

A PILOT STUDY FOR CARE HOMES & DEMENTIA COMMUNITIES

Therapeutic area	Psychology
Sponsor	
Title	The emotional, cognitive and behavioural impact of COSMA in people with dementia
Indication	People with dementia and pre-dementia
Type of study	Non-Interventional, Device Based Study.
Investigators	Psychologists
Treatment duration	9 months or 1 year as per care home choice
Study population	Males and females, in care homes, at any age, diagnosed with dementia (any type and at any stage) or pre-dementia.
Study design	<p>The COSMA therapy intervention will be introduced in care homes in the UK.</p> <p>Each Tablet, which can have a maximum of 5 users, and a portal will be provided. The carers will communicate with the family about the study and to upload pictures on the COSMA portal.</p> <p>Baseline questionnaires will be taken on Day 1 of the study. Participants will be required to play COSMA games, alone or with the help of a care home staff member at least 3 days a week for a minimum of 30 minutes compulsorily. The participants are asked to play the games for 270 days (9 months).</p> <p>The baseline questionnaires will be measured again at an interval of 3 months. Carers mental well-being will also be measured every 3 months.</p> <p>A follow-up is measured on day 360, after the study has been completed.</p> <p>Optional: After 6 months, the EEG Headset will be introduced into the study for the last 3 months. The headset will be worn by the participants to measure their brain activity whilst playing COSMA to provide targeted treatment.</p>



STUDY AIMS	<ol style="list-style-type: none"> 1. To evaluate the benefits of COSMA for people with cognitive impairments and their carers. 2. To improve the cognitive, emotional, behavioural and quality of life for adults with dementia.
STUDY OBJECTIVES	<ol style="list-style-type: none"> 1. To improve CQC rating of BUPA suggested care homes. <ol style="list-style-type: none"> a) To improve the dementia patients cognitive, emotional, behavioural aspects, aiming at providing longer and better quality of life. b) To assess the mental well-being of the carers. c) To improve Care Management by improving both carer and patient benefits.
INCLUSION CRITERIA	<ul style="list-style-type: none"> • Early diagnosis of any type of dementia • Males and females • Above 50 years old • Ability to verbally communicate • Being able to use a tablet • Be able to play the COSMA games without any assistance
EXCLUSION CRITERIA	<ul style="list-style-type: none"> • Mental illness and/or neuropsychiatric diagnosis • Primary visual impairments • Subjects who are mentally unable to comprehend the responsibilities and adhere to the stipulations of the protocol. • Subjects, who in the opinion of the manager or the staff care home member are not eligible for enrolment in the study • Sensory and motor impairments that might suppress subjects' ability to play the COSMA games
STUDY OUTCOME MEASURES	<p>Emotional questionnaires:</p> <ol style="list-style-type: none"> 1. PANAS 2. Depression, anxiety, stress scales 3. Apathy Evaluation Scale <p>Behavioural questionnaires:</p> <ol style="list-style-type: none"> 1. Edinburgh Feeding Evaluation in Dementia Questionnaire 2. The Blessed Dementia scale as a screening test for dementia 3. Functional activities questionnaire <p>Quality of life questionnaires:</p> <ol style="list-style-type: none"> 1. Bath Assessment of Subjective Quality of Life in Dementia 2. Quality of Life in Alzheimer's Disease 3. Alzheimer's Disease-related Quality of Life scale <p>Cognitive tests:</p> <ol style="list-style-type: none"> 1. Clock drawing test 2. Test your memory test 3. Verbal fluency test <p>Carers Questionnaire:</p> <ol style="list-style-type: none"> 1. Depression, anxiety, stress scales



NUMBER OF SUBJECTS	Minimum of 20 patients recruited in each care home
	1. Gamification Platform - COSMA Software from BrainBerry Ltd. 2. COSMA Headset
DATA CAPTURING	1. COSMA Cognitive Scores and individual tracking on emotion, behaviour and quality of life 2. COSMA Report for Care Home & Care Home Improvement 3. COSMA Patient group analysis report 6. Carers Mental well-being 7. Group Patient Improvement Report

*The same study can be done for a duration of 6 months with 5 months in treatment and 1-month follow-up.

COSMA OFFER FOR RESEARCH PILOT STUDY

Description	Pricing	9-Month	12-month
*Upfront Deposit/Tablet	15/month	£90/Tab	£180/Tab
User License/month	£10/month	£60/User	£120/User
COSMA Headset/User (OPTIONAL)	£30/month		**£90/User
Final Pilot Study Report/Care-home	£2500 (fixed fee)	£2500	£2500
a) Dementia Patients' individual Report on cognition, emotional and behaviour b) COSMA Report for Care Enhancement & CareHome Facilities Improvement c) COSMA Patient Group Analysis Report and Improvement d) Carers Mental well-being			

*Tablet - Samsung Galaxy Tab A7 (10.4-inch, RAM 3 GB, ROM 32 GB, Wi-Fi-only)

*Tablets needs to be returned with no damage by end of the study; Deposit will be refunded.

**COSMA headset is optional in a 1-year study for the last 3 months to show the benefits of targeted therapy for dementia patients.

*** The pilot study results may be published in scientific journal with no disclose of any personal information of any patients or carers involved in the study.

