CORGANICS

Advancing Cannabinoid Education & Science Study

Primary Investigators

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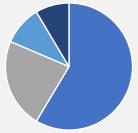
Background

01

- Retail Cannabidiol (CBD) is broadly commercially available and recent surveys indicate that 1 in 5 Americans have taken CBD and 3 in 5 Americans see CBD as "valid medical therapy."
- CBD that is broadly available via retail outlets is unregulated and third-party audits show that 73%–84% of retail CBD products are mislabeled or contain potentially dangerous chemicals.
- Many cancer patients seek alternative treatment solutions to mitigate treatment side effects and/or to treat pain, sleep disturbance, and anxiety.**
  - Few cancer patients who use Cannabidiol (CBD) discuss with their HCP.
  - In a study of 100 cancer patients, up to 65% used CBD to mitigate uncontrolled negative symptoms.
  - Motivation to use CBD included pain (84%), anxiety (35%) and sleep (29%).
  - Only 13% learned about CBD from a healthcare professional.

1 in 5
Americans use CBD*
Gallup 2019

3 in 5
Americans use CBD as a valid medical therapy*
Gallup 2019



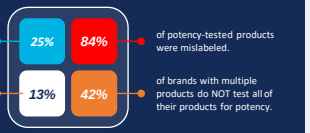
- Stress/Anxiety
- Pain
- Sleep
- Overall Health/Wellbeing

Consumer reports, National Survey 2020

Leaf Report audited 2,946 products from 136 brands and found large discrepancies in quality, potency and consistency

Goal was to check the current status of the retail CBD industry when it comes to purity and potency testing

21% Contained *Detectable* THC



Objectives

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- The objective is to evaluate the effectiveness of Corganics broad-spectrum Cannabidiol (CBD) in an Institutional Review Board (IRB)-approved randomized controlled trial.
- This report summarizes the results of Corganics Clinical Cannabidiol (CBD) Softgels in 208 participants and the impact on well-being, anxiety, pain, and sleep quality in participants over the course of 4 weeks.
- For the trial, patients were recommended to take one 25 mg softgel once daily with food for the duration of the four-week trial.

Note: Corganics Clinical CBD products are available/dispensed exclusively via approved healthcare professionals

Methods

03

- Mean change calculated in each participant's Kemp-QOL, WHO-5 Well-being Index, PROMIS Anxiety 4A, PROMIS Sleep Disturbance SF 8B, and PEG-3 scores from baseline to study completion (four weeks).

Key Outcomes and Measures

- Well-Being was assessed using the WHO-5 Well-Being Index, which assesses mental well-being on a scale of 0 to 25, with higher scores signifying greater well-being.
- Sleep Quality was measured using the Patient-Reported Outcomes Measurement Information System (PROMIS) Sleep Disturbance SF 8B, which assesses sleep disturbance on a scale of 8 to 40, with higher scores signifying lower sleep quality.
- Anxiety was measured using the Generalized Anxiety Disorder (GAD)-7 scale, a 7-item measure which assesses the presence and severity of anxiety symptoms associated with GAD on a scale of 0=21, with higher scores signifying more severe anxiety symptoms.
- Pain was measured using the PEG-3 Scale, which assesses pain (specifically, average pain intensity [P], interference with enjoyment of life [E] and interference with general activity [G] on a scale of 0 to 30, with higher scores signifying greater pain.
- Regression analyses were run to assess score change through time in the full sample and by baseline condition severity.
- T-tests were completed to compare the mean change in outcome scores from baseline to study completion

Note: Any findings that were 'significant' meant that the likelihood of falsely rejecting the null hypothesis that there were no differences between groups is very small (less than 5%).

Results

04

- People taking Corganics Clinical CBD Softgels saw significant improvements in well-being, anxiety, and pain throughout the study period.
  - Participants experienced significant improvements throughout the study period, relative to those who took no product, with the mean well-being score increasing by approximately 66% from baseline to week 4.
  - 64% of participants experienced clinically meaningful improvements in their anxiety throughout the study period, relative to those taking no product, realizing "distinct and palpable" improvement in their quality of life through improved anxiety symptoms.
  - 53% of those with sleep difficulties experienced clinically meaningful improvement in their sleep disturbance score, meaning they realized a distinct and palpable difference in their quality of life through improved sleep quality.
  - 64% of participants with pain reported that their pain symptoms were "better" or "much better" throughout the study period.

The Endocannabinoid System (ECS)

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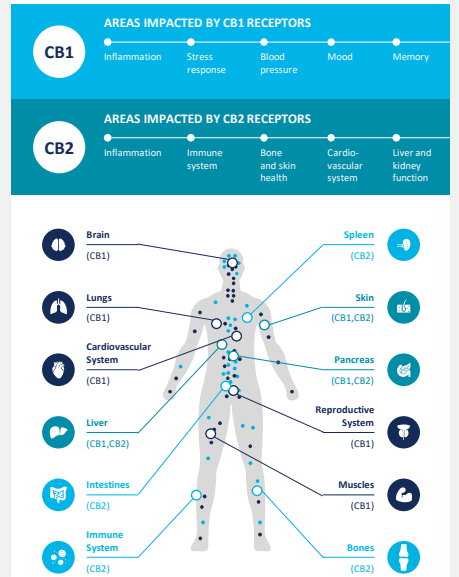

Conclusions/ Discussion

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- Participants taking Corganics Clinical CBD Softgels saw "clinically meaningful" improvement in well-being, anxiety, sleep quality, and pain throughout the 4-week study period.
- Corganics Clinical Softgels, 25 mg were well tolerated, with 10% of participants reporting side effects, none were serious.
  - **Reported side effects were associated with the reasons why participants entered the trial (pain, anxiety, insomnia).**
- Largest improvements from baseline occurred in the first week of the study.
- Noticeable effect most often between 1 and 4 hours of taking product.
- Participants most often reported that they took the product in the evening (43%), followed by the morning (29%), afternoon (24%), and early morning (4%).

Sources: Gallup, 2019; Leaf Report, 2021; *Cancer, 2017; Pergram SA, Woodfield MD, Lee CM, Cheng GS, Baker KK, Marquis SR, Fann JR; Sources: **Oncology Nurse Advisor, 2021
***Future Med Chem., 2009 Oct: 1333-1349;