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Efficacy of Medicinal Cannabis Related to the Treatment of Anxiety and Agitation in Patients with Dementia: A Protocol for a Systematic Review of Interventions in Humans

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Alexandre Duarte Pierantoni¹, Gabriel Mendes Ribeiro¹, Patrícia olombo-Souza¹

¹Universidade Santo Amaro, R. Prof. Enéas de Siqueira Neto, 340 - Jardim das Imbuías, São Paulo - P, 04829-300



Alexandre Duarte Pierantoni

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We use this protocol and it's working

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Keywords: dementia treatment, cannabis therapy, behavioral symptoms, elderly care, evidence-based medicine., cannabis in dementia care, efficacy of medicinal cannabis, medicinal cannabis, compounds like cbd, interventions in humans dementia, cannabis, challenging symptoms of dementia, cbd, treatment of anxiety, dementia, humans dementia, agitation in patient, dementia care, affected brain, anxiety, traditional treatment option, difficult symptoms like anxiety, agitation, controlled trial, clinical trial, treatment, based treatment, efficacy

Abstract

Dementia affects millions of people worldwide and often comes with difficult symptoms like anxiety and agitation, which can seriously impact quality of life. While there are traditional treatment options, recent research suggests that medicinal cannabis may offer a promising alternative. In this systematic review, we will carefully investigate whether cannabis-based treatments—especially compounds like CBD and THC—are effective and safe in helping to relieve these symptoms in older adults with dementia. We'll examine all randomized controlled trials published since 2014, using major databases like PubMed, Scopus, and clinical trial registries. Each study will be closely reviewed by our team, with special attention to how these treatments impact symptom severity and what side effects may occur. To ensure the reliability of our findings, two independent reviewers will assess every piece of evidence.

Following PRISMA guidelines, our goal is to provide healthcare professionals with clear, evidence-based answers about the potential role of cannabis in dementia care. We're especially interested not just in whether these treatments work, but in how they interact with the dementia-affected brain. Before starting the full analysis, we'll register our detailed protocol with PROSPERO to promote transparency and avoid duplication of research. We believe the findings from this review could help shape future approaches to managing some of the most challenging symptoms of dementia.

Keywords: dementia treatment, cannabis therapy, behavioral symptoms, elderly care, evidence-based medicine.

Attachments



[systematic review of...](#)

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Guidelines

Dementia is categorized as any type of decline in a patient's cognition that is significant enough to intervene with a patient's daily function. Approximately 57 million people are affected, and this number is expected to triple by 2050, as per data established by the World Health Organization. This could be defined as a syndrome rather than a disease. The causes of dementia itself vary widely and include neurological, neuropsychiatric, and medical conditions; however, it is possible that multiple diseases contribute to dementia. Neurodegenerative dementias can be observed in patients with diseases such as Alzheimer's disease, whereas vascular dementias can be observed in patients with mixed dementias. Furthermore, in addition to the most common diseases, we can also observe the effects of dementia on neurologic trauma and overdoses of toxins. Accompanied by dementia, it is not unusual to observe psychiatric symptoms, as approximately 90% of patients with such syndromes develop some of the most common behavioral and psychiatric symptoms, such as aggression, agitation, anxiety, depression, and sleep-wake cycle complications. Most patients have a long-term prevalence (90%), whereas only 50% of patients are diagnosed with dementia of all types. This research focuses on the following symptoms: agitation and anxiety. It is known that cognitive decline alone is not capable of triggering such symptoms. Helen C. Kaves directly described the factors that may lead to the triggering of symptoms, such as neurobiologically related disease factors, acute medical illness, unmet needs, preexisting personality and psychiatric illness factors, caregiver factors, and environmental factors. An agitation cause of dementia is commonly observed in patients with dementia, as approximately 76% of patients with Alzheimer's dementia show signs of agitation, which can be classified as "mental disturbances or perturbation showing itself usually by physical excitement," as reported by the Oxford University Press in 2004. In terms of anxiety, a symptom that is common in many psychiatric conditions, such as in the DSM-5, it is defined as anticipation of the future. When related to dementia and anxiety, changes in behavior and cognitive functions are common, and such changes may impact patients and caregivers. Importantly, dementia and anxiety are conditions that are difficult to differentiate, and while patients may experience anxiety related to brain lesions, we cannot forget that most patients will see themselves transformed from one that is independent to one that is fully dependent on others. Since 2019, there has been a notable increase in research on interventions involving the use of compounds of cannabidiol, such as CBC, THC, and other components that provide efficiency and security, to be introduced as medical interventions for patients. As of 2025, more than 7,589 articles and 5,357 have been published from 2019 to 2025 alone, only in PubMed, when the intervention of cannabidiol is debated. Importantly, as noted by Sophie Pautex and other researchers, we are able to notice a reduced level of NPIs, and other scales that were used in such studies proved the reduced levels. Moreover, the intervention acts at high speed, resulting in improvements in the first weeks of the trials. The research focus is to evaluate the performance of medicinal cannabis compounds in the treatment of agitation and anxiety in adult patients with dementia. Considering their efficacy, safety, and mechanisms of action, such studies will focus on patients above the age of 65 years of both genders. The conclusion of this review highlights the efficiency of cannabidiol and assists medical personnel in understanding that interventions with cannabidiols are rather effective and safe procedures.



