

Case study: Metastatic breast cancer in remission following standard cancer treatment and adjunctive medical cannabis & Psychedelics

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Diagnosis

- Nicole was diagnosed in August 2018
- She was diagnosed with an ER+, PR-, HER2+, BRCA- De Novo metastatic breast cancer which included bone, liver, and lymph node involvement.

Prognosis

- Her oncologist gave us a less than favorable prognosis indicating that at best Nicole would live a life of perpetual treatment if the initial clinical strategy proved to be successful.
- The average lifespan of ten years post-diagnosis lifetime of treatment



Fig 1A. Pet/ CT images demonstrate FDG avid tumour in left breast pre-treatment

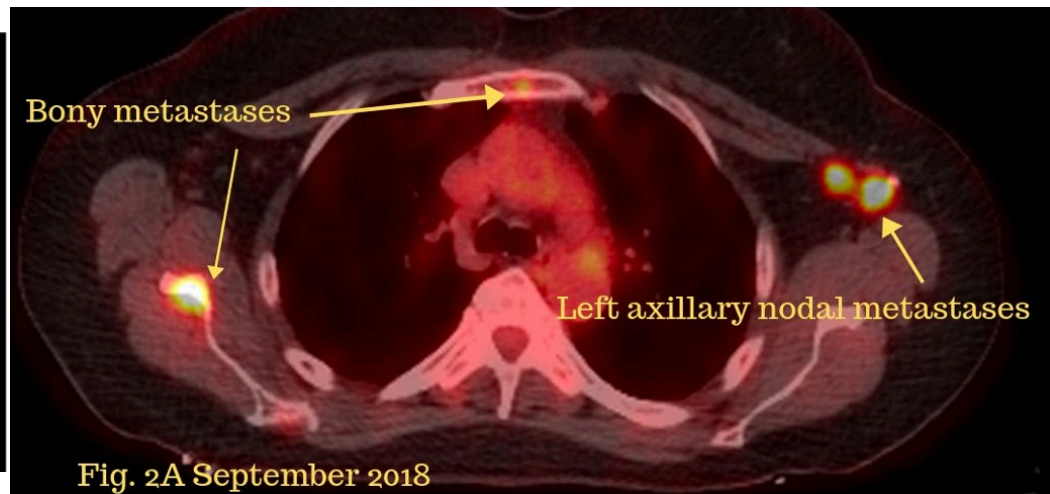


Fig 2A Increased FDG activity within the right scapula, sternum and left axillary nodes reflecting metastases pre-treatment

Chemo/Radio/Targeted therapy

| Drug | Dose Administered | Date |
|-----------|--------------------|-------------|
| Taxotere | 139 mg IV Q4weeks | 9/18 – 1/19 |
| Perjeta | 420 mg IV Q4 weeks | 9/18 – 1/19 |
| Herceptin | 455 mg IV Q4 weeks | 9/18-1/19 |

Cannabinoids as adjunct to standard cancer treatment

- Work synergistically with HER2-targeted therapies, such as trastuzumab, resulting in additive anti proliferative responses. (Mangal N. Et al. 2021)
- Inhibit hypoxia inducible factor (HIF-1) which is an essential mediator for downstream nuclear signaling that modulates cancer cell growth. (Blázquez C et al. 2004)
- Independently reduce ErbB2-driven breast cancer progression through inhibiting cell-signalling pathways. (Caffarel et al. 2010)*
- Palliative effects that reduce side effects of standard cancer therapies. Cannabinoids reduce Anxiety, mediate pain, relieve nausea, increase appetite and facilitate sleep. (Sakal, Nutt et al., 2021)

