

FAST FACTS

WF2304-A172401 Complementary Options for Symptom Management In Cancer (COSMIC): Assessing Benefits and Harms of Cannabis and Cannabinoid Use Among a Cohort of Cancer Patients Treated in Community Oncology Clinics

Inclusion Criteria

1. Adults aged 18 years or older with one of the following newly diagnosed cancers: breast cancer, colorectal cancer, melanoma, non-Hodgkin lymphoma, or non-small cell lung cancer (e.g., adenocarcinoma, squamous cell carcinoma, large cell carcinoma, adenosquamous cell carcinoma, and not otherwise specified).
2. Planned treatment with systemic chemotherapy (single or multi-agent, includes targeted therapy) and/or immune checkpoint inhibitor therapy (targeting PD-1, PD-L1 or CTLA-4). If unable to engage participant before treatment starts, enrollment is allowed up to the start of Cycle 2 treatment.
3. Participants must be able to comprehend English or Spanish (for survey completion).
4. Participant must have a working email address and be willing to complete surveys online. This can be completed at home, in the clinic or other location.
5. Completion of the confidential **Self-reported Screening Survey** and receipt of a screening result - eligible for enrollment.
6. Participant must reside in the United States, officially determined per patient report on **Self-reported Screening Survey**
7. In the treating provider's opinion, the participant should have a life expectancy of ≥ 6 months. Participants in hospice are not eligible.

Exclusion Criteria

1. Currently enrolled in an interventional supportive treatment trial to manage cancer symptoms.
2. Participants with known pregnancy.
3. Participant received systemic therapy treatment for prior cancer(s) including chemotherapy, immunotherapy, targeted therapy, and hormonal therapy.
4. Participants enrolled in hospice.

SCHEMA

Study Design: This prospective cohort study will examine the association between cannabis and cannabinoid use and cancer-related symptoms for a period of one year in adults with newly diagnosed breast, colorectal, melanoma, non-Hodgkin lymphoma, or non-small cell lung cancer (NSCLC) who are planning or recently started to receive one or more systemic cancer directed therapies with chemotherapy and/or immune check point inhibitors (ICIs) targeting PD-1, PD-L1 or CTLA-4. In a subsample of non-small cell lung cancer patients, this study also examines potential drug interactions and impacts of cannabis and cannabinoid use on inflammatory and immune response.

Identification of Potentially Eligible Patients
(cancer type [breast, colorectal, melanoma, non-Hodgkin lymphoma, non-small cell lung] and treatment regimen [chemotherapy and/or ICI])

Obtain Informed Consent

Confidential Online Self-reported Screening Survey:
cannabis use, use of complementary therapies, and state of residence.

Strata

Cannabis and Cannabinoid Use:

- **Non-Current Users (did not use in the past 30 days)**
 - Never users
 - Non-recent users (used more than 30 days ago)
- **Current users (used in the past 30 days)**
 - Frequent Users (one or more times per week, every day or almost every day)
 - Infrequent Users (one or more times a month but less than weekly)

Cannabis Policy of State of Residence: (Medical only, Recreational/Medical, CBD only/no cannabis)

Enroll potential participant if they meet all eligibility after the screening survey is complete.

Baseline

Confidential Baseline Online Survey: cancer-related symptoms, cannabis and cannabinoid use (e.g., modes, cannabinoid type, concentration, frequency, perceptions of benefits and harms, adverse effects, reasons for use), other substance use, demographics, health-related quality of life, social support, and use of other medications and complementary therapies.

Medical Record Data Forms: cancer and medical history, cancer treatment, select labs, comorbidities, concomitant medications, and participant 9-digit zip code for location analysis.

Months 1-12 (every 30 days)

Confidential Monthly Online Survey: cancer-related symptoms, cannabis and cannabinoid use (see above), use of other medications and complementary therapies.

***Months 6 & 12 additional items:** health-related quality of life, social support, cannabis use disorder (users only)

Medical Record Data Forms will be updated at least quarterly (i.e., Months 3, 6, 9 and 12).