# SAFETY AND EFFECTIVENESS OF DULOXETINE, EXERCISE & CANNABIDIOL FOR CHEMOTHERAPY-INDUCED PERIPHERAL NEUROPATHY; PRELIMINARY RESULTS FROM THE MEDICAL CANNABIS AND EXERCISE STUDY

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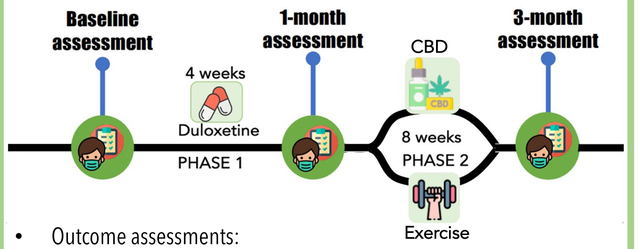
MASCC/JASCC/ISOO 2023 NARA ANNUAL MEETING JUNE 22-24

## BACKGROUND & OBJECTIVE

- Chemotherapy-induced peripheral neuropathy (CIPN) can affect up to 80% of cancer survivors (Kautio *et al.*, 2011).
- Duloxetine is a serotonin-norepinephrine re-uptake inhibitor and is considered the standard treatment for CIPN (Hou *et al.*, 2018).
- Exercise (EX) & cannabidiol (CBD) may relieve CIPN through their anti-inflammatory properties (Bland *et al.*, 2019; Pacher *et al.*, 2006; Nagarkatti *et al.*, 2009).
- Our objective is to investigate the safety and effectiveness of duloxetine, CBD and exercise for alleviating CIPN.

## METHODS

- Observational study/registry
  - ⇢ Cancer survivors (≥18-yr old) with CIPN secondary to taxane and/or platinum-based chemotherapies
  - ⇢ ***Phase 1:*** Duloxetine (DLX), 60 mg/daily x 1-month
  - ⇢ ***Phase 2:*** CBD (up to 300mg/daily) or exercise program x 2-months




- Outcome assessments:
  - ⇢ Pain score by painDETECT questionnaire (Bennett *et al.*, 2007)
  - ⇢ Quality of life by the Functional Assessment of Cancer Therapy/ Gynecologic Oncology Group-Neurotoxicity scale (FACT/GOG-Ntx) (Cheng *et al.*, 2020)
  - ⇢ Godin-Shephard leisure-time physical activity questionnaire (Amireault *et al.*, 2015)
- Tolerability assessments:
  - ⇢ Weekly phone calls

## RESULTS

**Table 1. Clinical characteristics of study participants (*n* = 18)**

| | Total Population |
|---|---|
| **Age (Years; mean +/- SD)** | 61.4 +/- 12.2 |
| | **Sex assigned at birth (n (%))** |
| Female | 14 (77.8) |
| Male | 4 (22.2) |
| | **Cancer Diagnosis** |
| Breast Cancer | 9 (50.0) |
| Endometrial Cancer | 2 (11.1) |
| Ovarian Cancer | 2 (11.1) |
| Oropharyngeal cancer | 1 (5.6) |
| Uterine Cancer | 1 (5.6) |
| Pancreatic Cancer | 1 (5.6) |
| Lymphoma Cancer | 1 (5.6) |
| Testicular Cancer | 1 (5.6) |
| | **Completed Study Phases** |
| Baseline | 6 (33.3) |
| Phase 1 | 1 (5.6) |
| Phase 2 | 11 (22.2) |
| | **Phase 2 Treatment** |
| CBD | 7 (63.6) |
| Exercise | 4 (36.4) |

**Table 2. Side effects of duloxetine, CBD & exercise**

| | DLX-1 month (n (%)) | | CBD-2 months |
|---|---|---|---|
| Only used 30mg/day | 5 (55.6) | Diarrhea | 2 (28.6) |
| Nausea | 4 (44.4) | Dry mouth | 1 (14.3) |
| Fatigue | 2 (22.2) | ↑ Appetite | 1 (14.3) |
| None | 2 (22.2) | Sleepiness | 1 (14.3) |
| Drowsiness | 1 (11.1) | Dizziness | 1 (14.3) |
| Sweating | 1 (11.1) | Paranoia | 1 (14.3) |
| Abdominal Pain | 1 (11.1) | | |
| Constipation | 1 (11.1) | | |
| Low energy | 1 (11.1) | | |
| | **Exercise- 1st month** | | |
| None | 2 (50.0) | | |
| Fatigue | 2 (50.0) | | |
| Muscle Soreness | 2 (50.0) | | |
| Muscle Cramping | 2 (50.0) | | |
| | **Exercise-2nd month** | | |
| None | 4 (100) | | |