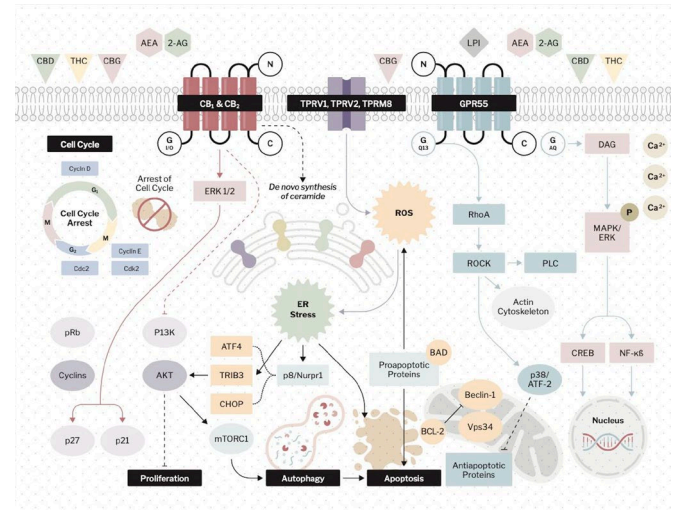


Figure 1. Mangal N, Erridge S, Habib N, Sadanandam A, Reebye V, Sodergren MH. Cannabinoids in the landscape of cancer. *J Cancer Res Clin Oncol.* 2021 Sep;147(9):2507-2534.

CANNABIS

| CANNABINOID | AUG | SEPT-OCT | NOV-JUN |
|-------------|----------|----------|----------|
| CBD | 245 mg | 130 mg | 294 mg |
| CBD-A | 245 mg | 960 mg | 701 mg |
| CBD-V | - | 16 mg | 16.6 mg |
| CBC | 1.24 mg | 34 mg | 50 mg |
| THC | 157 mg | 317 mg | 509 mg |
| THC-A | 226 mg | 475 mg | 499 mg |
| THC-V | 1.25 mg | 1.25 mg | 1.25 mg |
| CBG | 20.97 mg | 74.73 mg | 53.76 mg |
| CBN | 0 mg | 0.3 mg | 0.1 mg |

High dose protocol titrated up slowly

Formulations are patentable and are the IP of Grace H&W Therapeutics

Formulations Used: Whole plant concentrate extracted with ethanol

Frequency of Use: Daily

Cultivars: High CBD strain, High THC strain, 1:1 CBD THC strain, THC indica

The whole-plant cannabis formulations administered to this patient contain the major cannabinoids THC and CBD as well as a mixture of over 140+ other minor cannabinoids, terpenes and flavonoids

Psychedelics as adjunct to standard cancer treatment

Psychedelic medicine

- Psilocin, which is the active metabolite of psilocybin fine-tunes anti inflammatory responses by changes in cell signalling. (Szabo et al. 2015)
- Psilocybin inhibits hypoxia (Szabo et al 2016)
- Recent studies have shown the efficacy of psilocybin for cancer related anxiety and pain (Griffiths et al 2016)

