

ORIGINAL ARTICLE

Oral THC:CBD cannabis extract for refractory chemotherapy-induced nausea and vomiting: a randomised, placebo-controlled, phase II crossover trial

P. Grimison^{1,2*}, A. Mersiades², A. Kirby², N. Lintzeris³, R. Morton², P. Haber⁴, I. Olver⁵, A. Walsh², I. McGregor⁶, Y. Cheung², A. Tognela⁷, C. Hahn⁸, K. Briscoe⁹, M. Aghmesheh¹⁰, P. Fox¹¹, E. Abdi¹², S. Clarke¹³, S. Della-Fiorentina¹⁴, J. Shannon¹⁵, C. Gedye¹⁶, S. Begbie¹⁷, J. Simes² & M. Stockler²

¹Department of Medical Oncology, Chris O'Brien Lifehouse, Sydney; ²NHMRC Clinical Trials Centre, Sydney; ³Drug and Alcohol Services, South Eastern Sydney Local Health District, Randwick; ⁴Sydney Medical School, University of Sydney, Sydney; ⁵Faculty of Health and Medical Sciences, University of Adelaide, Adelaide; ⁶Lambert Institute for Cannabinoid Therapeutics, University of Sydney, Sydney; ⁷Macarthur Cancer Therapy Centre, Campbelltown Hospital, Campbelltown; ⁸Consumer Partnership Council, Chris O'Brien Lifehouse, Sydney; ⁹Mid North Coast Cancer Institute, Coffs Harbour; ¹⁰Department of Medical Oncology, Wollongong Hospital, Wollongong; ¹¹Central West Cancer Care Centre, Orange Health Service, Orange; ¹²E.A. Abdi Cancer Care and Haematology Unit, The Tweed Hospital, Tweed Heads; ¹³Northern Cancer Institute, Sydney; ¹⁴Southern Highlands Cancer Centre, Bowral; ¹⁵Nepean Cancer Care Centre, Nepean Hospital, Sydney; ¹⁶Department of Medical Oncology, Calvary Mater Newcastle, Waratah; ¹⁷Mid North Coast Cancer Institute, Port Macquarie, Australia



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Background: This multicentre, randomised, double-blinded, placebo-controlled, phase II/III trial aimed to evaluate an oral THC:CBD (tetrahydrocannabinol:cannabidiol) cannabis extract for prevention of refractory chemotherapy-induced nausea and vomiting (CINV). Here we report the phase II component results.

Patients and methods: Eligible patients experienced CINV during moderate-to-high emetogenic intravenous chemotherapy despite guideline-consistent antiemetic prophylaxis. Study treatment consisted of one cycle of 1–4 self-titrated capsules of oral THC 2.5 mg/CBD 2.5 mg (TN-TC11M) three times daily, from days –1 to 5, and 1 cycle of matching placebo in a crossover design, then blinded patient preference for a third cycle. The primary end point was the proportion of participants with complete response during 0–120 h from chemotherapy. A total of 80 participants provided 80% power to detect a 20% absolute improvement with a two-sided *P* value of 0.1.

Results: A total of 81 participants were randomised; 72 completing two cycles were included in the efficacy analyses and 78 not withdrawing consent were included in safety analyses. Median age was 55 years (range 29–80 years); 78% were female. Complete response was improved with THC:CBD from 14% to 25% (relative risk 1.77, 90% confidence interval 1.12–2.79, *P* = 0.041), with similar effects on absence of emesis, use of rescue medications, absence of significant nausea, and summary scores for the Functional Living Index-Emesis (FLIE). Thirty-one percent experienced moderate or severe cannabinoid-related adverse events such as sedation, dizziness, or disorientation, but 83% of participants preferred cannabis to placebo. No serious adverse events were attributed to THC:CBD.

Conclusion: The addition of oral THC:CBD to standard antiemetics was associated with less nausea and vomiting but additional side-effects. Most participants preferred THC:CBD to placebo. Based on these promising results, we plan to recruit an additional 170 participants to complete accrual for the definitive, phase III, parallel group analysis.

