



Provincial Health Services Authority

Medical Cannabis for Cancer-Related Symptoms Clinical Trial: An aggregate n-of-1 study

Findings for Health Professionals

AUTHOR: Dr. Pippa Hawley

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Summary of conclusions

Thanks to the contributions of 91 study participants, we have found that medical cannabis oil may be worth considering as an option for symptom management for people with cancer, particularly those experiencing fatigue, sleep problems, anxiety or several symptoms at the same time.

Using the results of this study, we have made a list of clinical recommendations for use by patients and clinicians. These have been added to the [patient information on the BC Cancer website](#) and in a [new page in the section of the website tailored to health professionals throughout BC](#).

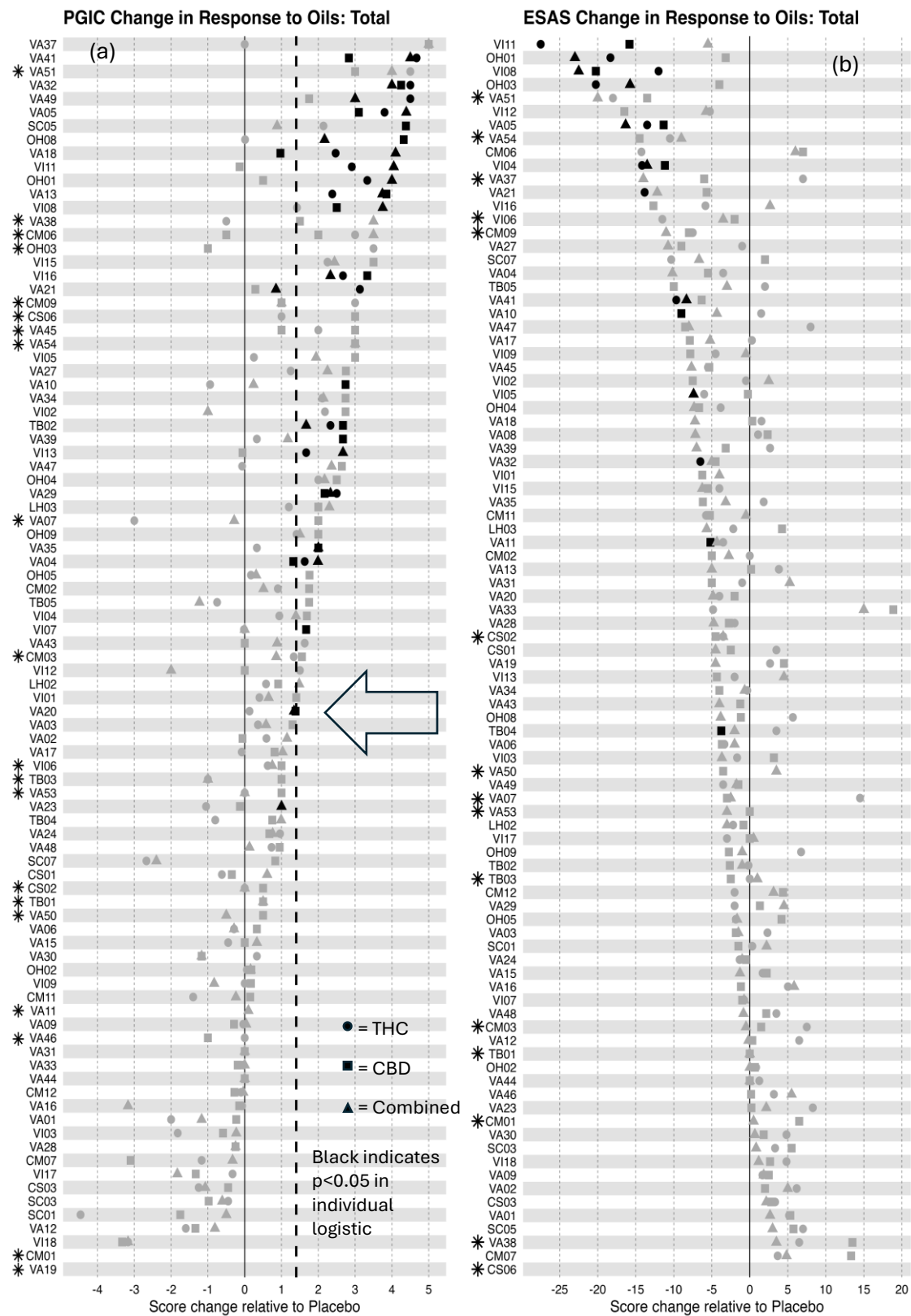
Conclusions:

1. There is an at least 50% chance that a person living with cancer-related symptoms will get a clinically meaningful benefit from at least one type of medical cannabis oil.
2. Side-effects from low doses of oil extracts are mild and resolve rapidly on dose reduction or discontinuation.
3. Though there may be clear differences in effects between oils in any one person, it is not possible to predict which kind of oil will be preferred by that person. Patients should be given the opportunity to try one of each of the three main types to determine if they respond or not, and if so, which is their preferred oil.
4. Four days was long enough to be able to tell what the effects of a single product would be, and to fine-tune the optimal dosing.
5. How medical cannabis works is more driven by the patient's personal endocannabinoid physiology than the kind of cancer or treatment they are on.
6. Reduction in tiredness, sleep disturbance and anxiety are the three symptoms that contribute most to overall improvement, regardless of which symptom is most troublesome, but reductions were also seen in night sweats, drowsiness, pain, loss of

appetite and depression. For very anxious people there was also a significant improvement in breathlessness, and improvement of nausea also contributed in the pain subgroup.

7. Based on the doses chosen by participants by the end of their last treatment cycle, a starting dose of 2.5mg of either THC, CBD, or the two together (i.e. 2.5mg total) is a reasonable starting dose, and a 4-8 hourly schedule can be suggested, expecting most patients to take it three times a day for continuous symptoms. Those with sleep disturbance may benefit from a higher single dose at bedtime but should still start with the 2.5mg dose and work up according to effect.
8. THC and CBD have independent effects, and when you add them together the effects are twice as strong, so the balanced oils should be dosed according to the total of THC and CBD added together.
9. There were more side-effects from mostly THC oils than balanced or mostly CBD oils, but despite this about a third of people still preferred the THC oil over the other two kinds.
10. There was no difference in effects between oils from the three different suppliers, suggesting that these conclusions apply to products of similar strengths from any approved producer.
11. There was also no difference in response rate according to age, sex or cancer stage, suggesting that these conclusions apply to all adult cancer patients at all stages of disease, including in survivorship.
12. The patient-centred study design allowed for highly statistically significant outcomes to be identified from a relatively small number of participants in a very efficient manner and should be used more widely where possible.
13. Symptom severity scores are not as good a way to tell if a treatment helps or not as asking patients if they feel better, but they do add contextual information that is helpful in exploring how the treatment worked.

Key Results



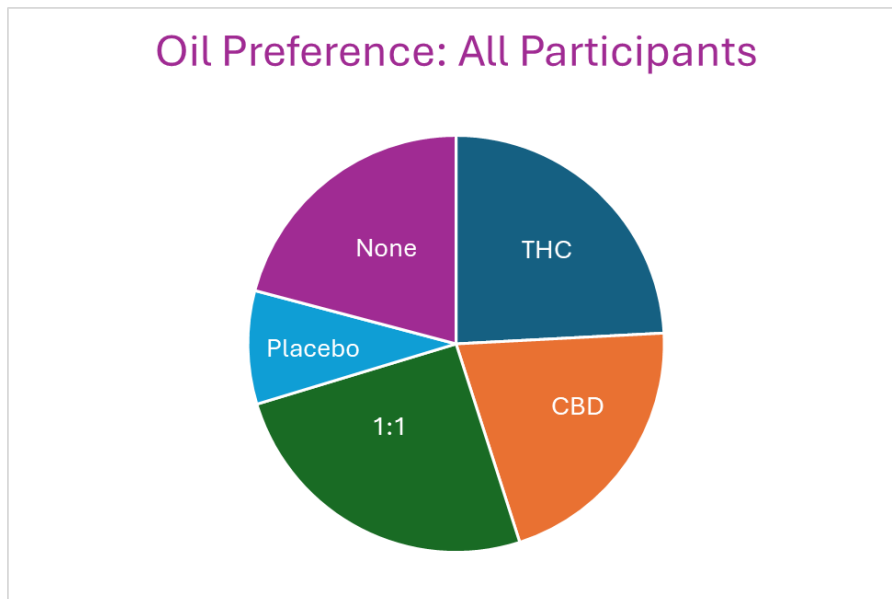
The chart on the left shows the results from each participant's global impression of change on their own line. The black line is their response to placebo, and the dotted line indicates a 20% improvement on top of that, which was our target for meaningful benefit. The three symbols represent the difference in response between that oil and the placebo: squares are for THC, the circles for CBD, and triangles for the combination. Any symbols to the right of the dotted line are considered clinically meaningful. Any to the left were either less than 20% better than placebo, the same, or worse. The arrow indicates the divide between responders to at least one oil (above the arrow) and those who did not meet the 20% better threshold for improvement with any oil (below the arrow).