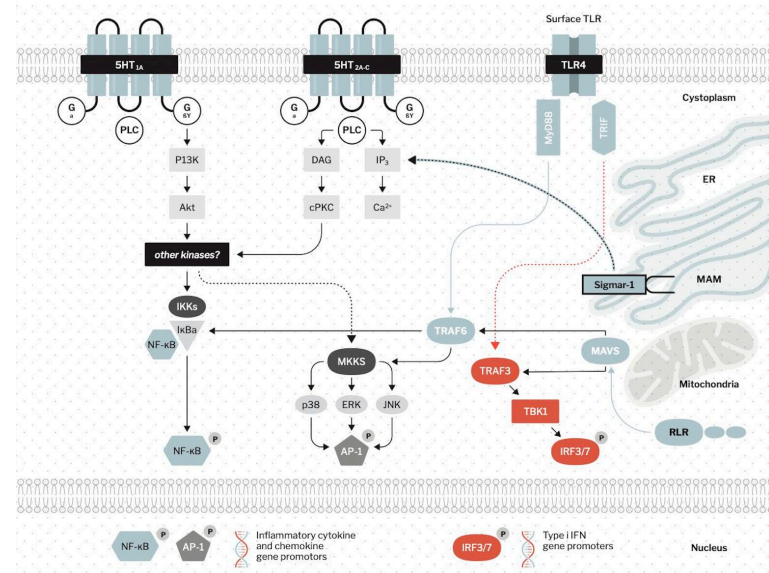
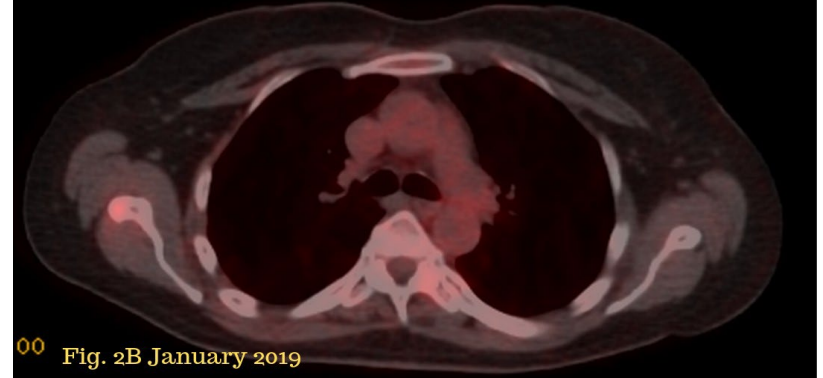
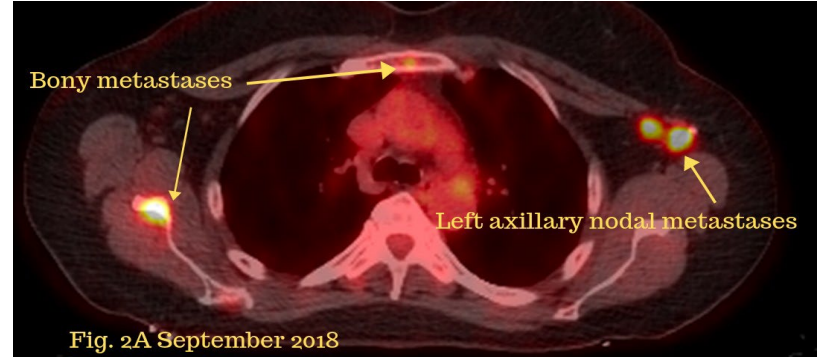
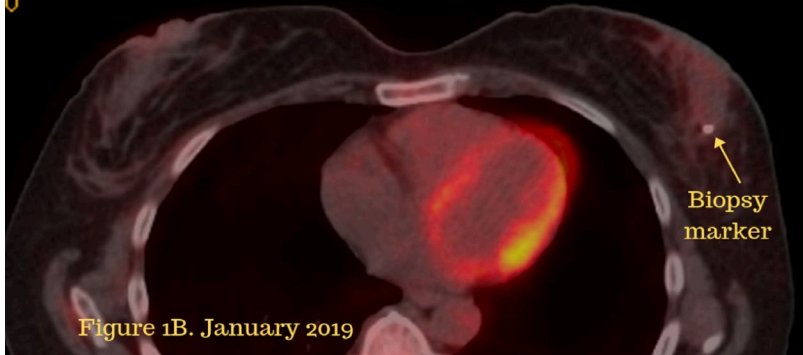
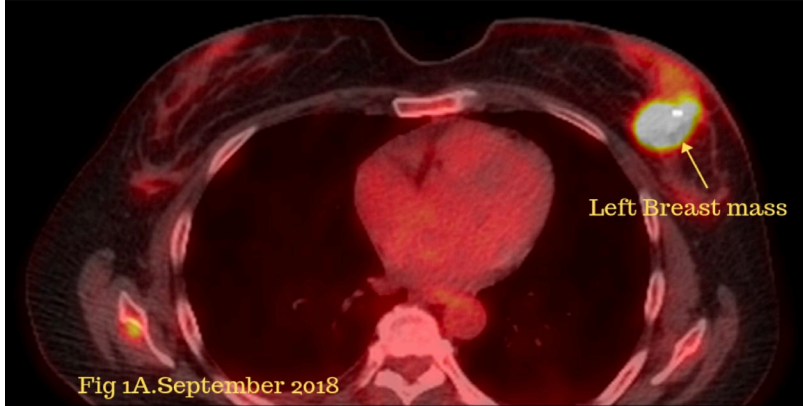


Figure2. Szabo A. Psychedelics and Immunomodulation: Novel Approaches and Therapeutic Opportunities. *Front Immunol.* 2015 Jul 14;6:358. doi: 10.3389/fimmu.2015.00358. PMID: 26236313; PMCID: PMC4500993.

