

# Supportive Care for people living with Brain Cancer

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COGNO

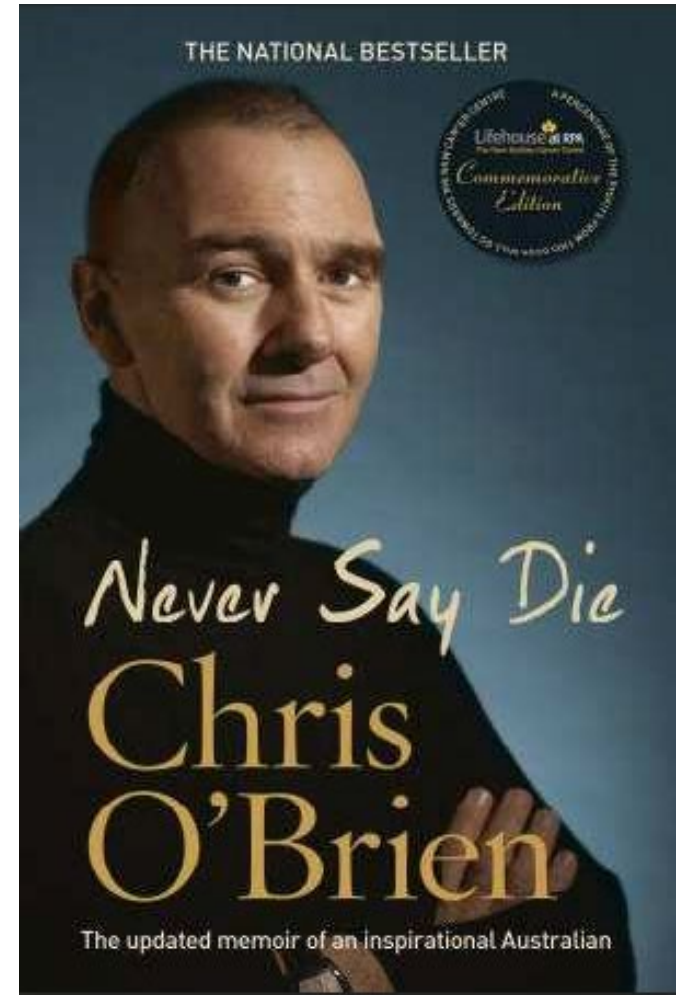
27<sup>th</sup> October 2019



# Disclosures

- Co-investigator on studies in medicinal cannabis funded by NSW health (CARE trial) and Bioceuticals
- I have no financial relationships with any companies.

# Prof Chris O'Brien AO



Director Sydney Cancer Centre 2003  
Diagnosed Nov 2006 - Deceased June 2009,  
aged 57  
10<sup>th</sup> Anniversary of his death this year from GBM

# My experience as a Clinician

- Working with patients and their carers with GBM and other brain cancers.
- Learning through clinic practice: one part of the complex puzzle of understanding the supportive care needs of patients