Trial Registration: Australian New Zealand Clinical Trials Registry ACTRN12616001036404; <https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=370473&isReview=true>.

Key words: antiemetic, cannabidiol, cannabis, chemotherapy-induced nausea and vomiting, randomised trial

INTRODUCTION

Despite adherence to the Multinational Association of Supportive Care in Cancer antiemetic guidelines for chemotherapy of high or moderate emetic risk, recent

observational cohort studies report that 46%–57% experience significant nausea, and 9%–37% experience vomiting.^{1–3} Chemotherapy-induced nausea and vomiting (CINV) is triggered by a multitude of receptors for neurotransmitters including serotonin, dopamine, substance P, and potentially the cannabinoid CB1 receptor.^{4–6}

Limited evidence suggests that medicinal cannabis in the form of tetrahydrocannabinol (THC) may reduce CINV, and addition of cannabidiol (CBD) may improve efficacy and tolerance.⁷ Prior studies evaluating smoked cannabis, synthetic oral THC (Dronabinol), or THC analogue (Nabilone)

*Correspondence to: Dr. Peter S. Grimison, Department of Medical Oncology, Chris O'Brien Lifehouse, PO Box M5, 119–143 Missenden Road, Camperdown, NSW 2050, Australia. Tel: +61-2-85140146

E-mail: peter.grimison@lh.org.au (P. Grimison).

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medicines showed limited efficacy, were underpowered, or did not compare cannabis with modern antiemetic regimens.^{5,6} Furthermore, THC-only medications can have a range of dose-dependent side-effects including dizziness, sedation, anxiety, and psychomotor impairment.^{5,8} None of these cannabinoid products are routinely prescribed for CINV prophylaxis, conceivably because of concerns regarding poor tolerability, limited accessibility, perceived insufficient evidence for efficacy, and effective alternatives.⁴ Cannabis extracts containing both THC and CBD offer key advantages over alternate cannabinoids. CBD can counteract the negative effects of THC on the central nervous system, and has inherent anxiolytic properties.^{7,9} A small pilot double-blind randomised trial of nabiximols, a buccally absorbed THC:CBD formulation in a 1:1 ratio, for the secondary prevention of CINV demonstrated activity, with an improvement in complete response from 22% to 71%, high patient acceptability, and manageable side-effects.¹⁰ These results provided the rationale for our study.

This randomised, double-blind, placebo-controlled, phase II/III trial aims to evaluate an oral THC:CBD cannabis extract in preventing refractory CINV over multiple chemotherapy cycles. The final analysis of the trial will determine the primary outcome for 250 participants, representing 80 participants from a phase II crossover component and 170 participants from a phase III parallel component. Here we report results from the phase II crossover component of the trial, which determined that the phase III trial with an additional 170 patients could continue.

METHODS

Patients

Details of the study protocol have been previously published.¹¹ Study schema is shown in Figure 1.

Eligible patients were aged ≥ 18 years, with any malignancy of any stage who were receiving intravenous chemotherapy of moderate or high emetogenic risk, were scheduled to receive at least two more consecutive cycles, and had refractory CINV (defined as emesis, and/or nausea of moderate severity on a 5-point rating scale, and/or requiring use of rescue medications) in earlier chemotherapy cycles despite guideline-consistent antiemetic prophylaxis consisting of corticosteroids, a 5-HT₃ antagonist, and an NK-1 antagonist with or without olanzapine where indicated. Patients were excluded if they had an Eastern Cooperative Oncology Group (ECOG) performance status of

>2 ; a contraindication to medicinal cannabis such as unstable cardiovascular disease, substance use disorder, or significant mental health disorder; were experiencing disease-related nausea and vomiting; were receiving concomitant oral chemotherapy; or had received/were planned to receive radiotherapy to the brain or gastrointestinal tract during the study period. Participants were required to abstain from extraneous cannabis products prior to and during the trial, to provide a urine sample negative for cannabinoids within 30 days prior to trial enrolment, and were not permitted to drive during and for 3 days following the last ingestion of study treatment due to state legislation. All participants provided written informed consent. The protocol and all amendments were approved by the Human Research Ethics Committee at all participating centres. The trial is registered in the Australian New Zealand Clinical Trials Registry (Registration No. ACTRN12616001036404).

