Alzheimer Europe

Making dementia a priority:
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CLINICAL TRIALS WATCH

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MedCanDem STUDY

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MedCanDem study

1. Study Information	
Name of the study	Medical cannabis for improving symptoms during severe dementia disorders in long-term care facility in Geneva
Study sponsor	Fondation pour l'accueil et l'hébergement des personnes âgées (FAHPA)
Disease	Severe dementia
Phase	Phase II/III

2. Information about the compound that will be tested in the study	
Name of compound	Cannabis Oil containing tetrahydrocannabinol (THC) and Cannabidiol (CBD)
Administration	Oral drops daily
Will all participants receive the same compound?	The study is divided into two 8-week periods. Participants will be selected by chance to receive one of the following options: • Oral drops of Cannabis Oil for eight weeks followed by oral drops of placebo or a further eight weeks • Oral drops of placebo for eight weeks followed up by a further eight weeks of oral drops of Cannabis Oil A placebo is also called a dummy treatment which is an inactive substance identical in appearance to the compound being tested with no active therapeutic effect. Neither the participant, the health staff of the care facilities nor the study team will know if the person is receiving the Cannabis Oil or the placebo.

3. Information about participating in the trial	
What are the researchers trying to find out?	• The purpose of the study is to evaluate the efficacy of medical cannabis oil in improving the quality of life of people with severe dementia experiencing behavioural and psychological symptoms.

How long will the treatment last?	• Participants will take medical cannabis oil for 8 weeks.
What your involvement will entail?	• During the study, participants will be asked to complete tests to assess agitation and psychiatric symptoms • To complete some laboratory/biological tests (i.e. blood tests, blood pressure) to evaluate the emergent adverse effects (unfavourable signs, symptoms or diseases temporally associated with the use of the compound tested in the study. Further information on the number of visits can be obtained from the study team.

4. Who can participate in this study?	
Who can participate in the study?	To take part in the study, participants must: • Be 55 years or older • Have a diagnosis of severe dementia (i.e. Alzheimer's disease, vascular dementia, mixed dementia) • Have a score above 3 in the Clinical Dementia Rating (CDR) test. This would suggest that the person has a severe cognitive impairment • Have a score above 10 in the Neuropsychiatric Inventory (NPI) test. This would suggest that the person has persisting behaviour problems • Have not had SARS -CoV-2 (COVID 19) within two weeks of commencing the trial or be fully vaccinated.
Who cannot participate in the study?	Exclusion criteria include: • A disease or medical condition that may interfere with the study assessments and will make the participant unsuitable for participation in or completion of the trial procedures (i.e.

	severe kidney failure, orthostatic hypotension or severe organ deficiency such as cardiac, pulmonary, hepatic, renal insufficiency) • Major changes or instability of psychotropic medication in the past week • Having taken tetrahydrocannabinol (THC) and/or Cannabidiol (CBD) in the past 7 days. The above list is not exhaustive. It includes the most common conditions and diseases that might exclude people from the study.

5. Where and when will the study be conducted?	
European country involved in the trial (active)	• Switzerland
Estimated start date of recruitment	September 2023

6. Information for your doctor	
Clinicaltrials.gov identifier	NCT05432206
Study contact information	Federica Bianchi +41 76 4947150 f.crova-bianchi@fahpa.ch Fondation FAHPA medcandem@fahpa.ch
Link to full text	https://clinicaltrials.gov/ct2/show/NCT05432206

- ✓ The information contained in this document is based on information available on public registries (e.g. clinicaltrials.gov website) in December 2023.
- ✓ This document has been reviewed by the pharmaceutical company running this trial.
- ✓ This document has been reviewed by a member of the European Dementia Carers Working Group.