- Research opportunities in the Clinical Supportive Care space



- Searching for ways to address the unmet needs of patients and carers



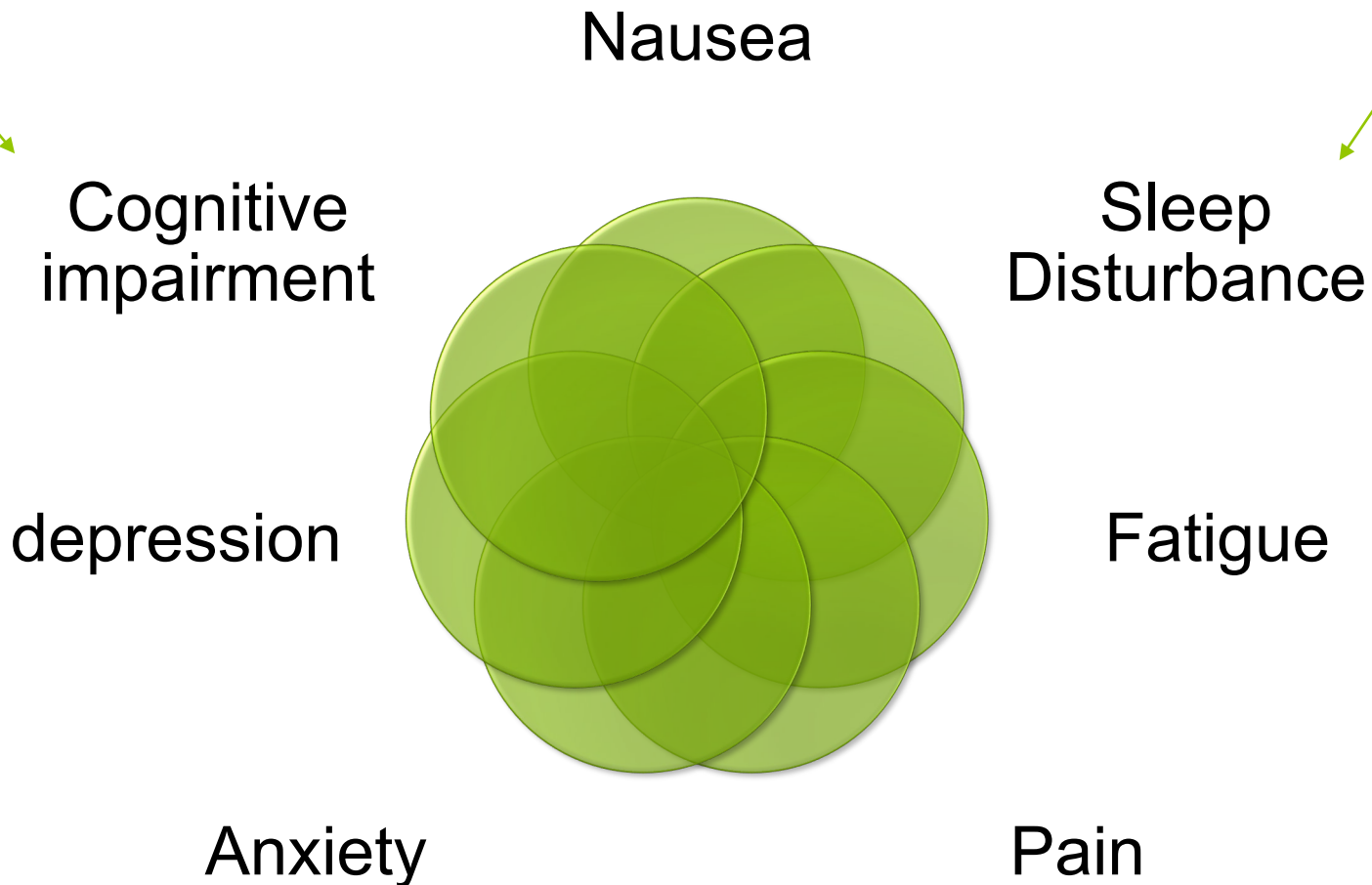
# Glioblastoma Multiforme (GBM)