Trial design and intervention

The crossover phase II component of this multicentre randomised, double-blind, placebo-controlled trial was conducted in New South Wales, Australia. Using a central web-based randomisation system, participants were randomised in a 1:1 ratio to receive either oral THC:CBD or matching placebo starting the day prior to chemotherapy (day -1), and continuing three times per day on the first day of chemotherapy (day 1) through to midday on day 5. Participants were able to gradually self-titrate dose of study treatment (each capsule containing 2.5 mg THC and 2.5 mg CBD, or matching placebo) up or down based on experience of CINV or side-effects, from an initial dose of 1 capsule 24 h before chemotherapy to a standard dose of 2 capsules, up to a maximum of 4 capsules (see [supplementary Table S1](https://doi.org/10.1016/j.annonc.2020.07.020), available at <https://doi.org/10.1016/j.annonc.2020.07.020>). For cycle A (the initial trial cycle), participants received either oral THC:CBD or placebo. For cycle B, (the second trial cycle), participants received the alternative treatment. For cycle C (the third trial cycle), where relevant, participants received their 'preferred' treatment with the blind maintained. Unblinding after cycle C allowed participants to receive ongoing THC:CBD, following completion of the study, if they had perceived a benefit and were continuing the same chemotherapy regimen. In addition to study treatment, all participants received the guideline-recommended CINV prophylaxis including rescue medications in the event of vomiting or distress by nausea.^{12–14}

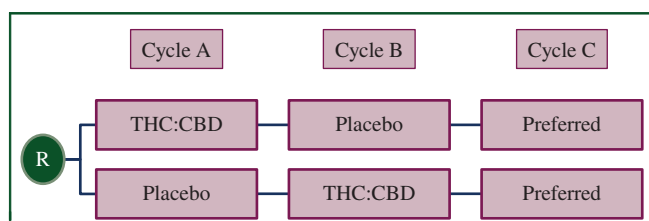


Figure 1. Study schema for crossover phase II component of trial (planned $N = 80$).

R, randomised; CBD, cannabidiol; THC, tetrahydrocannabinol.

Assessments

Participants underwent clinical assessment on days -1 and 8 of each cycle, and between 30 and 42 days after the end of study treatment. 'Day 1' represents the first day of the chemotherapy cycle, and 'day -1 ' is one day prior to 'day 1'. Self-reported experience of nausea and vomiting, use of rescue medications, and dose of study treatment were recorded in a patient diary for days -1 to day 6 of each cycle. Quality of life was assessed by the Functional Living

Index-Emesis (FLIE)¹⁵ and Assessment of Quality of Life-8 dimensions (AQOL-8D) multiattribute utility instrument¹⁶ questionnaires at baseline, day -1 of each cycle (relating to the previous cycle), and end of treatment. Following completion of cycle B, participants were asked to consider both control of nausea and vomiting as well as other side-effects from medications, and nominate an overall preference for the regimen administered during cycle A, cycle B, or no preference. There was daily contact with trial staff on the days of study treatment to ensure appropriate use of study medication, accuracy of the patient diary, recording of a structured checklist of cannabinoid-specific adverse events, and advice on management of adverse events.

Objectives and end points

The primary end point for the crossover phase II component of the trial was the difference between cycles A and B in the proportions of participants with complete response, defined as no vomiting and no use of rescue medications during the overall phase of treatment (0–120 h), as recorded in the patient diary. Secondary end points include differences for self-reported ‘complete response’, ‘no emesis’, ‘no clinically significant nausea’, which is defined as nausea <2 on a 10-point scale, and ‘no use of rescue medications’ during the acute (0–24 h), delayed (24–120 h), and overall phase (0–120 h) of chemotherapy; summary scales (nausea and vomiting) of the FLIE with 5-day recall, and individual items, domains, and utilities of the AQOL-8D. Adverse events were recorded according to the NCI Common Terminology Criteria for Adverse Events version 4.03,¹⁷ and a structured checklist of cannabinoid-specific adverse events.¹⁸ Acceptability was recorded by study drug adherence (patient diaries and pill counts), and patient preference between cycles A and B.

