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FROM THE ALZHEIMER'S ASSOCIATION INTERNATIONAL CONFERENCE 2026

TOPLINE RESULTS FROM LIBBY TRIAL SHOW THC/CBD COMBINATION SIGNIFICANTLY REDUCES AGITATION FOR PEOPLE WITH DEMENTIA AT END OF LIFE

Key Takeaways

- **A new treatment combining THC and CBD significantly reduced agitation in people with late-stage Alzheimer's and other dementias, who were eligible to receive or received hospice care, with benefits seen in two weeks.**
- **Nearly 9 in 10 study participants who received the treatment showed overall improvement in target symptoms at study end at week 12.**
- **The LiBBY study demonstrates that dementia patients at late stages of their illness can participate in clinical trials, helping expand much needed clinical research.**

LONDON, July 14, 2026 — A combination of CBD and THC rapidly and significantly reduces agitation in hospice eligible people with dementia, suggest topline results from the Phase 2 LiBBY (Life's End Benefits of cannaBidiol and tetrahYdrocannabinol) clinical trial. The findings were reported for the first time at the Alzheimer's Association International Conference® (AAIC®) 2026 in London.

"This is a robustly positive, randomized, controlled trial that represents a major step forward in treatment for a population that has been historically overlooked in clinical research," said lead investigator Jacobo Mintzer, M.D., psychiatrist at the Ralph H. Johnson VA Healthcare System and professor, College of Health Professions, Medical University of South Carolina, Charleston. "We now have evidence supporting a new and very effective treatment approach for agitation that may be appropriate for people in the final stages of dementia at the end of life, offering them grace and peace in what is often an extremely difficult time for patients and their families."

The multicenter, randomized, double-blind, placebo-controlled study evaluated a novel oral formulation (2 mg THC/100 mg CBD dissolved in digestible oil, provided twice a day) in 120 participants with dementia who were eligible or received hospice care and were experiencing clinically significant agitation. The trial achieved its primary and key secondary endpoints.

Key Findings

- At Week 2, participants receiving THC/CBD showed a 6.27-point greater reduction in agitation scores than those receiving placebo, which was statistically significant, indicating rapid symptom relief.
- Benefits were sustained through Week 12, with participants receiving THC/CBD experiencing an 8.23-point greater reduction in agitation scores than those receiving placebo.
- Clinician-rated global improvement:
    - Week 2: 83.9% of treated participants improved vs. 30.5% on placebo.
    - Week 12: 87.2% of treated participants improved vs. 23.6% on placebo.

Overall adverse event rates were similar between groups (46.7% vs. 42.4%). Over 12 weeks, 23.3% of participants in the treatment arm experienced serious adverse events, compared with 11.9% in the placebo arm. Investigators determined that none of the serious adverse events were related to the study medication.

Agitation affects about half of people living with dementia near the end of life, and more than one-third continue to experience symptoms despite off-label treatment with benzodiazepines, opioids and antipsychotics — therapies that can be difficult to manage and carry significant risks.

In severe dementia and in the late stages of life, agitation is a common neuropsychiatric symptom characterized by emotional distress, excessive motor activity and verbal or physical tension. Because individuals in the late stages of dementia, especially towards the end of life, often lose their ability to communicate effectively, agitation frequently serves as a direct behavioral signal of physical discomfort, fear or unmet needs. Symptoms, which may be distressing to patients, families and caregivers, may include:

- Pacing or wandering
- Fidgeting and repetitive movements
- Loud, sudden vocal outbursts or calling out continuously.
- Repetitive phrases
- Moaning or groaning
- Verbal hostility
- Hitting, kicking, scratching, biting or pushing others
- Throwing or destroying property

“The LiBBY study directly addresses one of the most challenging and under-discussed aspects of Alzheimer’s disease — end-of-life agitation,” said Elizabeth Edgerly, Ph.D., Alzheimer’s Association vice president, care and support. “These results not only highlight a promising therapeutic option, but also underscore the importance of prioritizing attention, care and research for individuals in mid- and late-stage Alzheimer’s and related dementias.”

Brigid Reynolds, APRN, a LiBBY study co-principal investigator and nurse practitioner with the Memory Disorders Program at Georgetown University, Washington, D.C., noted, “One of the most meaningful aspects of these findings is the potential to provide a more humane and dignified experience for patients and families. Reducing agitation can help restore a sense of calm and comfort in a very vulnerable time. Proving the clear benefit of THC/CBD over placebo can bring hope to millions of patients, their families, caregivers and loved ones.”

The Alzheimer's Association supports a careful, individualized approach to managing behavioral and psychological symptoms of dementia, and encourages patients, caregivers and clinicians to review the prescribing information carefully and engage in shared decision-making when considering treatment.

Non-pharmacological strategies, including environmental modifications, structured routines and psychosocial interventions, are recommended as a first-line approach.

LiBBY, which was conducted by the National Institute on Aging (NIA)-funded Alzheimer's Clinical Trial Consortium (ACTC), is among the first randomized, controlled trials in a hospice-eligible population with dementia.