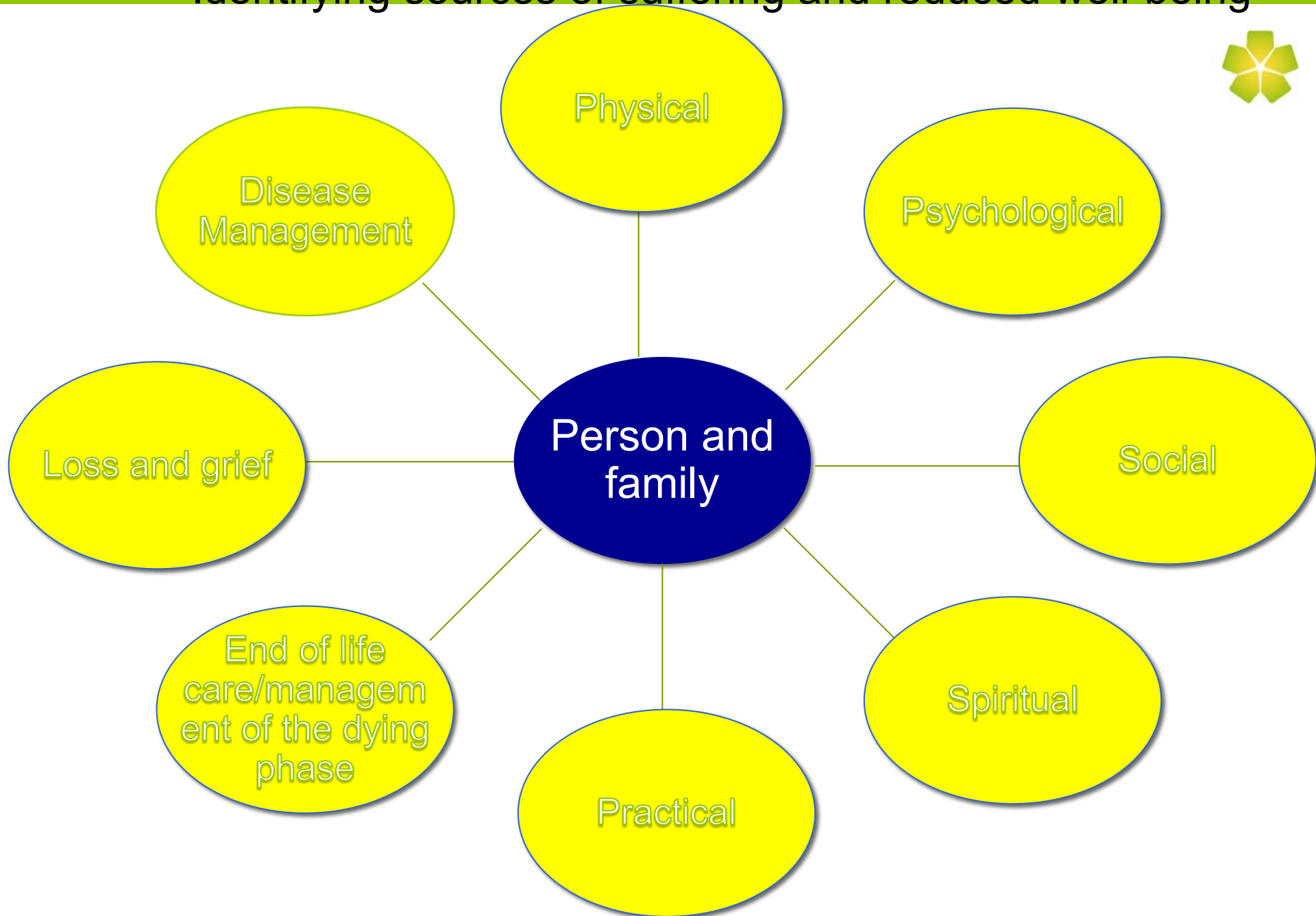
Estimated 2076 new cases of CNS cancers/yr in Australia... 1.3% of all cancers  
Approx 1500 will die/year. Survival rate of GBM at 5 yrs is 4.6% ACRF 2017



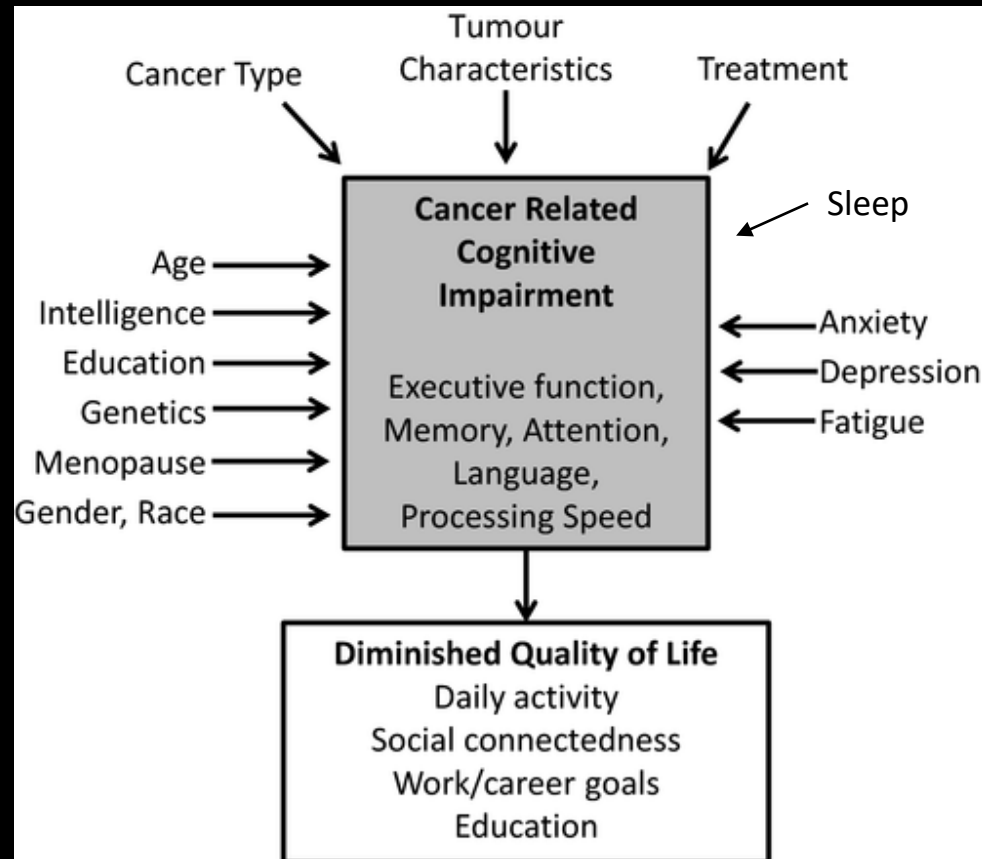
People with high grade Gliomas often have Symptom Clusters... we need to address the whole person.