Statistical analyses

The sample size of 80 participants for the phase II crossover component of the trial (40 per arm), randomising participants to either study drug followed by placebo or placebo followed by study drug, has 80% power at a two-sided significance level of 10% to detect a 20% increase in complete response from 22% in the placebo group to 42% in the cannabis group during cycles A and B of chemotherapy. This sample size allows drop-out/ineligibility rate of 20%. Only participants who have received both interventions have been included in the efficacy analyses. Data on safety were sourced from the safety population (all participants who received ≥ 1 dose of study drug). The primary analysis was a comparison of the proportion of participants with complete response between the two treatment arms during two overall phases of treatment (0–120 h) of cycles A and B, using McNemar’s test to account for the within-patient correlation. Continuous outcomes were analysed with a linear model, and accounted for the correlation within a participant. All tests used a two-sided significance level of 10%. Secondary analyses have not been adjusted for multiple comparisons. Analyses were completed using SAS 9.4

Table 1. Baseline characteristics (N = 78)

Characteristic	n (%)
Age (years)	
18–29	1 (1)
30–49	23 (29)
50–69	49 (63)
≥ 70	5 (6)
Sex	
Female	61 (78)
Male	17 (22)
Previous cannabis use	
No	45 (58)
Yes	33 (42)
Alcohol use (average days per week)	
0	44 (56)
1	16 (21)
>1	18 (23)
History of motion sickness	
No	57 (73)
Yes	21 (27)
History of nausea during pregnancy	
No	22 (41)
Yes	32 (59)
ECOG Performance Status	
0	39 (50)
1	36 (46)
2	3 (4)
Malignancy	
Breast	26 (33)
Colorectal	10 (13)
Lung	9 (12)
Oesophageal/gastric	7 (9)
Gynaecological	7 (9)
Pancreatic	7 (9)
Haematological	3 (4)
Testicular	3 (4)
Other	6 (8)
Treatment intent	
Curative	43 (55)
Palliative	35 (45)
Chemotherapy	
First-line	55 (71)
Second-line	10 (13)
Third-line or greater	13 (16)
Chemotherapy regimen	
Doxorubicin + cyclophosphamide	20 (26)
FOLFOX \pm biological	13 (17)
Cisplatin based	12 (15)
FOLFIRINOX	6 (8)
Other	27 (35)
Emetogenic risk	
High	35 (45)
Moderate	43 (55)
Background antiemetic prophylaxis	
Steroid	78 (100)
5-HT ₃ antagonist	78 (100)
NK-1 antagonist	62 (79)
Olanzapine	3 (4)

(SAS Institute Inc., Cary, NC, USA). In accordance with the study protocol, the results of the within-patient crossover comparison analyses for the phase II crossover component were provided to the Independent Data Safety Monitoring Committee (IDSMC) with study investigators and trial management committee remaining blind to study results, and only released after the IDSMC decided to proceed from the phase II crossover component to the phase III parallel trial component. The results of the between-patient parallel comparison analyses remain blinded to the IDSMC.

RESULTS

Patients

A total of 81 participants were randomised from 10 sites between December 2016 and June 2019. Baseline characteristics of the 78 participants who did not withdraw consent were as follows: mean age of 55 years (range 29–80 years); typically female with good ECOG performance status (0 or 1); or typically receiving first-line chemotherapy for breast, colorectal, or lung cancer with either curative or palliative intent (Table 1). A total of 72 participants completed both cycles A and B of treatment, and were eligible for the efficacy analyses. Of the nine participants excluded from the primary efficacy analyses, three withdrew consent or had no data, five had only completed cycle A, and one had died (Figure 2); 68 participants had complete quality of life data. The typical number of capsules

[median (interquartile range)] taken per dose was 2 (1–3) for THC:CBD, equating to 5 mg THC and 5 mg CBD tds, and was 3 (2–4) for placebo.

