A Multi-centre, Phase 2a, Double-blind, Placebo-controlled, Randomised Study to Examine the Safety, Tolerability, and Efficacy of KNX100 in the Treatment of Subjects with Agitation Associated with Dementia (CARES-X).

The CARES-X study aims to test a potential new treatment to manage agitation in dementia.

This project is approved by Austin HREC (HREC/109044/Austin-2024)

Participation

Researchers will assess whether administration of a potential new treatment reduces agitation compared to a placebo. During the study, the treatment will be taken orally, as a capsule, twice a day for 4 weeks. Throughout this time, participants and their caregivers will visit the clinic to assess wellbeing and to collect necessary data for evaluating the investigational treatment. Participants will attend 5 clinic visits and receive at least 1 phone call over the study period.

You may qualify for pre-trial screening if you meet in the following criteria:

- Are between 50 and 90 years of age (inclusive)
- Have been diagnosed with dementia and experience significant agitation two or more times per week on average
- Live at home
- Have a consenting caregiver/study partner who is available to attend all study visits in person, and is willing and capable of providing accurate information in relation to the participant's behavioural symptoms and daily diary completion
- Can attend at least 5 clinic visits and one phone call over approximately 10 weeks.

Taking part in the CARES-X study will include:

✅ Reimbursement of costs - For out-of-pocket expenses, such as travel and meals.

✅ Free study-related medical care - Access potential new research treatments before they are widely available.

✅ Contribution to research - Results from this study may benefit others in the future.

Participation could help advance research and treatment for dementia-related agitation.

👉 Find more information here: http://agitationstudy.com/

This study is being conducted at the following sites;

PARC Clinical Research, located in the Royal Adelaide Hospital

Participant duration:	Up to 10 weeks, including screening and follow-up.
Available to people living in:	Adelaide, South Australia
Study begins:	26 July 2024
Study ends:	End Dec 2025

Contact us now for more information: 7074 4404 or researchclinic@adelaide.edu.au