# Identifying sources of suffering and reduced well-being



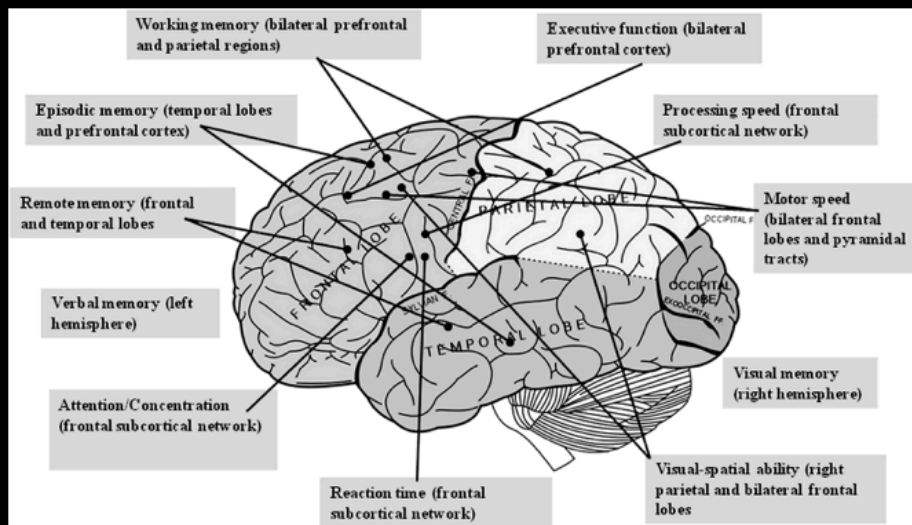
# What is known and unknown about cancer-related cognitive impairment (CRCI) in patients?





# Cancer related Cognitive impairment in the CNS cancer population

## Presentation of CRCI: Specific Cognitive complaints



"I have complete memory blocks"

"My mind feels like jello.."

"Some days I feel like a ditz"

"I cannot multi-task"

"I lose my place and attention when trying to read"

memory  
executive function  
processing speed  
and attention

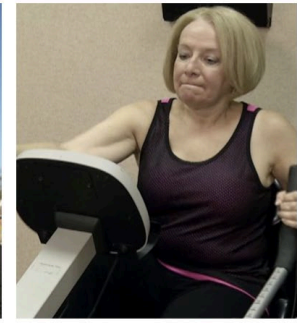
# Sleep Disturbance in the brain cancer population

- Sleep-wake disturbances occur in 15%–20% of the general population and 33%–57% of those with solid tumors, including brain.
- Sleep disturbance can impact on fatigue and cognitive function
- Steroids ( eg:dexamethasone ) and other medications can impact on sleep
- Multiple approaches to sleep disturbances in general cancer population being evaluated



# Exercise : the role in brain cancers

- maintain function
- improve function
- improve fatigue
- ??cognitive impairment



Exercise & Lifestyle &  
Nutrition

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# Role of Cannabis in patients with Brain cancer

