

Conclusion: Based on pooled data, brexpiprazole was well tolerated in patients with AAD, and had a clinical safety profile consistent with that of brexpiprazole in other indications. Patients receiving brexpiprazole had a similar incidence of sedation, EPS events, falls, cardiovascular events, and cerebrovascular events compared with placebo, and no worsening of cognition. The incidence of death was low, and no deaths were considered related to study treatment.

P171: Identifying pre-agitation biometric signature in dementia patients: A feasibility study

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Objectives: Agitation and aggression (AA) occur frequently in patients with dementia (PwD), are challenging to manage, and are distressing for PwD, families, caregivers, and healthcare systems. Physiological parameters, such as Actigraphy, Heart Rate Variability, and Electrodermal Activity, measured via wearable sensors are correlated with AA in PwD. It is unclear whether these parameters could be compiled into an operational algorithm to create a pre-agitation biometric marker (i.e. parameters of Autonomous Nervous System's arousal: elevated EDA, more frequent HR, lower heart rate variability (HRV), as well as higher motor activity) capable of predicting episodes of AA. This study will assess the feasibility and clinical utility of collecting physiological parameters via wearable multi-sensor Empatica E4 device in relation to clinically recorded episodes of AA in PwD.

Methods: This study is leveraging a clinical trial (ClinicalTrials.gov/NCT04516057) taking place at Ontario Shores Centre for Mental Health Sciences. Participants are inpatients, males and females, 55-years old or older, with clinically significant AA, and a diagnosis of a Major Neurocognitive Disorder due to Alzheimer's disease or multiple aetiologies. Participants wear the E4 device for 48 to 72 hours on three occasions during the 8-week study period. Participant demographics, and clinical measures used to assess behavior are collected at specific time intervals during the study period.

Results: The study is ongoing and currently to-date we have been able to acquire approximately 240 hours of recordings from patients. We will be presenting feasibility data (proportion of participants successfully completing a minimum 48-hours of recordings), correlation analysis between physiological measures and clinical measures to identify pre-agitation triggers. Further, we will use generalized linear models to test whether physiological measures can predict pre-agitation triggers. This study will allow estimation of sample size needed to detect a meaningful effect size, which will be determined from the prediction model. Deep learning using Python will be used to create a predictive algorithm using the physiological data to profile participants' behaviors and detect pre-agitation triggers.

Conclusion: Early detection of AA in PwD will allow caregivers to offer timely, 260ndividualized, non-medical or medical interventions which will help avoid crises and critical incidents and improve quality of life of the PwD and their caregivers.

P174: Project Connect 80+

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Introduction: -Patients with a memory deficit, as well as patients with small deficits in various cognitive areas, with the requirement that there is no functional impairment in their domestic or work life, do not meet the

criteria to be diagnosed with dementia, but they do meet the criteria for a diagnosis of mild cognitive impairment (MCI), which constitutes a transitional state between normal aging and mild dementia.

-Every year, 15% of patients with MCI with involvement only in the memory section, go on to be diagnosed with dementia.

In recent years, the use of a food for special medical purposes (FSMP), Souvenaid®, has been introduced into clinical practice, which, due to the composition of its active ingredient, Fortasyn connect (omega-3 fatty acids, uridine, choline, vitamins C, E, B6 and B12, selenium and folic acid) helps to:

- Promote the development of neuronal synapses, demonstrating that it maintains the integrity of white and gray matter.
- Reduce loss of functional connectivity.
- Increase hippocampal cholinergic synapses and cholinergic neurotransmission.
- Improve cognitive performance dependent on the hippocampus

Objective: A survey has been developed to explore the impact of a nutritional intervention, through the use of an FSMP in the areas related to cognition, functionality, and behavior, in a geriatric cohort with MCI older than 80 years. (Connect - Survey in the environment of mild cognitive impairment).

Survey: Each Geriatrics and Neurology professional had to select 5 cases that met the following characteristics: Presence of MCI, Age ≥ 80 years, and Receiving Souvenaid.

The professional sent CRO Alpha Bioresearch the list of caregivers with their contact details. The CRO contacted the subjects by telephone 3, 6, and 12 months after starting Souvenaid to carry out the survey.

Methodology: The survey collects the perception of the patient and caregiver's cognition, functionality, and behavior, through a Likert scale with 5 possible response alternatives. The questionnaire is divided into two different parts:

-Data about the treatment (questions 1 to 5)

-Questions about the patient's health (questions 1 to 12);

The last one is divided into three parts: data on cognition 3 questions (questions 1 to 3), data on functional abilities with 5 questions (questions 4 to 8), and data on behavior 4 questions (questions 9 to 12).

Results: Regarding the treatment at 12 months, there is a tolerance that reaches 76%, and 88% do not present problems with the administration of what is prescribed. The most common time of day for administration is breakfast and snacks. The most used flavor was vanilla and cappuccino. The most common way to acquire it was the direct route.

Regarding cognitive functions, the ability to remember is improved by 20%, orientation by 12%, and recognition by 8%, maintaining stability without changes by around 60-70%. Functional capacities improved between 8 and 16%, presenting no changes between 68-80%. Regarding the behavior, the improvement is between 12 to 28% in the evaluated items, presenting no changes between 60-84%.

Conclusions: There is stabilization at 3, 6, and 12 months both in cognition, functionality, and behavior. The positive impression of the perceived improvement in memory (around 20%) and apathy (exceeding 20% and reaching 28% per year) are striking.

P176: Efficacy of Melatonin in Delayed Sleep Phase Disorder: An Umbrella Review

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