PSILOCYBE CUBENSIS (GOLD CAP)

| DAYS OF USE | DOSE | COMPLIMENTARY THERAPY DURING TREATMENT SESSION |
|---------------|----------|--|
| November 2018 | 4 g | Sensory deprivation and post-treatment therapy session |
| January 2019 | 4 g | Sensory deprivation and post-treatment therapy session |
| November 2018 | 10-20 mg | Intermittent micro-dosing |

Effect of treatment on FDG-PET tumour uptake



A clinical trial to investigate the role of adjunctive cannabinoid therapy in the treatment of Breast cancer

- Late-stage oncology treatments are limited, poor in prognosis and accompanied by debilitating side effects
- Increasing numbers of patients have begun to use less conventional treatment options, such as cannabis or psychedelics, for symptom management.
- A recent systematic review has determined many plausible therapeutic mechanisms of action of cannabinoids to treat cancers (Mangal et al., 2021)
- A growing number of case studies, patient reported outcomes (PROs) and real-world evidence (RWE's) but no clinical studies have been initiated
- Currently limited investigation regarding the direct neoplastic effects of cannabinoids to treat cancer but a few studies showing its efficacy as a palliative adjunctive therapeutic tool



Br J Cancer. 2006 Jul 17; 95(2): 197–203.

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PMCID: PMC2360617

PMID: 16804518

A pilot clinical study of Δ^9 -tetrahydrocannabinol in patients with recurrent glioblastoma multiforme

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ABSTRACT

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Δ^9 -Tetrahydrocannabinol (THC) and other cannabinoids inhibit tumour growth and angiogenesis in animal models, so their potential application as antitumoural drugs has been suggested. However, the antitumoural effect of cannabinoids has never been tested in humans. Here we report the first clinical study aimed at assessing cannabinoid antitumoural action, specifically a pilot phase I trial in which nine patients with recurrent glioblastoma multiforme were administered THC intratumorally. The patients had previously failed standard therapy (surgery and radiotherapy) and had clear evidence of tumour progression. The primary end point of the study was to determine the safety of intracranial THC administration. We also evaluated THC action on the length of survival and various tumour-cell parameters. A dose escalation regimen for THC administration was assessed. Cannabinoid delivery was safe and could be achieved without overt psychoactive effects. Median survival of the cohort from the beginning of cannabinoid administration was 24 weeks (95% confidence interval: 15–33). Δ^9 -Tetrahydrocannabinol inhibited tumour-cell proliferation *in vitro* and decreased tumour-cell Ki67 immunostaining when administered to two patients. The fair safety profile of THC, together with its possible antiproliferative action on tumour cells reported here and in other studies, may set the basis for future trials aimed at evaluating the potential antitumoural activity of cannabinoids.

Keywords: cannabinoid, glioblastoma multiforme, pilot clinical study, antitumoural drug

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Case report



Lung cancer patient who had declined conventional cancer treatment: could the self-administration of 'CBD oil' be contributing to the observed tumour regression?



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Abstract



Conventional lung cancer treatments include surgery, chemotherapy and radiotherapy; however, these treatments are often poorly tolerated by patients. Cannabinoids have been studied for use as a primary cancer treatment. Cannabinoids, which are chemically similar to our own body's endocannabinoids, can interact with signalling pathways to control the fate of cells, including cancer cells. We present a patient who declined conventional lung cancer treatment. Without the knowledge of her clinicians, she chose to self-administer 'cannabidiol (CBD) oil' orally 2–3 times daily. Serial imaging shows that her cancer reduced in size progressively from 41 mm to 10 mm over a period of 2.5 years. Previous studies have failed to agree on the usefulness of cannabinoids as a cancer treatment. This case appears to demonstrate a possible benefit of 'CBD oil' intake that may have resulted in the observed tumour regression. The use of cannabinoids as a potential cancer treatment justifies further research.