Efficacy

The addition of THC:CBD to guideline-consistent anti-emetics during chemotherapy increased the proportion of participants with complete response during the overall phase of treatment (0–120 h) from 14% to 25% [relative risk (RR) 1.77, 90% confidence interval (CI) 1.12–2.79, $P = 0.041$] compared with placebo, with no evidence of a difference in efficacy for participants who received THC:CBD followed by placebo or the reverse order (P value for carry-over effect = 0.29; Table 2). There were similar effects for proportions of participants with no emesis, no use of rescue medications, no significant nausea, and complete response

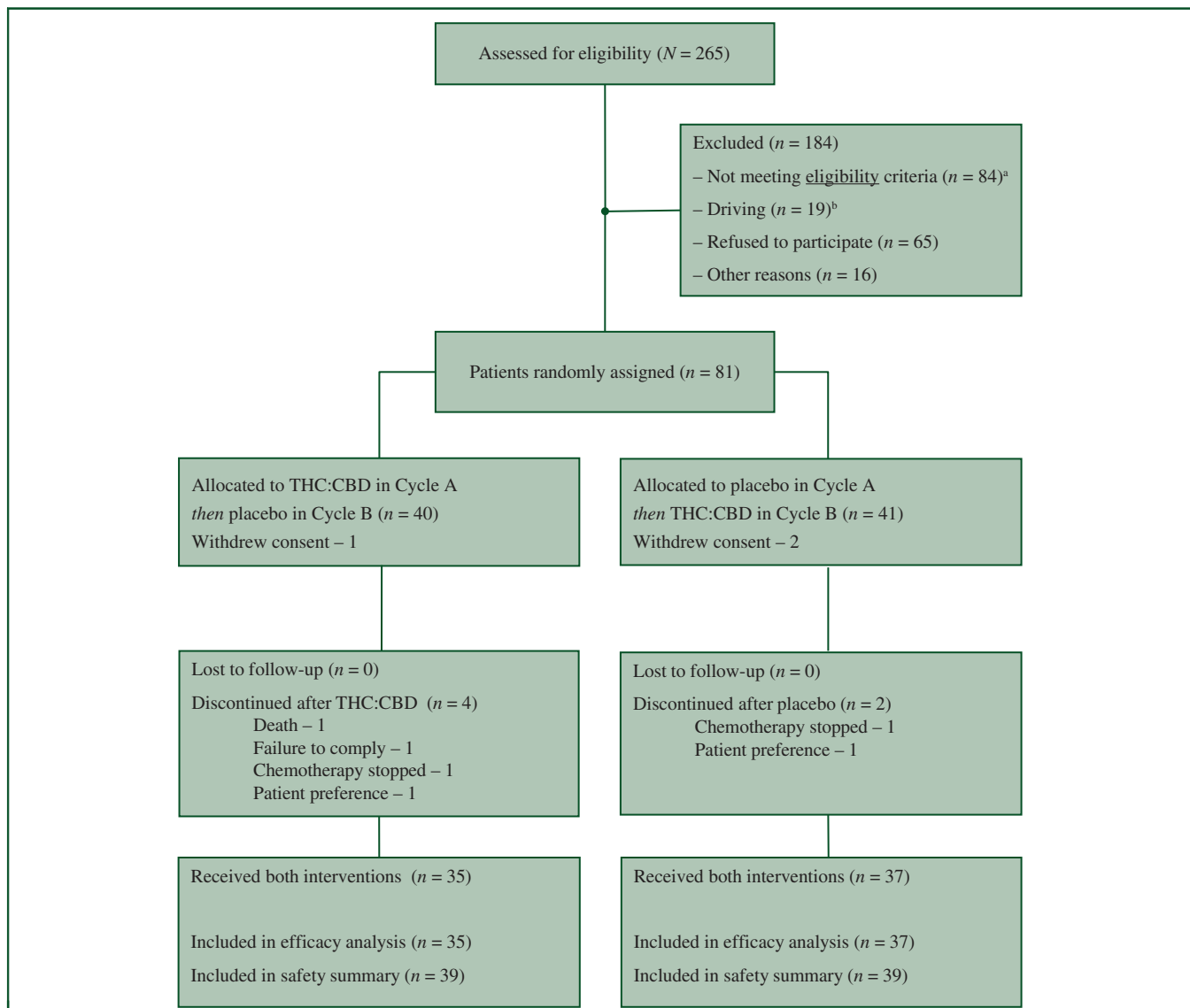


Figure 2. CONSORT diagram.

