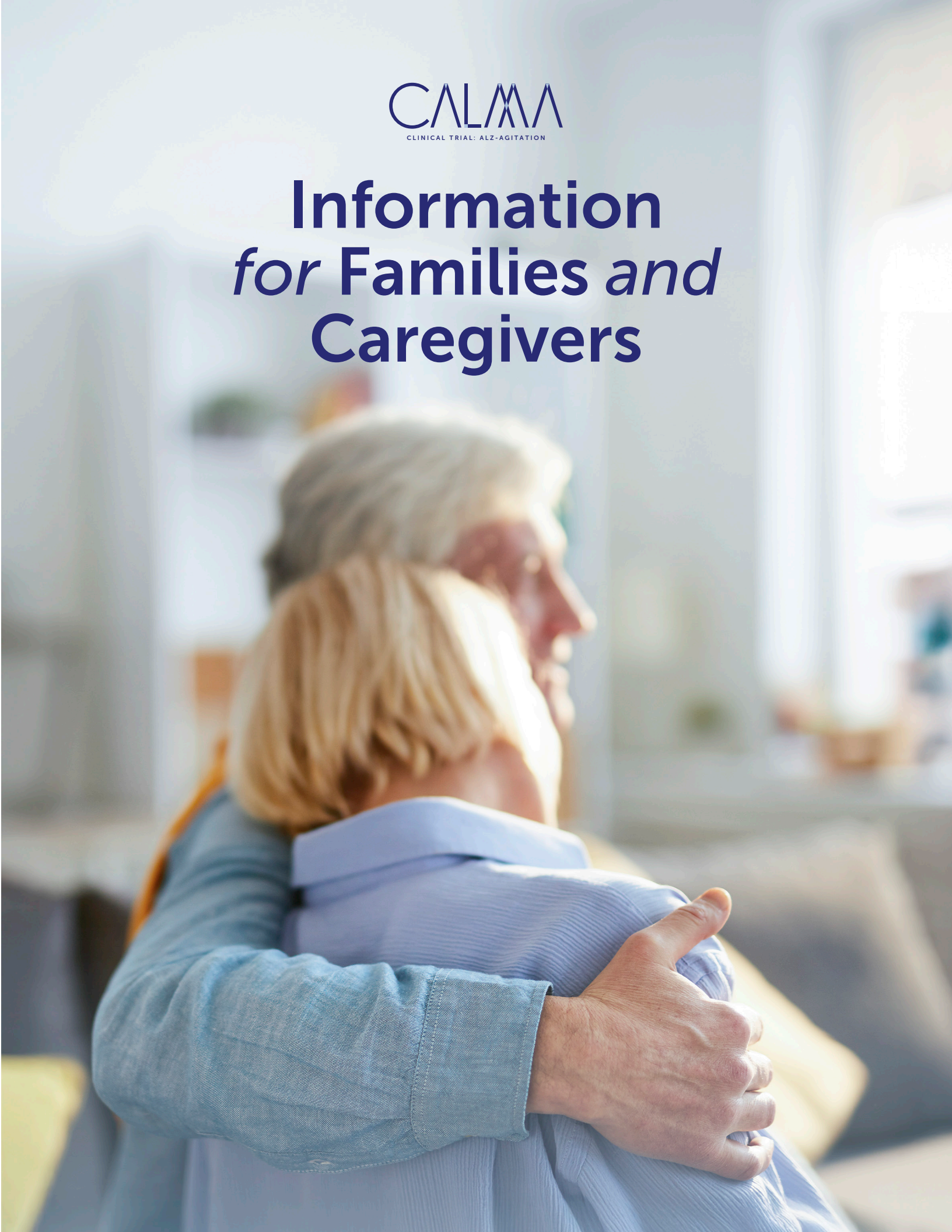




Information *for Families and* Caregivers



General Information

The **CALMA** Clinical Trial is a **Phase 2**, FDA-registered research study for people living with **Alzheimer's disease** who experience agitation.

Agitation can include **restlessness, pacing, repeated questions, irritability, verbal outbursts, or aggression**. These symptoms are very challenging for both patients and caregivers.

The purpose of **CALMA** is to study an investigational medicine, **IGC-AD1**, an oral liquid solution that contains tetrahydrocannabinol (THC) and melatonin. In earlier research, this medicine was shown to be safe and well-tolerated. Now, we are testing whether it can help **reduce agitation symptoms** and continue researching safety and tolerability.