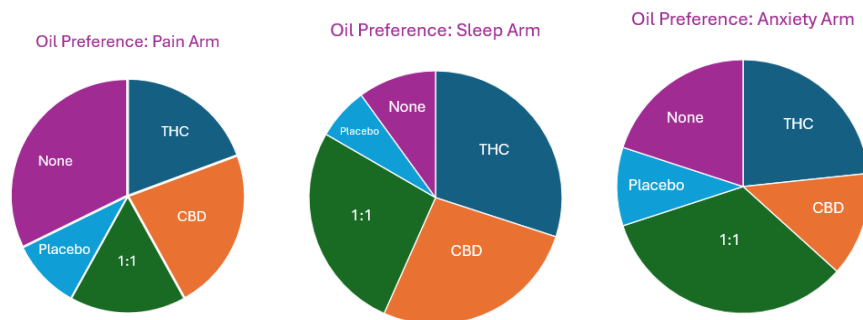
The chart on the right shows the total symptom score for the participants, in the same order as for the PGIC on the left. Symbols to the left of the line indicate they were less severe than with placebo, any to the right being worse than with placebo. As with the PGIC, the best and worst extract for each participant was split evenly between the three kinds.

For both charts, for those that completed 2 or 3 cycles the darker symbols show that there was a statistically significant difference between the extract and placebo in that individual participant. Those marked with a * only completed one cycle and had clinically significant outcomes but were not subject to statistical analysis individually.

Oil Preference

Participants were asked which oil they preferred at the end of the study, and the results are shown in the pie charts. These correspond well with the results from the PGIC and the symptom scores, confirming the validity of the PGIC and symptom score results.





Pooled Group Analysis

The tables below show the statistical significance test results for all the participants' PGIC and total symptom severity ratings combined, which is a necessary analysis in order to compare with traditionally designed parallel group studies where each person only gets to try one extract. The smaller a p-value, the less likely it is that the difference seen is due to chance, and the p-values for superiority of all three extracts over placebo were as small as you can get. The placebo effect had a high level of significance, indicating that the blinding of the oils worked well. Though the magnitude of difference between placebo oil and the extracts may look small, remember that this is *on average*, including all the people who responded well to the oils AND those that didn't.

The lack of significant difference in outcomes between the first cycle and the second or third for those that completed more than one cycle is included to demonstrate why those that only completed 1 cycle could be included in the pooled analysis. For the symptom severity ratings there was an increase in effect in the second and third cycles, suggesting that it was worthwhile having participants take more time beyond the first 4 days to optimize their dosing.

Predictors	Estimates of change	Standard Error	95% Confidence Intervals	P-value
Placebo (Intercept)	2.03	0.18	1.67 – 2.39	<0.001
Additional change Combined extract	1.14	0.26	0.62 – 1.65	<0.001
Additional change CBD	1.06	0.26	0.55 – 1.56	<0.001
Additional change THC	1.06	0.25	0.57 – 1.54	<0.001
Cycle 2 vs cycle 1	0.04	0.07	-0.10 – 0.18	0.607
Cycle 3 vs cycle1	0.07	0.08	-0.09 – 0.23	0.384

Table 1. PGIC pooled analysis

Predictors	Estimate of change	Standard Error	95% Confidence intervals	p-value
Placebo (Intercept)	-5.99	1.23	-8.40 – -3.58	<0.001
Additional change Combined extract	-2.83	0.68	-4.16 – -1.51	0.002