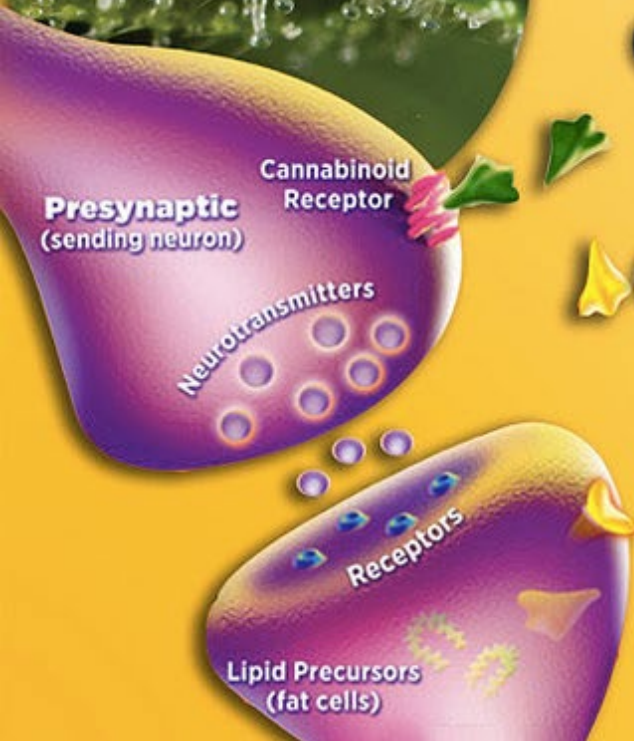
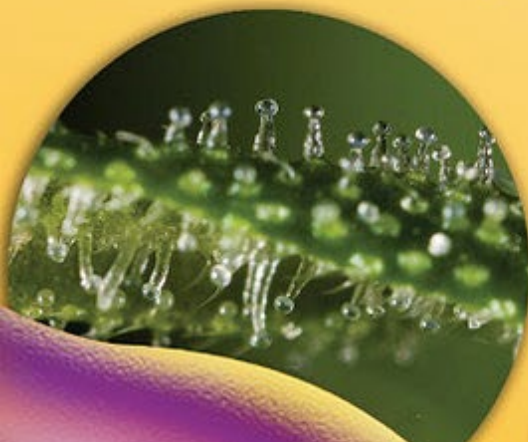


# The Human Endocannabinoid System

THC and CBN are known to "fit" like lock and key into network of existing receptors. The Endocannabinoid System exists to receive cannabinoids produced inside the body called "Anandamide" and "2-Arachidonyl-glycerol". Stimulating the ECS with plant-based cannabinoids restores balance and helps maintain symptoms.

CB1 receptors are concentrated in the brain and central nervous system but also sparsely populates other parts of the human body.

Receptors are found on cell surfaces



Tetrahydrocannabinol



Cannabidiol

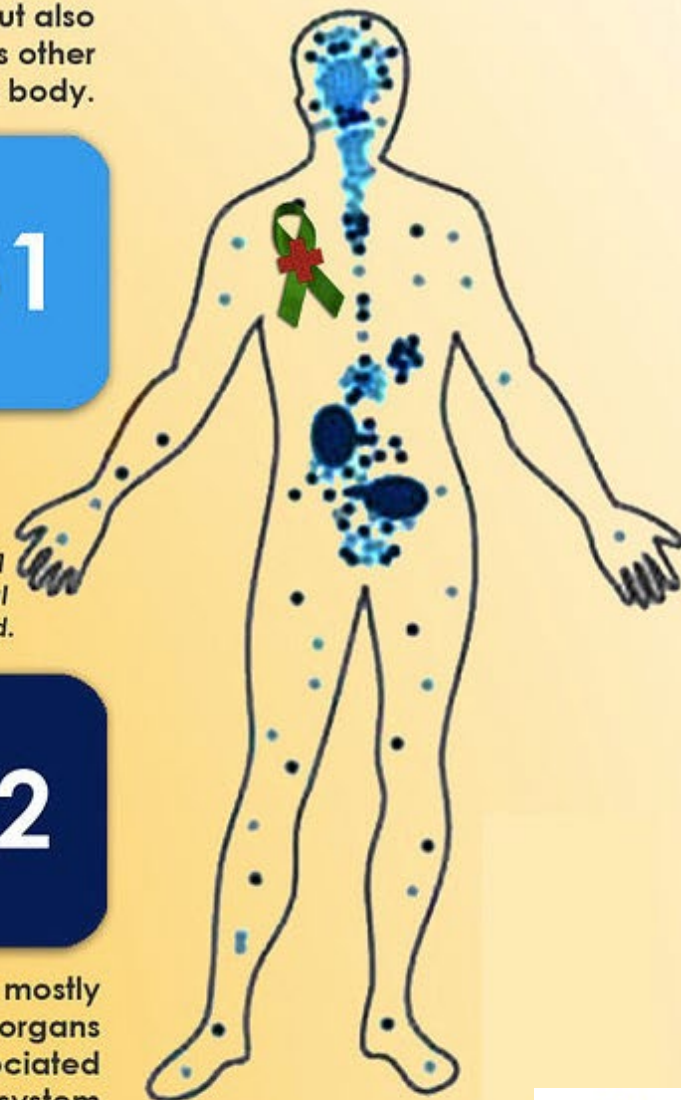
CBD does not directly "fit" CB1 or CB2 receptors but has powerful indirect effects still being studied.



