documented diagnosis of invasive cancer requiring therapy with any combination of surgery, radiation, and chemotherapy/drug therapy including single modality therapy only. Patients with a cancer history of only superficial skin cancers or in situ malignancy are not eligible.

4.1.2 Must have been ≥3 months, but not more than 24 months since the completion of definitive cancer therapy (i.e., time since the last day of chemotherapy administration) with either no evidence of residual disease or with stable disease, as established by imaging, clinical exam, or laboratory testing at the time of screening.

4.1.3 Must have completed all planned anticancer therapy with the exception of maintenance therapy when appropriate. Maintenance therapy includes planned chronic immunotherapy, hormonal therapy, targeted therapy or chemotherapy given to prevent recurrence of disease rather than to treat active disease (*e.g.* long-term PD-1 or PD-L1 inhibitors in NSCLC patients following initial chemotherapy). Time frame applies to the most recent completion of treatment if participant has experienced cancer recurrence(s).

4.1.4 Must have pain indicated by a score of ≥ 4 on *PROMIS Pain Intensity (1a) scale*, using the Pain Eligibility Interview within the ***Screening Interview*.**

4.1.5 Must have a score of "Most Days" or higher on the *Graded Chronic Pain Scale Revised (Abbreviated)* using the Pain Eligibility Interview within the ***Screening Interview***.

4.1.6 Must be on a stable analgesic regimen (*i.e.*, no changes to the prescribed analgesic regimen) over a period of at least 14 days prior to enrollment. Eligible patients should not have planned upward dose titration of their analgesics during the study period up to the 10 Week Follow-up Visit (T2). Patients may elect to decrease their analgesic use during the study as per discussions with their provider. Unexpected dose adjustments including dose escalations as a result of unforeseen clinical need is allowed in all patients at all times during the study.

4.1.7 Must have pain of new onset or significantly exacerbated since the time of cancer diagnosis or initiation of cancer treatment

4.1.8 Must be expected to be able to complete all study activities including the 22- and 34-week follow-up assessments according to the treating/referring clinician (*e.g.*, treating clinician feels the patient is unlikely to develop progressive disease requiring additional active cancer therapy through the 6-month follow-up period).

4.1.9 ECOG performance status of 0, 1, or 2.

4.1.10 Age ≥18 years at the time of study entry

4.1.11 Must be able to speak, read and understand English

4.2 Patient: Exclusion Criteria

4.2.1 Has a disability that precludes completion of study activities (*e.g.*, severe vision or hearing impairment, diagnosis of dementia or clinical evidence of severe cognitive impairment, diagnosis or clinical evidence of severe psychiatric disorder, or diagnosed drug or alcohol abuse disorder), as per patient report or documented in the medical record.

4.2.2 Reports only preexisting pain conditions ***unrelated*** to cancer or cancer treatment (*e.g.*, migraine or tension headache, arthritis, back disorders, bursitis/tendonitis, injuries, fibromyalgia).

4.2.3 Has a known or suspected diagnosable substance use disorder or opioid overuse disorder (according to DSM-5 criteria), or is actively receiving treatment for a substance use disorder, as per patient report or documented in the medical record.

4.2.4 Currently being prescribed buprenorphine or suboxone.

4.2.5 Suspected or proven progressive cancer by clinical history, exam or imaging evaluation. [Must have stable disease or considered to have no evidence of disease (NED)].

4.2.6 Patients enrolled on hospice care or end-of-life palliative care are not eligible for enrollment. Patients whose local care network provides an opportunity for palliative (symptom management) or supportive care concurrent with active treatment following diagnosis (*i.e.* not solely as a palliative or end-of-life measure) are considered eligible for this study.

4.2.7 Does not have reliable access to Internet or sufficient personal data plan, and is not willing to participate in the Tablet Lending Program provided for this study.

4.2.8 Does not have a working email address.

4.3 Patient: Inclusion of Women and Minorities

Both men and women (as applicable) and members of all races and ethnic groups are eligible for this trial. We will encourage local NCORP study staff at participating sites to invite all potentially eligible participants, regardless of gender or race/ethnicity. We will seek to recruit participants diverse in race, ethnicity, and socioeconomic status. As the painTRAINER® intervention currently is available only in the English language, individuals without English proficiency will not be eligible to participate. We will not require established computer literacy as our prior research has established that adults with low levels of computer literacy can successfully use painTRAINER®[27]. Additionally, we will not require that participants have access to a computer, Internet, or Internet-enabled device. The WF NCORP RB will maintain a limited number of Internet-enabled tablet devices and will provide such devices to local NCORP sites to be loaned to participants without Internet access for the duration of the study.