Materials

The following databases were used for the study: PubMed, SciELO, Scopus, and PsycInfo. No single platform was used for the study. The study registry used was ClinicalTrials.gov; furthermore, any online resources, such as but not limited to tables of content and print conferences, were used. This study relies on the use of citation searching, and the method used for locating these citations involves browsing reference lists and citation indices. Furthermore, other studies were sought by contacting authors, experts, and manufacturers. For all the databases, the same pattern was used to perform the research, and all the following advanced research was performed. The keywords used were "Cannabis," "Dementia," "Agitation," "Anxiety," "Clinical Trials," "Endocannabinoid System," and the Boolean operators "AND," "OR," and "NOT." Limitations to the research were as follows: studies published after March 15, 2014; only clinical trials; and studies published in the following languages: English, German, Spanish, and Portuguese. It was decided that limitations would be required to ensure a clearer and better approach, and language selection was performed on the basis of the ability of the researchers to determine their trust in the understanding of these languages.

Before start

Dementia is categorized as any type of decline in a patient's cognition that is significant enough to intervene with a patient's daily function. Approximately 57 million people are affected, and this number is expected to triple by 2050, as per data established by the World Health Organization. This could be defined as a syndrome rather than a disease. The causes of dementia itself vary widely and include neurological, neuropsychiatric, and medical conditions; however, it is possible that multiple diseases contribute to dementia. Neurodegenerative dementias can be observed in patients with diseases such as Alzheimer's disease, whereas vascular dementias can be observed in patients with mixed dementias. Furthermore, in addition to the most common diseases, we can also observe the effects of dementia on neurologic trauma and overdoses of toxins.^{1, 2}

Accompanied by dementia, it is not unusual to observe psychiatric symptoms, as approximately 90% of patients with such syndromes develop some of the most common behavioral and psychiatric symptoms, such as aggression, agitation, anxiety, depression, and sleep–wake cycle complications. Most patients have a long-term prevalence (90%), whereas only 50% of patients are diagnosed with dementia of all types. This research focuses on the following symptoms: agitation and anxiety.^{3, 4}

It is known that cognitive decline alone is not capable of triggering such symptoms. Helen C Kaves directly described the factors that may lead to the triggering of symptoms, such as neurobiologically related disease factors, acute medical illness, unmet needs, preexisting personality and psychiatric illness factors, caregiver factors, and environmental factors. An agitation cause of dementia is commonly observed in patients with dementia, as approximately 76% of patients with Alzheimer's dementia show signs of agitation, which can be classified as "mental disturbances or perturbation showing itself usually by physical excitement", as reported by the Oxford University Press in 2004. The Intervention for such.^{5, 6}