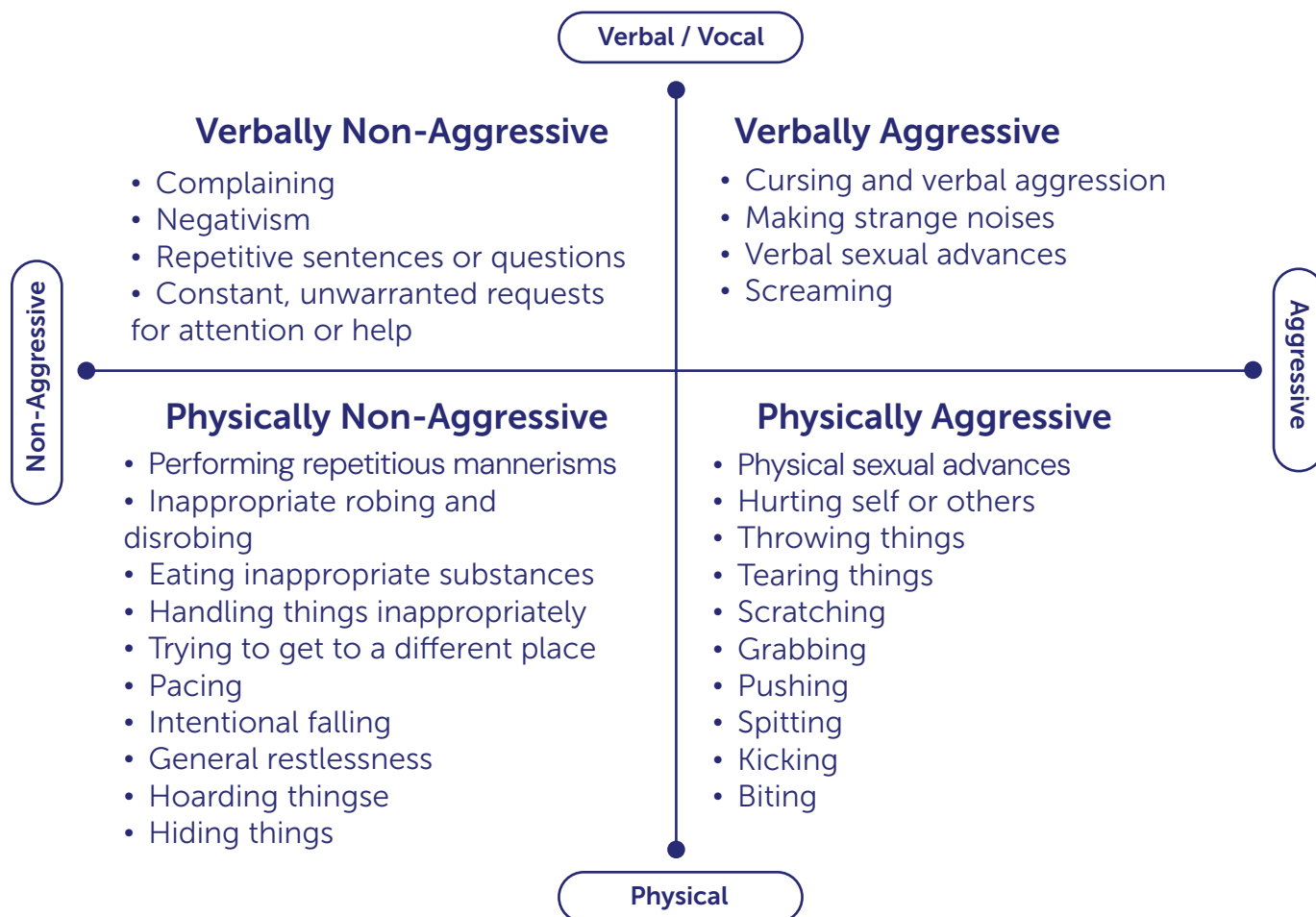
Eligibility Criteria



A **person may qualify** if they:

- Have a diagnosis of probable **Alzheimer's disease**
- Have a **caregiver** who knows them well, can attend study visits, and help with at-home monitoring
- Experience agitation symptoms such as **restlessness, pacing, aggression, verbal outbursts, or repeated behaviors**

Agitation Behaviors



Who may not qualify:

People with unstable or serious medical conditions (e.g., heart, liver, kidney or lung problems)

Those with a history of seizures, schizophrenia, or bipolar disorder

Anyone who has previously had an allergic reaction to cannabinoids, melatonin, or other ingredients in the study drug

Individuals who had serious falls or uncontrolled high blood pressure within the last six months

People with a history of alcohol or drug use disorder within the last year

The study doctor will make the final decision about eligibility after medical screening.

Benefits



If you decide to participate, you will receive at **no cost**:

- All study-related medications
- Comprehensive **study-related** care and regular check-ins
- Access to **specialized doctors** and researchers in Alzheimer's disease
- An easy-to-use digital blood pressure monitor and weighing scale for at-home monitoring
- **Compensation for time and effort** for both the participant and caregiver
- Coverage of travel expenses, parking, and transportation for visits

Health insurance is not required to take part in the CALMA study.

→ The study lasts about **8 weeks** (50–57 days)

→ There are 4 to 6 in-person clinic visits plus phone check-ins

→ The participant will take either **IGC-AD1** or a placebo (an inactive solution that looks the same)

→ Participation can be stopped at **any time**

What to *Expect*



Rights and Support



Participation is **voluntary**



You may **ask questions** at **any time** before or during the study



Caregivers are recognized as partners in this process and **receive** ongoing **support** from the study team

Contact *us*:



calma@igcpharma.com



<https://igcpharma.com/calma>

A close-up photograph of a middle-aged couple smiling warmly at the camera. The woman, on the left, has blonde hair tied back and is wearing a light pink long-sleeved shirt. The man, on the right, is balding with grey hair on the sides and is wearing a blue and red plaid shirt. They are both smiling broadly, showing their teeth. The woman's hands are resting on the man's shoulders, and she is wearing a thin gold ring on her left ring finger and a thin bracelet on her right wrist. The background is a soft, out-of-focus outdoor setting with greenery and a bright sky.

CALMA

CLINICAL TRIAL: ALZ-AGITATION