ScienceDirect

View PDF

Access through your institution

Purchase PDF

The American Journal of Geriatric Psychiatry
Volume 29, Issue 4, Supplement, April 2021, Pages S110-S111

Poster Number: NR-8

Caring for Behavioral Symptoms of Dementia (CBD): A New Investigation into Cannabidiol for the Treatment of Anxiety and Agitation in Alzheimer's Dementia

Kaitlin McManus BA [1], Eleanor Ash BA [1], David Harper PhD [2], Rosemary Smith BS [1], Staci Gruber PhD [2], Brent Forester MD, MS [2]

Show more

Outline | Share | Cite

https://doi.org/10.1016/j.jagp.2021.01.107

Get rights and content

Introduction

Alzheimer's disease (AD) is a debilitating neurodegenerative disease accounting for 60-80% of dementia cases worldwide. In the United States alone, 13.8 million Americans are predicted to develop AD by 2050. The neuropsychiatric symptoms (NPS) of dementia affect up to 97% of AD patients over the course of their disease. A common NPS is agitation, characterized by problem behaviors that include combativeness and restlessness. Agitation is commonly associated with greater caregiver burden, shorter time to institutionalization, and anxiety. Anxiety symptoms affect 25-70% of the dementia population, and this wide range speaks to the inability to discern anxiety from agitation. Despite the pervasiveness of anxiety and agitation in the AD population, there are no FDA-approved medications that treat the behavioral symptoms of AD. Current treatments for these symptoms include time-intensive behavioral therapies and prescription of off-label antipsychotic medications that include an FDA warning of increased mortality in this population. Thus, the need for developing safe and efficacious treatments for anxiety and agitation in AD is dire. One potential treatment is cannabidiol (CBD), the major non-intoxicating constituent of cannabis sativa and industrial hemp, a variety of the cannabis plant that contains <0.3% delta9-tetrahydrocannabinol (THC), the main intoxicating constituent in cannabis, by weight. CBD modifies the endocannabinoid system and is thought to modulate effects via the 5-HT serotonergic system, μ-opioid receptors, and TRPV1/TRPV2 receptors. These interactions seem to result in an anxiolytic effect, as studies demonstrate CBD's ability to attenuate acute responses to stress in rats, act as a panicolytic in rats, and attenuate anxiety in humans. The utilization of CBD may extend beyond its role as an anxiolytic, as preclinical studies suggest widespread therapeutic impacts of CBD, including its ability to offer neuroprotective properties and inhibit tau hyperphosphorylation. Despite pre-clinical and animal evidence that CBD could modify neurodegeneration and behavioral symptoms in AD, no human clinical trials have investigated the impact of CBD on anxiety or agitation in AD. The present open-label clinical trial seeks to address this gap in knowledge by assessing the efficacy and tolerability of a high-CBD/low-THC sublingual solution as a treatment for anxiety and agitation in older adults with Alzheimer's disease.

Methods

An 8-week open-label clinical trial of an industrial hemp-derived custom-formulated high-CBD/low-THC sublingual solution developed by Dr. Staci Gruber, PhD, at McLean Hospital. We will recruit 12 research participants with mild to moderate Alzheimer's dementia and behavioral symptoms of anxiety with or without agitation. Our primary efficacy outcome measures are the anxiety domain of the Neuropsychiatric Inventory-Clinician Version (NPI-C) and the Generalized Anxiety Disorder-7 Item Scale (GAD-7). Our secondary safety outcome measures include continuous monitoring for serious adverse events and medication side effects, cognitive decline estimates from the Mini Mental Status Exam (MMSE), and the emergence of possible delirium from the 3D-Confusion Assessment Method (3D-CAM). Agitation and aggression domains on the NPI-C

FEEDBACK

Cohen-Mansfield Agitation Inventory (CMAI), and caregiver burden estimates from the Zarit Caregiver Burden Interview will be included as additional exploratory measures.

Results

Dr. Gruber's team is currently conducting a clinical trial for the treatment of anxiety in adults with moderate to severe anxiety using a similar custom-formulated high-CBD/low-THC sublingual solution. Preliminary analyses of Dr. Gruber's ongoing trial reveal that subjects experience significant reduction in anxiety symptoms along with improvements in mood, quality of life, and executive function over 4 weeks of treatment. Given these data and evidence of CBD's anxiolytic effects, we hypothesize that twice daily treatment with a high-CBD/low-THC solution in older adults with AD for 8 weeks will be associated with a statistically significant reduction in anxiety and agitation symptoms compared to baseline, as measured by our efficacy outcome measurements. We predict that the solution will be well-tolerated by the study population, as measured by our safety outcome measurements.

Conclusions

We seek a safe and effective treatment for the neuropsychiatric symptoms of anxiety and agitation in older adults with AD. With no current FDA-approved treatments for these behavioral symptoms, patients with AD risk ineffective therapies or mortality-associated antipsychotic treatments to address their NPS. Treating anxiety and agitation in these patients not only alleviates their symptoms but could also reduce caregiver burden and lengthen the time to institutionalization. CBD is a promising anxiolytic treatment that could advance our available treatment options for anxiety and agitation in AD.

Funding

The Spier Family Foundation

Previous Next

Recommended articles Citing articles (0)

View full text

Copyright © 2021 Published by Elsevier Inc.

ELSEVIER

About ScienceDirect

Remote access

Shopping cart

Advertise

Contact and support

Terms and conditions

Privacy policy

RELX™

We use cookies to help provide and enhance our service and tailor content and ads. By continuing you agree to the **use of cookies**.
Copyright © 2021 Elsevier B.V. or its licensors or contributors. ScienceDirect ® is a registered trademark of Elsevier B.V.
ScienceDirect ® is a registered trademark of Elsevier B.V.

FEEDBACK