Case Rep Oncol. 2013 Sep-Dec; 6(3): 585–592.

Published online 2013 Nov 28. doi: [10.1159/000356446](https://doi.org/10.1159/000356446)

PMCID: PMC3901602

PMID: 24474921

Cannabis Extract Treatment for Terminal Acute Lymphoblastic Leukemia with a Philadelphia Chromosome Mutation

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Abstract

Go to:

Acute lymphoblastic leukemia (ALL) is a cancer of the white blood cells and is typically well treated with combination chemotherapy, with a remission state after 5 years of 94% in children and 30–40% in adults. To establish how aggressive the disease is, further chromosome testing is required to determine whether the cancer is myeloblastic and involves neutrophils, eosinophils or basophils, or lymphoblastic involving B or T lymphocytes. This case study is on a 14-year-old patient diagnosed with a very aggressive form of ALL (positive for the Philadelphia chromosome mutation). A standard bone marrow transplant, aggressive chemotherapy and radiation therapy were revoked, with treatment being deemed a failure after 34 months. Without any other solutions provided by conventional approaches aside from palliation, the family administered cannabinoid extracts orally to the patient. Cannabinoid resin extract is used as an effective treatment for ALL with a positive Philadelphia chromosome mutation and indications of dose-dependent disease control. The clinical observation in this study revealed a rapid dose-dependent correlation.

Key words: Acute lymphoblastic leukemia, Philadelphia chromosome, Cannabinoids, Hemp oil

FDA- Pathway for medical approval

Research shows CannaboBreast products have sixfold improvement in killing cancer cells

USA - English ▾

The composition of cannabinoids and mushrooms in combination with standard chemotherapy improved the effectiveness in killing cancer cells from 10% mortality to 60% mortality

A Coala-T-Cannabis Survey Study of Breast Cancer Patients' Use of Cannabis Before, During, and After Treatment

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BACKGROUND: The goal of this study was to characterize cannabis use among patients with breast cancer, including their reasons for and timing of use, their sources of cannabis information and products, their satisfaction with the information found, their perceptions of its safety, and their dialogue about cannabis with their physicians. **METHODS:** United States-based members of the Breastcancer.org and Healthline.com communities with a self-reported diagnosis of breast cancer within 5 years (age \geq 18 years) were invited to participate in an anonymous online survey. After informed consent was obtained, nonidentifiable data were collected and analyzed. **RESULTS:** Of all participants (n = 612), 42% (n = 257) reported using cannabis for relief of symptoms, which included pain (78%), insomnia (70%), anxiety (57%), stress (51%), and nausea/vomiting (46%). Furthermore, 49% of cannabis users believed that medical cannabis could be used to treat cancer itself. Of those taking cannabis, 79% had used it during treatment, which included systemic therapies, radiation, and surgery. At the same time, few (39%) had discussed it with any of their physicians. **CONCLUSIONS:** A significant percentage of survey participants (42%) used cannabis to address symptoms; approximately half of these participants believed that cannabis could treat cancer itself. Most participants used cannabis during active cancer treatment despite the potential for an adverse event during this vulnerable time. Furthermore, most participants believed that cannabis was safe and were unaware that product quality varied widely and depended on the source. This study reviews the research on medicinal cannabis in the setting of these findings to help physicians to recognize its risks and benefits for patients with cancer. *Cancer* 2022;**128**:160-168. © 2021 American Cancer Society.