CBD, cannabidiol; THC, tetrahydrocannabinol.

^aMost common reasons for not meeting eligibility criteria: contraindication to cannabinoid treatment ($n = 15$), <2 cycles of chemotherapy remaining ($n = 11$), use of cannabis or cannabinoid-based medications within 30 days of study entry and/or unwilling to abstain for the duration of the study ($n = 10$).

^bDriving: Unwilling to avoid driving or operating machinery during and for 72 h after taking study medication.

Table 2. Efficacy of THC:CBD versus placebo during 0–120 h, within-patient comparisons between cycles A and B (N = 72)

Outcome	THC:CBD	Placebo	Absolute difference (90% CI)	Relative risk (90% CI)	P*
Complete response, n (%)	18 (25)	10 (14)	11% (3 to 19)	1.8 (1.1 to 2.8)	0.04
No vomiting, n (%)	50 (69)	41 (57)	12.5% (2 to 23)	1.2 (1.0 to 1.4)	0.05
No use of rescue medications, n (%)	20 (28)	11 (15)	12.5% (3 to 22)	1.8 (1.1 to 2.8)	0.04
No significant nausea (score <2), n (%)	15 (21)	7 (10)	11% (4 to 19)	2.0 (1.2 to 3.4)	0.03
Complete response and no significant nausea, n (%)	9 (13)	4 (6)	7% (0.2 to 14)	2.1 (0.96 to 4.8)	0.12
Mean number of vomits per day, mean ± SD	0.2 ± 0.0	0.6 ± 0.2	−0.4 (−0.7 to −0.2)		0.003
Maximum number of vomits per day, mean ± SD	0.5 ± 0.1	1.4 ± 0.3	−0.8 (−1.2 to −0.4)		0.001
Mean nausea score ^a , mean ± SD	3.2 ± 0.2	4.7 ± 0.2	−1.4 (−1.8 to −1.0)		<0.001
Maximum nausea score ^a , mean ± SD	4.3 ± 0.3	6.1 ± 0.3	−1.8 (−2.3 to −1.2)		<0.001

CBD, cannabidiol; CI, confidence interval; SD, standard deviation; THC, tetrahydrocannabinol.

^a Scale 0–10. Higher score indicates worse nausea.

* P value from a model without the carry-over effect. No significant period effect for comparisons (defined as a change from cycle 1 to cycle 2). No significant carry-over effect for comparisons (defined as no residual effect of the treatment received in the first cycle).

with no significant nausea. There was also a statistically significant reduction in the mean and maximum number of vomits per day, and self-reported mean and maximum nausea scores.

Adverse events

Grade 3 or 4 adverse events occurred in 14 participants while receiving THC:CBD, and 10 participants while receiving placebo during cycles A and B (Table 3). Serious adverse events occurred in five participants while receiving THC:CBD and seven participants while receiving placebo during cycles A and B (Table 3). All grade 3 or 4 and serious adverse events were attributed to background chemotherapy, disease, or other medical conditions, and none to study treatments.

Self-reported cannabinoid-related adverse events

Self-reported moderate-to-severe cannabinoid-related adverse events occurred in 22 participants (31%) while receiving THC:CBD, compared with 5 (7%) while receiving placebo (Table 4). The most common moderate-to-severe

cannabinoid-related adverse events were sedation, dizziness, and disorientation. Anxiety was uncommon, and no moderate or severe hallucinations or palpitations were reported.

Patient preference

At the completion of cycle B, 60 of the 72 (83%) participants who completed the study reported a preference for THC:CBD, and 11 of 72 participants (15%) reported a preference for placebo (P < 0.001). One participant reported no preference.