**Figure 1. CBD & exercise improve pain severity**

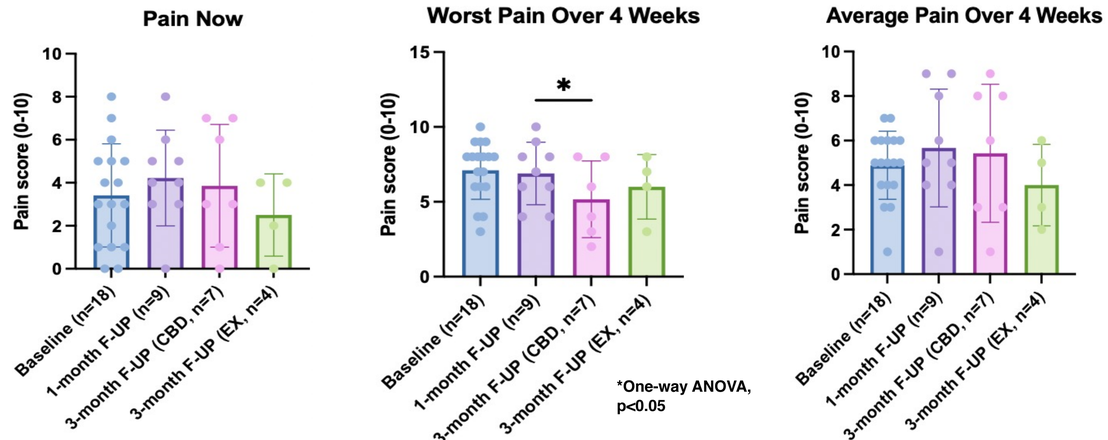



**Figure 2. CBD & exercise improve quality of life**

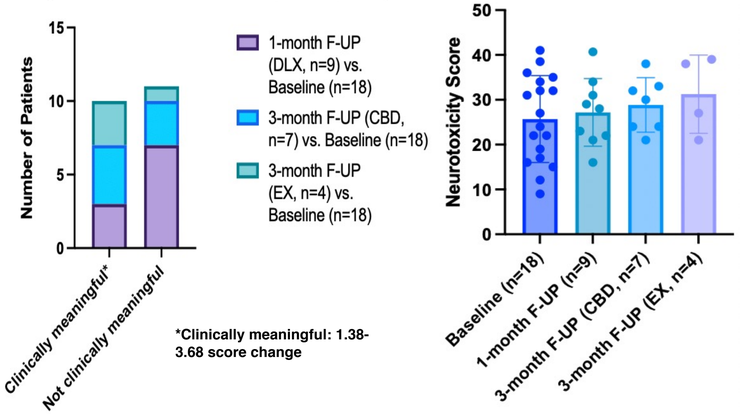
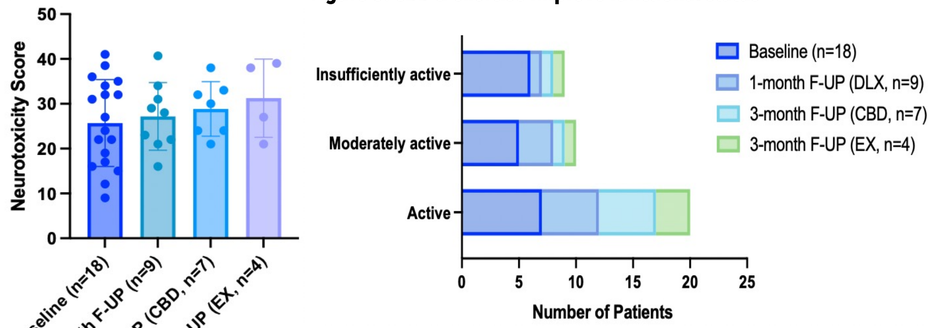



**Figure 3. CBD & exercise improve functional status**




## CONCLUSIONS

- Preliminary observations suggest that in cancer survivors with CIPN: **1)** Duloxetine is partially effective but poorly tolerated.
  **2)** CBD is partially effective but better tolerated than duloxetine.
  **3)** Exercise is generally effective and well tolerated.
- Recruitment is on-going to increase sample size and confirm these initial observations.

## FUNDING

Operating grants:

Salary awards (MariaLuisa Vigano):