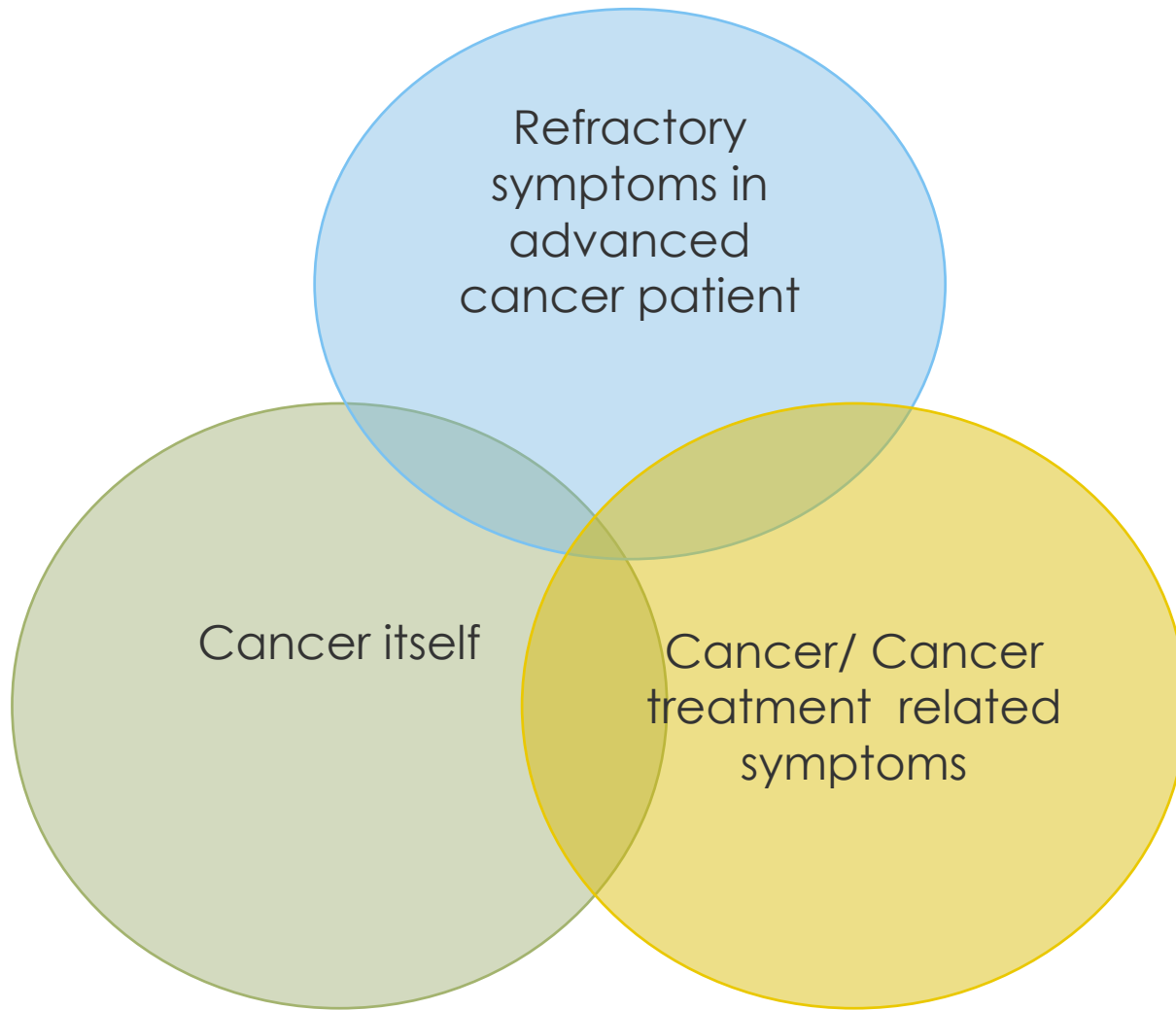
Cannabinol



CB2 receptors are mostly in the peripheral organs especially cells associated with the immune system.