In terms of anxiety, a symptom that is common in many psychiatric conditions, such as in the DSM-5, it is defined as anticipation of the future. When related to dementia and anxiety, changes in behavior and cognitive functions are common, and such changes may impact patients and caregivers. Importantly, dementia and anxiety are conditions that are difficult to differentiate, and while patients may experience anxiety related to brain lesions, we cannot forget that most patients will see themselves transformed from one that is independent to one that is fully dependent on others.^{7, 8}

Since 2019, there has been a notable increase in research on interventions involving the use of composites of cannabidiol, such as CBC, THC, and other components that provide efficiency and security, to be introduced as medical interventions for patients. As of 2025, more than 7,589 articles and 5,357 have been published from 2019 to 2025 alone, only in PubMed, when the intervention of cannabidiol is debated. Importantly, as noted by Sophie Pautex and other researchers, we are able to notice a reduced level of NPIs, and other scales that were used in such studies proved the reduced levels. Moreover, the intervention acts at high speed, resulting in improvements in the first weeks of the trials.^{9, 10}



The research focus is to evaluate the performance of medicinal cannabis compounds in the treatment of agitation and anxiety in adult patients with dementia. Considering their efficacy, safety, and mechanisms of action, such studies will focus on patients above the age of 65 years of both genders. The conclusion of this review highlights the efficiency of cannabidiol and assists medical personnel in understanding that interventions with cannabidiols are rather effective and safe procedures.

Methods

- 1 The systematic review will be conducted in accordance with the methodological guidelines established by PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses). In addition, a research question, structured according to the PICO framework, will be guided. The guiding question was "What is the efficacy of interventions using cannabis-based compounds in improving symptoms of anxiety and agitation in elderly patients with dementia?"
- 2 Study designs: Only randomized controlled trial (RCT) articles, following a dual-review screening process, will be included. No language restrictions will be applied, and studies published prior to 2014 will be excluded.
- 3 Participants: Male and female patients aged over 60 years, with a prior clinical diagnosis of dementia of any type and severity, will be included.
- 4 Interventions: The intervention consisted of the administration of cannabis-derived compounds, such as Δ 9-tetrahydrocannabinol (THC) and cannabidiol (CBD), while the control group received a pharmacologically inert placebo.
- 5 Outcome: It's expected that within data analysis, the outcome is seen a variation on NPI scale and other scales in terms of agitation and anxiety.
- 6 The following databases were used for the study: PubMed, SciELO, Scopus and PsycInfo.
No single platform was used for the study. The study registry used was ClinicalTrials.gov;
furthermore, any online resources, such as but not limited to tables of content and print conferences, were used. This study relies on the use of citation searching, and the method used for locating these citations involves browsing reference lists and citation indices. Furthermore, other studies were sought by contacting authors, experts, and manufacturers.
- 7 For all the databases, the same pattern was used to perform the research, and all the following advanced research was performed. The keywords used were "Cannabis," "Dementia," "Agitation," "Anxiety," "Clinical Trials," "Endocannabinoid System," and the Boolean operators "AND," "OR," and "NOT." Limitations to the research were as follows: studies published after March 15, 2014; only clinical trials; and studies published in the following languages: English, German, Spanish, and Portuguese. It was decided that limitations would be required to ensure a clearer and better approach, and language selection was performed on the basis of the ability of the researchers to determine their trust in the understanding of these languages.

- 8 The research filters were used as originally designed, no modifications were made, and no search strategies from other literature reviews were used to keep the searches updated. It uses the methods of rerunning and email alerts. Both will be started once the collection phase of the study is complete and will end once the article is over. In addition to the research for the articles that are going to be used in the study, a peer review process where both researchers look for articles and, once done, is needed. Both researchers will exchange the collected data and analyze them alone and together after.
- 9 While identifying articles in the database, the following numbers were found, following the limitations placed beforehand:
 - 9.1 23 PubMed
 - 9.2 4 SciELO
 - 9.3 19 ClinicalTrials.gov
- 10 Other articles may be found via contact with authors, reference checking, conference proceedings, dissertation and thesis databases, trial and study registries, and "snowballing".
- 11 The process used to ensure that no duplicates were within the collected data was the utilization of EndNote, and the software was also used to manage records and data through the review.

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