**SCHEMA**

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

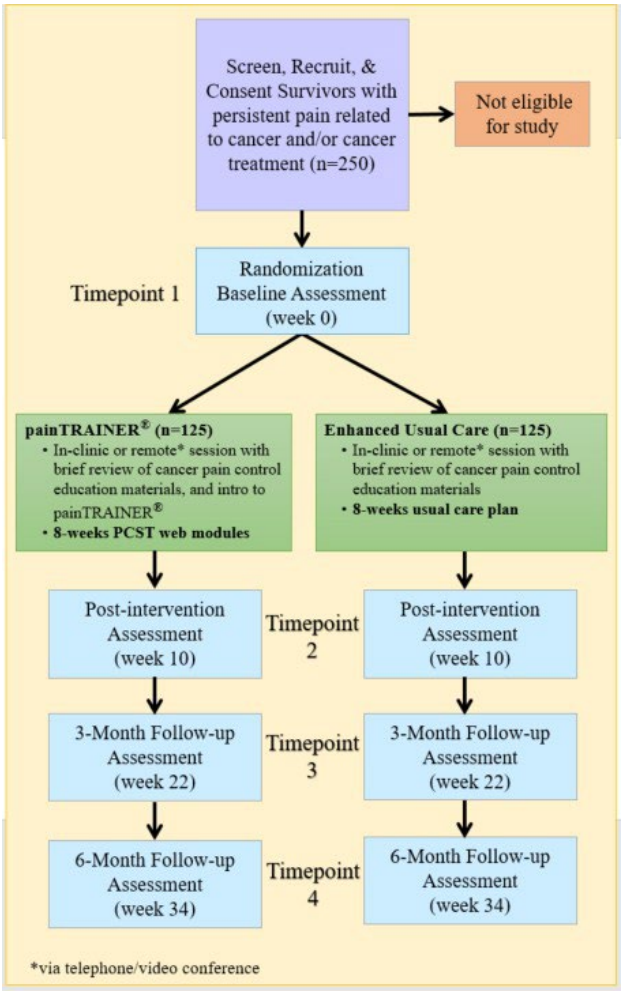
**Primary Endpoint:** Pain interference (pre- to post-intervention change)

**Secondary Endpoints:** Pain severity (pre- to post-intervention change), pain severity/interference (3- and 6-month (T3 and T4) 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 (in person or via telephone/video conference) where they will receive printed educational materials addressing cancer pain and control, which will be briefly reviewed.

**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 (in person or via telephone/video conference) where they will receive printed educational materials addressing cancer pain and control, which will be briefly reviewed, 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 = 250 participants (125 per arm)
**Study Duration:** 34 weeks

**Brief Eligibility Criteria**

- Must have a documented diagnosis of invasive cancer that has been treated with either single modality therapy or any combination of surgery, radiation, and chemotherapy/drug therapy.
- May be either off all treatment OR actively receiving anticancer therapy in an adjuvant setting, maintenance setting, or for active cancer.
- Patients who are no longer receiving anticancer therapy must be ≤ 5 years since the completion of their anticancer therapy (e.g., time since the last day of chemotherapy administration, time since last day of radiotherapy, etc.).
- 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***.

- Patients do not have to be on analgesic medications of any kind in order to participate. If they are taking analgesics, they 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

The goal of the eligibility criteria is to identify patients who are expected to have relatively stable disease, either following all anticancer therapy or while receiving an ongoing anticancer regimen, for the duration of the 3-month intervention period. These patients should also be expected to have relatively steady pain complaints and have maintained a stable analgesic regimen at the time of enrollment,

## 4.1 Patient Inclusion Criteria

**4.1.1** Must have a documented diagnosis of invasive cancer that has been treated with either single modality therapy or any combination of surgery, radiation, and chemotherapy/drug therapy (e.g. cytotoxic therapy, targeted therapy, immunotherapy, hormonal therapy, etc.). Patients with a cancer history of only superficial skin cancers or in situ malignancy are not eligible.

**4.1.2** May be either off all treatment OR actively receiving anticancer therapy in an adjuvant setting, maintenance setting, or for active cancer.

- Patients who are currently undergoing anticancer therapy should not have any plans to change or adjust their treatment during the intervention period. This includes changing to another therapy or ending therapy entirely.
- Patients who are currently receiving anticancer therapy at the screening process must have been on current therapy for at least four weeks. Alternatively, if they are planning to discontinue therapy before enrolling, they must have been off therapy for four weeks prior to enrollment.
- A minimum of four weeks must have elapsed since the completion of the most recent course of radiation therapy.
- A minimum of four weeks must have elapsed since the most recent MAJOR surgical intervention.
- A minimum of two weeks must have elapsed since the most recent MINOR surgical procedure (e.g., port placement).
- In addition, eligible patients must not have a planned surgical procedure or course of radiation therapy during the 3-month study intervention period (i.e., the three months leading up to primary outcome evaluation-timepoint 2 (T2)).

**4.1.3** Patients who are no longer receiving anticancer therapy must be ≤ 5 years since the completion of their anticancer therapy (e.g., time since the last day of chemotherapy administration, time since last day of radiotherapy, etc.).

**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** Patients do not have to be on analgesic medications of any kind in order to participate. If they are taking analgesics, they 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 3-month study intervention period (i.e., the three months leading up to primary outcome evaluation-timepoint 2 (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. Cannabis prescribed for medicinal purposes would qualify as an analgesic in this context.

**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** 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.

**4.2.6** 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.

**4.2.7** 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 site staff at participating sites to invite all potentially eligible participants.