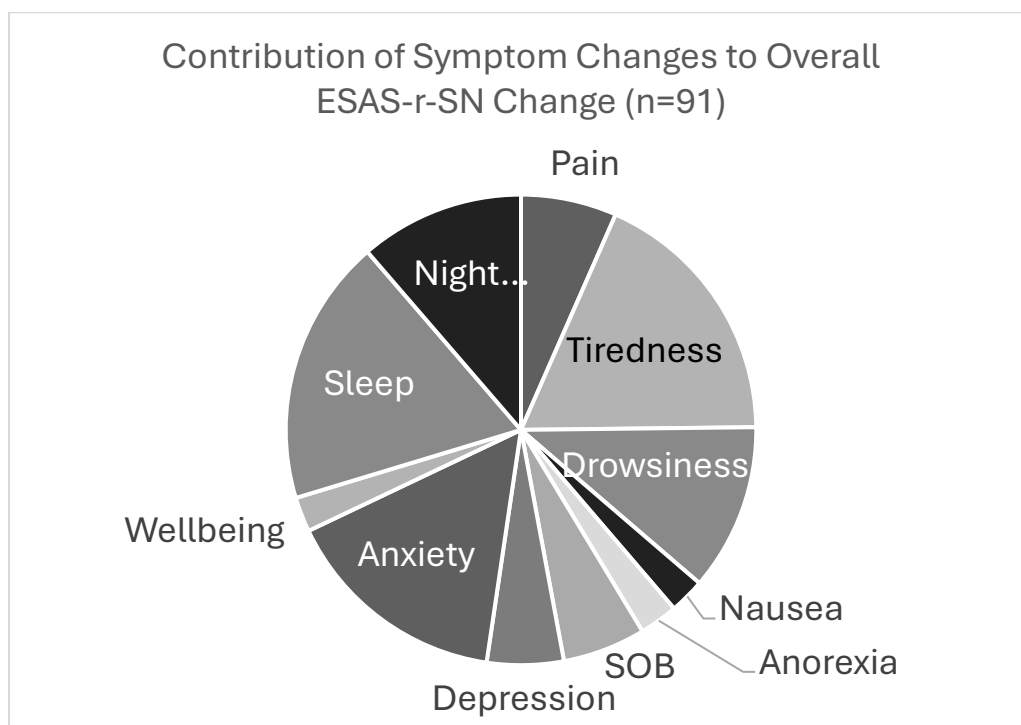
Additional change CBD	-1.68	0.74	-3.14 – -0.23	0.024
Additional change THC	-2.16	0.69	-3.52 – -0.80	<0.001
Cycle 2 vs cycle1	-2.37	0.47	-3.29 – -1.45	<0.001
Cycle 3 vs cycle 2	-2.41	0.55	-3.49 – -1.34	<0.001

Table 2. ESAS-r-SN pooled analysis

The combined oil showed a trend to being the best-performing between the three extracts in both PGIC and symptom ratings, but the differences were small and not statistically significant.

Relative Contributions of Symptoms to Improvement

These pie charts show the proportion of each symptom's contribution to the overall improvement in each symptom subgroup, which had equal numbers (30-31 participants each). The symptoms are in the same order so you can see which symptom was which across the charts where the text would have been too small to fit in that "slice".





Recommendations to Health Care Providers, Regulators and Producers:

Patients without contraindications to cannabinoid therapy should be given the opportunity to try one of each of the three main types of extract to determine if they are a responder or not; and if a responder, to determine which is their preferred oil.

- Combined THC and CBD
- CBD-predominant
- THC- predominant

To facilitate this, medical cannabis suppliers should be encouraged to provide “sample packs” of small amounts of the three kinds of extract for patients to try at low cost before choosing whether to continue with one extract or not.

Patients can expect an about a 1 in 2 chance of finding at least one kind of extract that will help reduce their symptoms. This is a better change than with many other symptom-relieving medications.

Medical cannabis can treat multiple symptoms simultaneously. Even if the main symptom does not change much individually, patients often derive worthwhile benefits from improvements in multiple other symptoms, which helps them feel better overall.

As with most symptom-relieving drugs, mild side-effects are expected, but a start low-go slow approach is safe and well-tolerated. Most patients who do find one helpful will be able to continue to benefit from an extract by reducing the dose if/when side-effects occur.