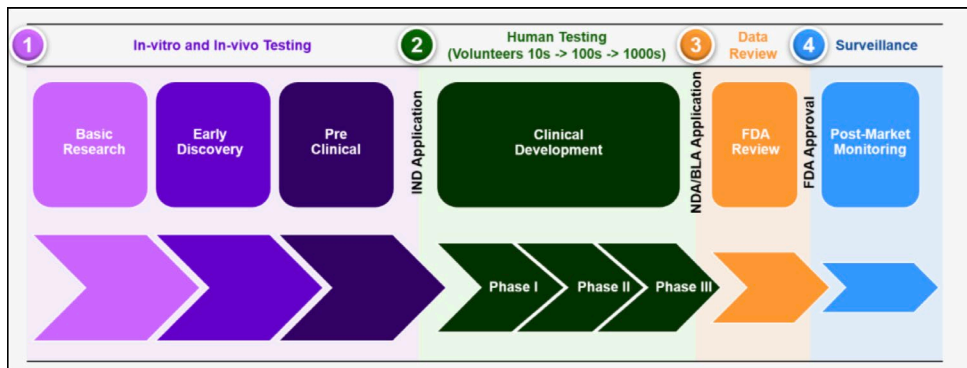
LAY SUMMARY:

- Almost half of patients with breast cancer use cannabis, most commonly during active treatment to manage common symptoms and side effects: pain, anxiety, insomnia, and nausea.
- However, most patients do not discuss cannabis use with their physicians. Instead, the internet and family/friends are the most common sources of cannabis information.
- Furthermore, most participants believe that cannabis products are safe and are unaware that the safety of many products is untested.

KEYWORDS: breast cancer, cannabis, marijuana, palliation.

Step 1: Discovery & Development

| Phase | Target Discovery | Target Validation | Lead Generation & Refinement | Preclinical Development |
|-------|---|---|---|---|
| Goal | Find All Targets | Eliminate Wrong Targets | Generate Molecules | Eliminate Molecules Advance Molecules |
| |  |  |  |  |



- To initiate a drug-development pipeline with collaborators from the University of Connecticut and from a world leading medical cannabis drug development academic group based in the UK
- This will involve the **screening of 7 selected strains** that will undergo in-vitro then in-vivo testing to identify efficacious molecules
- IND applications will be submitted to the FDA following drug discovery stage and we will initiate Phase 1-III clinical trials to determine safety and efficacy for selected compounds for breast cancer.

Pharmaceutical Botanical Preparations

- Whole plant cannabis medicines require many stages and quality controls in order to ensure consistent phytocannabinoids content across batches
- Specialized cannabis genetic selection, cultivation and extraction techniques were required as well as chromatography analysis across each batch in order to consistently reproduce specific strains

Extraction Methods

- Cryo ethanol supercritical extractions (Scalable, Speed, Safe, Economical) (Buffalo extracts 2021)
- Ethanol cannabis extractions have also been reported in the German pharmacopoeia *Cannabis flos* monograph, which describes this as the method of choice for cannabinoid extraction. (Bekanntmachung zum Deutschen Arzneibuch 2018)
- Acidic cannabinoid formulations are highly unstable and degrade and oxidize easily. To prevent decarboxylation of acidic cannabinoids compounds must be properly stored at the correct temperature and without light (Millay et al 2015)

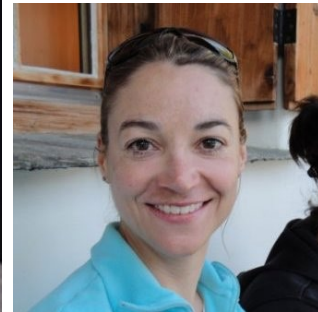
Whole-plant medical cannabis vs Isolates in cancer

- Extensive preclinical research has demonstrated that cannabinoids, the active ingredients of *Cannabis sativa*, trigger antitumor responses in different models of cancer. Most of these studies have been conducted with pure compounds, mainly THC. (Blasco-Benito et al 2018).
- Technion study showed THC did not produce the same effects on these cell lines as the whole-plant *Cannabis* extracts. (Baram et al, 2019)
- Whole-plant medical cannabis was more potent than pure THC in producing antitumor responses in cell culture and animal models of ER+/PR+, HER2+ and triple-negative breast cancer (Blasco-Benito et al 2018).
- These results suggest that standardized cannabis drug preparations, rather than pure cannabinoids, could be considered as part of the therapeutic armamentarium to manage breast cancer.
- Our whole plant extracts have been through Mass Spectrometry analysis – Mapping out 90% of cannabinoid/terpene profile

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