# The most common reasons people ask about medicinal cannabis in the cancer space : my experience



# Can cannabis improve cancer related symptoms in advanced brain cancer?

Refractory  
symptoms in  
Advanced  
Cancer  
Patient



# Can Cannabis control my cancer?

Cancer itself





# A PHASE 2 RANDOMISED, DOUBLE BLIND CLINICAL TRIAL ASSESSING THE TOLERABILITY OF TWO DIFFERENT RATIOS OF MEDICINAL CANNABIS IN PATIENTS WITH GLIOBLASTOMA MULTIFORME (GBM).

## Investigators:

Lead Investigator:

Dr Janet Schloss

Co Investigators:

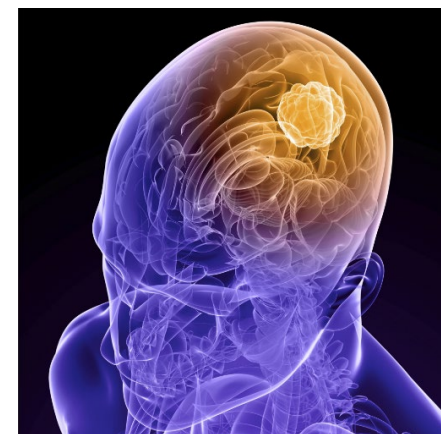
Justin Sinclair

A/Prof Judith Lacey

Prof David Sibbritt

Dr Amie Steel

Prof Charlie Teo



Study Centre: Centre for Minimally Invasive Neurosurgery, Prince of Wales Private Hospital, Randwick


Funding Body: FIT-Bioceuticals Pty Ltd

Protocol no: ACTRN12617001287325  
POW HREC: 18/028  
UTS HREC: ETH 18-2761  
Endeavour HREC: 20180821

# Where are we up to in the medical Fraternity? The example of palliative care

Review |  Open Access | 

## Systematic review and meta-analysis of cannabinoids in palliative medicine

Martin Mücke , Megan Weier, Christopher Carter, Jan Copeland, Louisa Degenhardt, Henning Cuhls, Lukas Radbruch, Winfried Häuser, Rupert Conrad

First published: 05 February 2018 | <https://doi.org/10.1002/jcsm.12273> | Cited by: 13

### Types of outcome measures

The study outcomes are summarized in the following section and in Table [1](#):

- i. **Efficacy**: responder (pain reduction  $\geq 30\%$ ), body weight, appetite, caloric intake, and nausea/vomiting (primary endpoints); sleeping dysfunction, fatigue, mood disorders, and health-related quality of life (secondary endpoints) at the end of each medication phase.
- ii. **Tolerability**: Number of patients, who discontinued the study because of adverse events; dizziness, mental health symptoms, and cognitive dysfunction.
- iii. **Safety**: Number of serious adverse; deaths during medication.

## Primary Objective:

- ❖ To investigate the **tolerability** of two different ratios of an oral administration of medicinal cannabis oil in GBM patients by specific quality of life questionnaires.

## Secondary Outcomes/Endpoints

- ❖ To **compare the effectiveness** of 1:1 CBD:THC to a 1:4 CBD:THC oil on progressive free survival in conjunction with standard treatment of GBM
- ❖ **Evaluate the absorption** of sublingual/oral administration of medicinal cannabis oil
- ❖ **Evaluate the safety** of oral administration of medicinal cannabis oil for GBM patients ( treatment related toxicity NCT CTC v4.0)
- ❖ **Investigating a dosage range** for oral administration of medicinal cannabis oil for this patient population for each ratio (1:1; 1:4).
- ❖ **Evaluate the impact of MC on Quality of life** and symptoms of patients
- ❖ **Evaluating the cost effectiveness** of using medicinal cannabis with standard treatment.