Self-reported quality of life

Data for both cycles A and B were available for 68 participants. The addition of THC:CBD to guideline-consistent antiemetics during chemotherapy was associated with reduced impact of CINV on daily life in both the nausea domain (mean difference 20.9 on a 100-point scale, P < 0.001) and the vomiting domain (mean difference 11.9 on a 100-point scale, P < 0.001), according to the FLIE questionnaire (Table 5). There was a small but significant improvement in AQOL-8D utility-based quality of life (mean difference 0.04, 95% CI 0.01–0.07, P = 0.019), and in the Physical Health Super Dimension (mean difference 0.06, 95% CI 0.03–0.09, P < 0.001; Table 5). Small improvements

Table 3. Grade 3 or 4 adverse events and serious adverse events for cycles A and B (N = 78)

	THC:CBD, n (%)	Placebo, n (%)
Grade 3 or 4 adverse event (AE) by CTCAE criteria		
Any AE grade 3–4	14 (18)	10 (13)
Infection/fever/febrile neutropaenia	3 (4)	4 (5)
Nausea/vomiting	3 (4)	2 (3)
Anaemia	3 (4)	1 (1)
Neutrophil count decreased	3 (4)	2 (3)
Platelet count decreased	1 (1)	0 (0)
Hypertension	1 (1)	0 (0)
Atrial flutter	0 (0)	1 (1)
Serious adverse event (SAE)		
Any SAE (by participant)	5 (6)	7 (9)
Infection/fever/febrile neutropaenia	3 (4) ^a	4 (5)
Vomiting	1 (1)	0 (0)
Atrial flutter	0 (0)	1 (1)
Neutrophil count decreased	1 (1)	1 (1)
Anaemia	1 (1)	1 (1)

CBD, cannabidiol; CTCAE, Common Terminology Criteria for Adverse Events; THC, tetrahydrocannabinol.

^a Includes two events in one participant.

Table 4. Self-reported cannabinoid-related adverse events rated moderate or severe (N = 78)

Side-effects	THC:CBD, n (%)	Placebo, n (%)	P*
Any (by participant)	22 (31) ^a	5 (7)	0.002
Sedation	15 (19)	3 (4)	0.008
Anxiety	1 (1)	1 (1)	1.0
Disorientation	2 (3)	0 (0)	0.5
Dizziness	8 (10)	1 (1)	0.03
Hallucinations	0 (0)	0 (0)	
Palpitations	0 (0)	0 (0)	

CBD, cannabidiol; THC, tetrahydrocannabinol.

^a Four participants experienced moderate or severe sedation and dizziness while receiving THC:CBD.

* Comparison for 72 participants who received both interventions; excludes those with [side-effect (n for THC:CBD, n for placebo)] any (3, 0), sedation (2, 0), and dizziness (1, 0) who did not receive both interventions.

Table 5. Self-reported quality of life: comparison of Functional Living Index (FLIE) and Assessment of Quality of Life-8 dimensions (AQOL-8D) scores by study allocation				
	THC:CBD (N = 68), mean ± SD	Placebo (N = 68), mean ± SD	Mean difference (95% confidence interval)	P
FLIE scale analyses ^a				
Nausea domain (scale 0–100) ^b	72 (25)	51 (29)	21 (12 to 29)	<0.001
Vomiting domain (scale 0–100) ^c	91 (15)	79 (29)	12 (6 to 18)	<0.001
AQOL-8D scale analyses ^a				
Independent living ^d	0.72 ± 0.18	0.70 ± 0.18	0.02 (–0.01 to 0.04)	0.13
Happiness	0.71 ± 0.16	0.70 ± 0.18	0.01 (–0.02 to 0.05)	0.50
Mental health	0.66 ± 0.12	0.63 ± 0.12	0.04 (0.01 to 0.06)	0.004
Coping	0.67 ± 0.14	0.66 ± 0.16	0.01 (–0.03 to 0.04)	0.67
Relationships	0.66 ± 0.15	0.65 ± 0.14	0.01 (–0.02 to 0.03)	0.61
Self-worth	0.75 ± 0.16	0.73 ± 0.17	0.03 (–0.00 to 0.06)	0.07
Pain	0.79 ± 0.19	0.71 ± 0.22	0.08 (0.03 to 0.13)	0.003
Senses	0.86 ± 0.11	0.84 ± 0.13	0.02 (–0.01 to 0.05)	0.18
Super Dimension Mental	0.33 ± 0.16	0.31 ± 0.16	0.02 (–0.01 to 0.05)	0.27
Super Dimension Physical	0.63 ± 0.17	0.58 ± 0.18	0.06 (0.03 to 0.09)	<0.001
AQOL-8D utility	0.65 ± 0.17	0.61 ± 0.19	0.04 (0.01 to 0.07)	0.019

CBD, cannabidiol; SD, standard deviation; THC, tetrahydrocannabinol.