Paul Aisen, M.D., director of the Epstein Family Alzheimer's Therapeutic Research Institute at the University of Southern California, San Diego, and one of the principal investigators of ACTC, noted, "The LiBBY study successfully demonstrated that it is feasible to recruit, enroll, and retain a representative cohort from this group, including individuals from historically underrepresented communities. The study introduced novel trial methods to address an essential therapeutic need."

"This trial shows that high-quality clinical research can and should be conducted in people with advanced dementia, including those receiving hospice-eligible care," said Mintzer. "That is essential for achieving equitable and meaningful progress in Alzheimer's treatment." In LiBBY, the participants' mean age was about 80 years; 55% were female; 58% from underrepresented ethnoracial groups; and 75% lived in community settings.

The LiBBY trial was a 12-week, Phase 2 study conducted across multiple U.S. sites. Participants with Alzheimer's or another disease that causes dementia and significant agitation were randomized to receive either the THC/CBD combination or placebo.

- Primary endpoint: Change in agitation on the Cohen-Mansfield Agitation Inventory at 2 weeks.
- Key secondary endpoints: Sustained agitation reduction at 12 weeks and global clinical change at 2 weeks and 12 weeks.

The study's drug intervention, known as T2:C100, contained 2mg THC and 100mg CBD. From the start of the study through week 1, participants received a half dose (2mg THC and 100mg CBD, twice daily) or a placebo. During weeks 2–12, participants received the full intervention dose (4mg THC and 200mg CBD, twice daily) or a placebo.

A 12-week open-label extension phase has been completed and will also be reported at AAIC 2026. The LiBBY trial and its open-label extension are primarily funded by the NIA, part of the National Institutes of Health (NIH). The Alzheimer's Association is a funder of the open-label extension phase.

About AAIC

AAIC is the world's largest gathering of researchers from around the world focused on Alzheimer's and other diseases that cause dementia. As a part of the Alzheimer's Association's research program, AAIC serves as a catalyst for generating new knowledge about dementia and fostering a vital, collegial research community.

- AAIC 2026: **alz.org/aaic**
- AAIC 2026 online pressroom: **alz.org/aaic/pressroom.asp**
- AAIC 2026 hashtag: #AAIC26

About the Alzheimer's Association
The Alzheimer's Association is a worldwide voluntary health organization dedicated to Alzheimer's care, support and research. Our mission is to lead the way to end Alzheimer's and all other dementia — by accelerating global research, driving risk reduction and early detection, and maximizing quality care and support. Our vision is a world without Alzheimer's and all other dementia®. Visit **alz.org** or call +1 800.272.3900.

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- Jacobo Mintzer, The Life's End Benefits of cannaBidiol and tetrahYdrocannabinol (LiBBY) study Funding: (National Institute on Aging (R01AG068324-01), Alzheimer's Association)

***** AAIC 2026 news releases may contain updated data that does not match what is reported in the following abstract.**

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Drug Development -> Human -> Neuropsychiatric / Behavioral Symptom Therapeutics
Part of: Developing Topics in Phase 2 Clinical Trials, Tues., July 14, 2-3:30 pm

The Life's End Benefits of cannaBidiol and tetrahYdrocannabinol (LiBBY) study

Background: Forty-five percent of patients with dementia experience agitation in the last stages of disease when they become hospice care eligible. However, there is no scientific body of knowledge to guide clinicians in treating agitation at the end of life in dementia.

Methods: LiBBY is a multicenter, randomized, double-blind, placebo-controlled, Phase 2 study designed to evaluate the efficacy, safety, and tolerability of an oral combination of purified tetrahydrocannabinol (THC)/cannabidiol (CBD) (total daily dose of 8mg THC and 400mg CBD) dissolved in a digestible oil in 120 hospice care eligible patients with agitation and Alzheimer's disease or other types of dementia (HAD). We hypothesized that treatment with the THC/CBD combination would reduce agitation as measured by the Cohen-Mansfield Agitation Inventory (CMAI) when compared to placebo at 2 weeks, and that reduction in agitation would be sustained over 12 weeks, leading to short term (2 weeks) and sustained (12 weeks) improvement in global functioning.

Results: 120 participants were recruited (55% female). The mean age was 80.5 years. Self-reported race included 1 Asian individual, 18 Black or African American individuals, and 101 White individuals (54 identified as Hispanic).

There was a statistically significant improvement in 2-week mean CMAI scores in the THC/CBD arm compared to the placebo arm, with a mean change between arms of -6.27 (95% CI: -9.66, -2.87; p=0.0004). There was a statistically significant improvement in mean CMAI score at 12 weeks in the THC/CBD arm compared to the placebo arm, with a mean area under the curve (AUC) contrast between arms of -8.23 (95% CI: -11.6, -4.86; p<0.0001). A statistically significant increase in improvement rates in Clinical Global Impression of Change in Behavior (CGIC-B) in the THC/CBD arm compared to the placebo arm was observed at 2 weeks (83.9% vs 30.5% (p<0.0001)) and 12 weeks (87.2% vs 23.6% (p<0.0001)). Adverse event (AE) rates were comparable between groups (46.7% vs 42.4%).

Conclusions: The LiBBY Study met both primary and secondary outcome measures, suggesting that the THC/CBD combination used in the study may be an important therapeutic tool for HAD patients.

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