# Medicinal Cannabis and GBM: Protocol



Group 1: Standard treatment plus CBD:THC (1:1) (6mg/mL:6mg/mL)

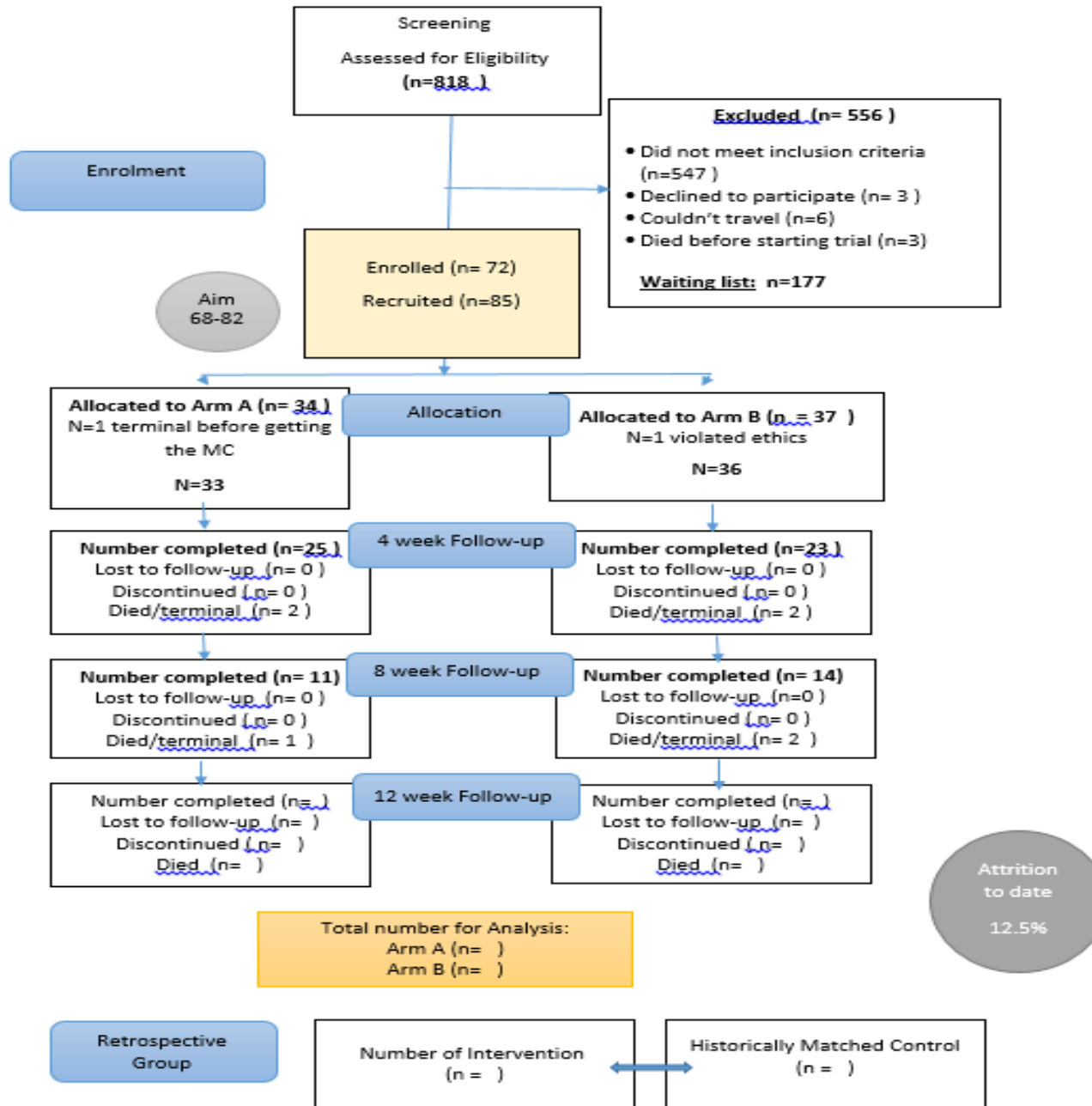
Group 2: Standard treatment plus CBD:THC (1:4) (3mg/mL:12mg/mL)

Dose: Based on Individual titration , the MC to be titrated up or down depending on ADL's. Monitored by Research nurse and team.

<u>Testing</u>	Time	Testing
	Baseline and 12 Weeks	MRI
	Week 0, 4, 8, 12	Pathology Bloods, Blood THC/CBD and metabolite testing via Mass Spec, FACT-Br, case study questions, clinical review
	Week 16, 36, 60 and 120	Telehealth follow up (after checking death registry)

Medicinal Cannabis and GBM Trial

Recruitment started end of November 2018 – this is current as of February 21, 2019



A woman in a blue long-sleeved shirt and black leggings is surfing inside the barrel of a large, curling blue wave. She is crouching low on her white surfboard, looking towards the camera with a focused expression. The water is a deep, vibrant blue, and the wave's crest is breaking over her, creating a tunnel-like effect. The background is a bright, overcast sky.

thankyou  
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