^a Higher score indicates better quality of life.

^b n = 67 (one participant with missing data).

^c n = 66 (two participants with missing data).

^d Data were imputed for one question for two participants in the Independent Living Dimension.

were also observed in the AQOL-8D mental health and pain dimensions.

DISCUSSION

The phase II crossover component of this randomised, double-blind, multicentre placebo-controlled, phase II/III trial has demonstrated the activity and tolerability of an oral THC:CBD cannabis extract for prevention of refractory CINV, and a sufficient accrual rate to complete the phase III parallel component of the trial. There was an improvement with oral THC:CBD cannabis extract in the control of nausea and vomiting.

We found that the additional side-effects were tolerable. Although almost one-third of participants experienced moderate-to-severe cannabinoid-related adverse events such as sedation, dizziness, and disorientation, 85% of participants preferred THC:CBD to placebo. Adverse events were as expected for background chemotherapy.

With regard to health-related quality of life, an overall improvement was observed in utility; however, this may not be a clinically meaningful improvement, as previous studies have suggested an improvement of 0.06 measured by AQOL instruments is required.¹⁹ Further research is necessary to determine the significance and durability of improvements observed in specific AQOL-8D dimensions.

Strengths of our trial include the novel multistage phase II/III design including crossover and parallel components, the success of recruiting 81 eligible patients over 2.5 years, and the excellent compliance of participants in completing the patient diary. Furthermore, this is the first adequately powered, randomised study of medicinal cannabis for CINV to include background modern guideline-consistent antiemetics, whereas previous studies compared cannabis with

outdated antiemetics.^{5,6} The patient preference question was a unique addition to the trial, which allowed participants to consider both control of nausea and vomiting, and side-effects from cannabinoids and other medications. We restricted study eligibility to patients with refractory CINV to avoid the potential adverse events, driving restrictions, and other legal ramifications of medicinal cannabis for patients whose CINV is well controlled with standard antiemetics, and increased the power of the study to detect an effect in an enriched population. However, this does limit the ability to compare our results with studies of antiemetics as *primary* prophylaxis for CINV. The main limitation of the results is the underlying phase II randomised crossover design, designed to guide further research, not to definitively establish that the addition of oral THC:CBD is more effective than guideline-consistent antiemetic prophylaxis alone. Completion of the phase III component of the trial is required to demonstrate more robust outcomes utilising a traditional between-patient comparison for cycle A for all 250 patients, and determine longer-term effectiveness, cost-effectiveness, and tolerability over multiple cycles of chemotherapy. Finally, few participants received olanzapine, which since commencement of our trial has been added as an option for highly emetic regimens.^{13,17}

Future research could explore whether ‘nonresponders’ would benefit from higher doses (although we allowed self-titration), or indeed whether different ratios of THC and CBD may impact upon efficacy or safety outcomes.^{20,21} Second, it is also unclear to what extent the properties of THC such as sedation, drowsiness, and euphoria contributed to most participants preferring oral THC:CBD over placebo. Third, our trial raises questions about the acceptability of prescribed cannabis products to some cancer patients

receiving chemotherapy, given that a large proportion assessed for eligibility were not enrolled, and male patients were underrepresented. Finally, future trials could compare the efficacy of cannabinoids with other antiemetics such as olanzapine.

In conclusion, the oral THC:CBD cannabis extract was active and tolerable in preventing CINV, when combined with guideline-consistent antiemetic prophylaxis for a study population with refractory CINV. Based on our results, we are continuing recruitment to the phase III parallel component of our trial.

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DISCLOSURE

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